National Environment Protection (Ambient Air Quality) Measure

Report of the Risk Assessment Taskforce

Prepared for the National Environment Protection Council

October 2000

Mr Roger Beale
Chair
NEPC Committee

I am pleased to transmit the Report of the Risk Assessment Taskforce to you.

The Taskforce investigated the potential for the use of health risk assessment in the NEPC context, particularly in relation to the review and establishment of ambient air quality standards for criteria pollutants addressed in the Ambient Air Quality NEPM.

This Report has been developed utilising the expertise of members of the Taskforce and of independent experts, and refined through a public consultation process.

The Taskforce considers that the recommendations in the Report provide the basis for policy decisions by the National Environment Protection Council for the review and establishment of ambient air quality standards for criteria pollutants. The Report should also inform the debate about standard setting requirements for "air toxics" (eg benzene), given that the principles of risk assessment are universal, even though the Taskforce did not specifically examine air toxics.

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20 October 2000

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1. INTRODUCTION

1.1 The Ambient Air Quality National Environment Protection Measure

The National Environment Protection Council's (NEPC) role is to harmonise environmental protection approaches across Australia.

In June 1998, in the National Environment Protection Measure (NEPM) for Ambient Air Quality, NEPC set standards for six pollutants; carbon monoxide (CO), nitrogen dioxide (NO_2), ozone (O_3), sulfur dioxide (SO_2), lead (Pb) and particles (PM_{10}). These pollutants are known as "criteria pollutants". The standards are the first step in developing a more consistent national approach to air quality management so that Australians can enjoy equivalent protection from the adverse health impacts of air pollution. The Measure (or NEPM) provides benchmarks for assessing ambient air quality in Australia.

1.2 How the NEPM ambient air quality standards were developed

Experts reviewed the scientific literature, advised on the potential health impacts of the six criteria pollutants and identified concentration ranges necessary to protect public health. Other Australian specialists formally reviewed this work. While there was not complete consensus on the concentrations of concern, there was significant agreement. Overseas specialists supported the consultants' conclusions.

This work drew largely on epidemiological studies, supplemented by controlled human exposure studies. Such research, dealing with physiological responses of the human body, is never precise and is still evolving. There is thus no *'right'* concentration of pollutant that will guarantee specific levels of health protection across a human population. Consideration of the concentrations at which health effects occur and the concentrations that are realistically achievable were used to propose a set of standards and a ten-year (1998 to 2008) goal for meeting them. Following public comment these were reviewed, amended where appropriate and incorporated into the final NEPM.

1.3 Health Risk Assessment and development of the NEPM

Health Risk Assessment (HRA) is increasingly used overseas to inform standard setting. In developing the NEPM, an attempt was made to carry out a health risk assessment on the criteria pollutants. A risk assessment approach had not previously been used in Australia to set ambient air quality standards.

NEPC concluded at the time that neither the methodology nor the available air monitoring information allowed risk assessment to be successfully undertaken. The outcomes of the quantitative HRA process were therefore not used to develop the NEPM standards. Subsequently, NEPC agreed to investigate the possibility of developing a risk assessment approach to inform the review of air quality standards.

1.4 Review of NEPM ambient air quality standards

When NEPC made the NEPM, it agreed future actions, including a staged review of some NEPM standards:

- by 2001 commence a review of the particles standard, in particular, the need for a standard for particles less than 2.5 micrometres;
- by 2003 commence a review of the practicability of developing a 10 minute sulfur dioxide standard;
- by 2003 commence a review of the practicability of setting a long term goal (>ten years) of achieving a one hour average standard for photochemical oxidants of 0.08 ppm, measured as ozone, within the major urban airsheds; and
- commence a review of the NEPM in 2005.

1.5 Risk Assessment Taskforce

Under 'Future Actions' NEPC also established a taskforce to "investigate a risk assessment approach to guide the application of standards, to report within three years". The Risk Assessment Taskforce (RATF) comprised four government, two industry and two environment movement representatives, with a Chair and Executive Officer from the NEPC Service Corporation. The membership of the Risk Assessment Taskforce is listed in Appendix 1.

With respect to the impact of health on the Australian population, the Terms of Reference of the RATF are:

1. *Investigate the adequacy of current risk assessment models for their applicability in the NEPC context, and in particular their ability to guide the application of standards for the Ambient Air Quality NEPM.*

2. *To assess the desirability and the viability of developing a standard methodology for risk based approaches.*

3. *To examine reporting protocols for risk assessment based approaches.*

4. *To review the adequacy of existing Australian epidemiological data and studies on the health effects of air pollution and recommend actions to address relevant inadequacies.*

5. *To review international epidemiological data relating health effects to air pollution and assesses the appropriateness of utilising such data in the Australian context.*

6. *To consider the elements of any communication strategy required to implement a risk assessment based approach in the NEPC context.*

7. *To report to NEPC Committee within 12 months of establishment of the Taskforce.*

1.5.1 Methodology

In the development of this report the RATF:

- Used its own expertise (most appendices were developed by the RATF);
- Engaged Mr Frank Sgro of Herma Risk Consultants Pty Ltd to review current worldwide HRA frameworks and models (refer to Appendix 2);
- Convened a seminar for HRA specialists and other stakeholders (Melbourne, July 1999);
- Consulted with Professor Steve E Hrudey of the University of Alberta, Canada;
- Consulted with UK and USA experts with extensive experience in using HRA to develop air quality standards (Perth, December 1999); and

- Examined information from a two-day conference on risk assessment and air quality standards, which was attended by most RATF members (Perth, December 1999).

The RATF conducted a public involvement program, involving visits to all capital cities except Darwin, in August/September 2000 to obtain feedback from key stakeholders prior to developing this report.

1.5.2 This Report

This report first sets the context in which health risk assessment (HRA) may be incorporated into the standards development process. It defines HRA, the steps involved and some of the characteristics of HRA that may influence how it is used, then considers each term of reference with discussion, conclusions and recommendations. Examples of how HRA could be used in the review of the Air NEPM standards and the issues to be addressed for criteria pollutants mentioned in the Future Actions document (ie particles, sulfur dioxide and ozone) is given in Appendix 6.

It should be noted that there are air pollutants of concern other than the criteria pollutants, including substances such as benzene and related compounds. Some of these are labelled 'air toxics'. This report does not specifically address these pollutants, but the many of the principles enunciated may be applicable to setting standards for them.

It should also be noted that whilst HRA may be used to assess the impacts of gaseous emissions from specific sources (eg industrial plants), this issue is outside the RATF's terms of reference.

2. STANDARD SETTING

An Air Quality Standard is a concentration of air pollutant adopted by a government to protect the health of its population. Standards may be used by governments as the goal for their air quality management plans at the strategic level and to guide emission controls on polluting activities.

The process of standard setting involves a range of environmental, health, technical, social, economic, political, legislative and cultural considerations. Figure 1 shows the context in which HRA fits into a generalised standard setting process. It should be noted that standards are primarily based on the protection of human health or environment including the built environment, vegetation and agricultural crops.

Once a decision has been made to embark on a standards development or review process and an initial issues identification phase has been carried out, the assessment of impacts can be done by various means, including risk assessment (eg HRA and/or ecological risk assessment), the adoption of overseas standards, the use of background pollutant concentrations, or the use of expert panels. HRA can be quantitative or qualitative.

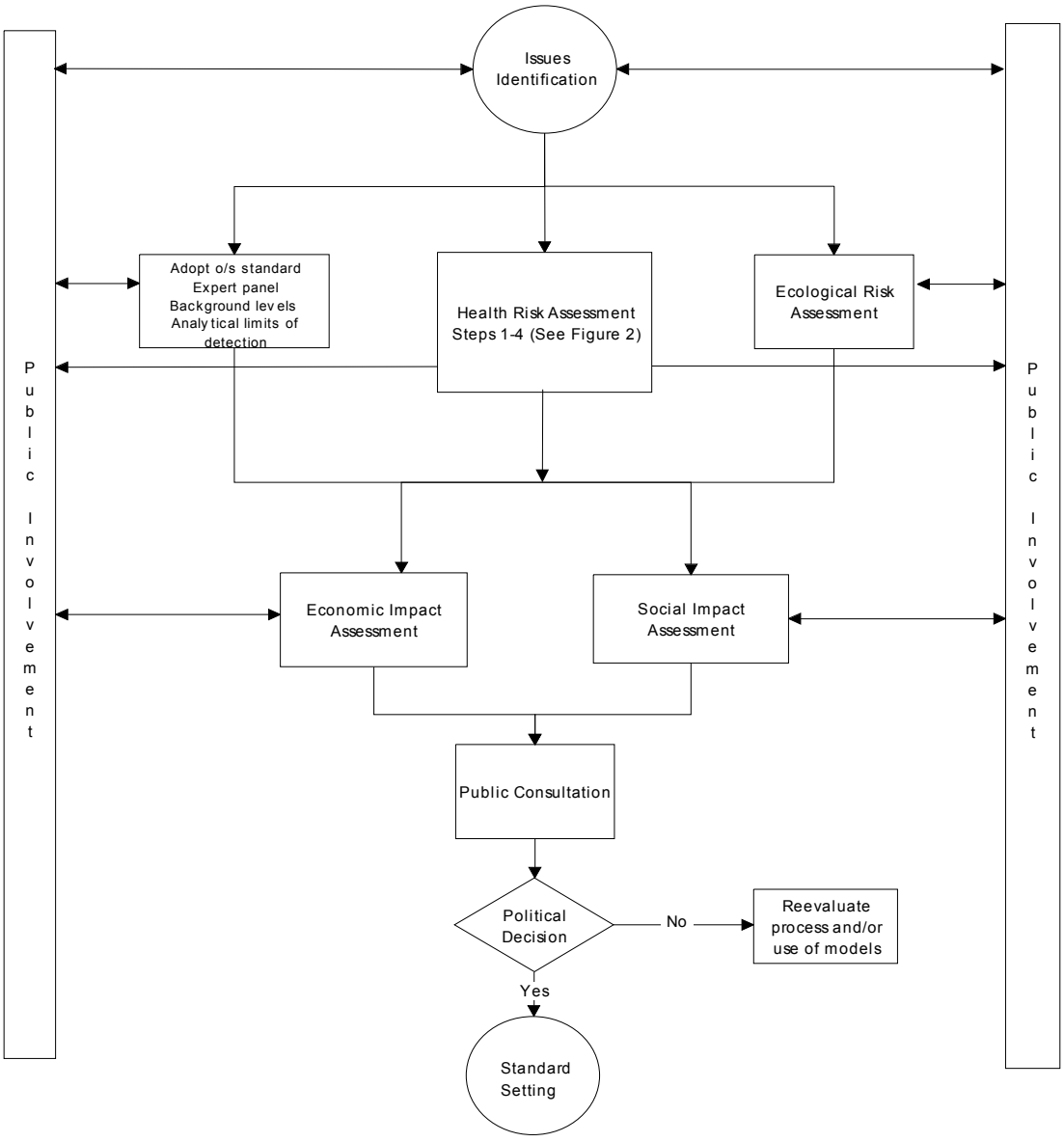
Factors influencing choice of standard setting process and the detail of that process include level of agreement between stakeholders as to the need for standards and the level at which they should be set[1], data availability, utility and availability of HRA models, and costs and

[1] If, for example, there is very widespread support for a particular existing standard a review may be able to conclude once that has been established.

timeliness. Full scale HRA would be used when it is judged able to add value. The rationale for the particular process used needs to be explained fully and clearly.

Public involvement must be an essential part of the HRA process, as is discussed below. It is essential in identifying issues and in developing of standards following a HRA, especially where there is a large degree of uncertainty in the HRA output.

Figure 1: Standard Development Process



Selecting standards from amongst those adopted by other countries

Setting standards takes into account scientific, medical and epidemiological information (on, for example, the health effects of pollutants) and social and economic impacts in relation to particular legislative frameworks. Whilst health effects may often be expected to be similar

from one country to another, the social, legislative and economic environments vary widely. Selection of standards from other countries may be useful where there is limited science available to support new standards. Problems may be encountered in implementing the standards if different socio-economic profiles exist in the country where the standards were developed. For example:

- the adoption of standards from another country without taking into account the necessary finances or institutional robustness to implement them; and
- different socio-economic profiles leading to different health profiles.

Expert panel

An expert panel may be established to develop and recommend standards. Such a panel may consider all aspects of the pollutant, its health effects, and population exposures (viz risk characterisation). This process may utilise the outputs from various sources, including HRA if appropriate. Depending on its terms of reference, an expert panel may also consider risk management issues in recommending standards. A limitation of the expert panel process is that it tends to lack transparency.

Background or natural pollutant concentrations

In the absence of information about health effects, or on the basis of evidence that the pollutant in question has an effect at very low concentrations, a jurisdiction may consider setting standards at background level. This assumes that background levels can be established and are detectable with analytical instruments using current technology.

Use of analytical limits of detection

Analytical limits of detection are dependent on the technology utilised in the development of the instruments, and on the development and refinement of analytical methods. The results may or may not link to levels of pollutants at which health effects occur. Standards set as a result of selecting analytical levels of detection could vary widely depending on the instrument technology available.

Health risk assessment

As discussed below, HRA does not provide a definitive outcome, nor certainty in its outcomes. For this reason, HRA must be a completely transparent process so that the inputs (including assumptions and default values), the mathematical models and the uncertainties in data, exposures and dose response relationships can be reviewed by scientific and stakeholder groups. The outcomes of HRA may be used in standard setting, or act as an input into other standard setting processes (eg expert panels).

Ecological risk assessment

Ambient air quality standards may be established to protect ecosystems or individual species. For example, Victoria's State Environment Protection Policy (Ambient Air Quality) includes an ozone objective to protect vegetation.

Summary

As outlined above, there are several approaches to standard setting. Any particular standard setting process may involve one or more of the above approaches. In addition, a given approach does not have an inherent level of transparency, rather transparency will depend on the planning and management of a particular standard setting process.

The RATF's Terms of Reference focus on the potential for the use of risk assessment in setting standards. Accordingly, the RATF has not examined in detail the other approaches enumerated above.

There is a need for on-going review of standards as changes occur in information about health effects, exposures and emissions management regimes. The Future Actions program for the Air NEPM recognises this need.

2.1 The Precautionary Principle

HRA inputs to the standard setting process are always uncertain, so it is appropriate for NEPC to apply the Precautionary Principle as per Section 15(a) of the NEPC Act. This states that NEPC must consider whether the NEPM is consistent with the principle as defined in the Intergovernmental Agreement on the Environment:

"Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. In the application of the Precautionary Principle, public and private decisions should be guided by: (i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment; and (ii) an assessment of the risk weighted consequences of various options."

In order to apply the Precautionary Principle, the HRA process must clearly:

- estimate the incidence and severity of potential effects;
- identify the size of the population at risk; and
- describe the uncertainty of the inputs into the HRA process and of the HRA output.

For example, if a suspected but uncertain health effect is severe and the size of the population at risk is large, a more cautious approach would be more appropriate than if the effect were less severe or if the population were smaller (World Health Organisation (WHO), 1999).

The Precautionary Principle provides a guide to action under (perhaps considerable) uncertainty, the condition under which most, if not all, public health decision making on environmental issues takes place (WHO, 1999).

3 HEALTH RISK ASSESSMENT

3.1 The Purpose of HRA

HRA is a systematic approach to characterising the nature and magnitude of the human health risks associated with environmental hazards, where hazard is the *potential for harm* and assessment of risk provides *an estimate of the likelihood of adverse effects occurring*.

For ambient air quality, HRA seeks to answer basic questions relating to human health effects of exposures to air pollutants at identified concentrations over a given length of time. HRA can be quantitative or qualitative.

HRA should:

- be transparent in the many assumptions it has to make;
- be applicable to those people or population sub-groups needing protection; and
- use scientific expertise and data, while effectively involving the community.

3.2 The HRA Framework for Estimating Risk

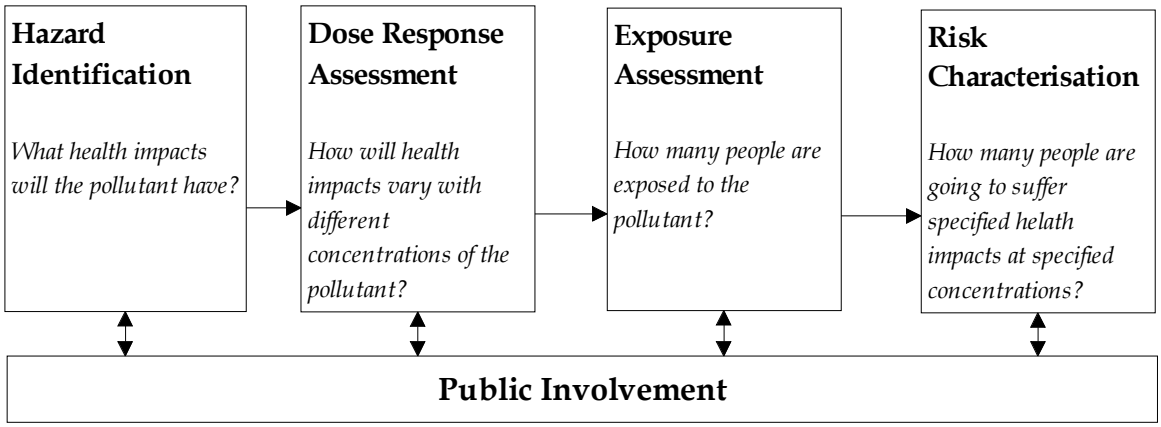
HRA is often considered to comprise five stages, including an initial issues identification stage. RATF has specifically separated issues identification from the HRA framework in the standards development process, because issues identification is the necessary first step in that process (see Figure 1). It should be noted that if the issues identification stage reveals that there is no disagreement about the need for a standard or the level at which a standard should be set then there is no need to pursue a risk assessment approach.

The systematic four-stage HRA framework (Figure 2) is applicable to a wide range of pollutants and health effects.

The dose response assessment, exposure assessment and risk characterisation stages may incorporate (mathematical) models. The specific models used for dose response assessment and exposure assessment depend on the pollutant (and its biochemical and physical properties) and the health end point (eg impairment of lung function, development of cancer). Thus there will normally be few models relevant to specific purposes, such as the development of air quality standards for criteria pollutants.

The outputs from HRA are used in the risk management phase, in which regulators consider the results of the risk assessment stages outlined above, apply the precautionary principle and take into account social and economic factors (Figure 1).

Figure 2: Four-Stage Framework of HRA



Perhaps the greatest difficulty with HRAs that quantify risk is that many of the assumptions inherent in HRA cannot be tested. Results are often taken to imply a level of accuracy that the original authors would not claim. This has led some countries (eg UK) to be cautious regarding HRA, while others (eg US) use HRA widely to assess risk.

3.3 Description of HRA Four-Stage Framework

3.3.1 Hazard identification

Hazard identification involves determining which adverse health effects may be caused by the pollutant and how quickly problems might be experienced. This involves reviewing available toxicological and epidemiological data, taking into account the strengths and weaknesses of the information being reviewed. WHO have recently published guidelines for assessing epidemiological data for HRA (WHO Working Group, 2000).

Setting air quality standards involves defining the effects from which the population is to be protected. Health effects range from premature death and acute illness, through to chronic and lingering diseases, to temporary physiological or psychological changes (WHO, 1999).

Serious effects, such as premature deaths or exacerbating illnesses requiring hospitalisation, are widely recognised. However, when health effects are temporary (such as small transient decreases in lung function), or involve biochemical of functional changes with uncertain clinical significance, there is often debate over considering these effects when deriving standards (WHO, 1999). Judgements as to whether the health effects are adverse can vary from country to country due to factors such as different cultural backgrounds and different levels of health status.

It is noted that a publication bias may exist in that studies that do not find a positive correlation may be less likely to be published. Any studies which do not report significant associations between air pollution and health effects should also be considered in this phase of the HRA.

The identification, ranking, prioritising and selection of health end points for the standard setting process is an essential part of HRA but can be an area of considerable debate between stakeholders. For example, there may be considerable debate about the importance of subtle health effects such as decreased lung function (see Appendix 6). Identification of suitable health end points must be made and agreed upon before embarking on subsequent stages of a HRA process.

The population at risk is another element in hazard identification. Generally, the populations at risk are those exposed to increased concentrations of air pollution (WHO, 1999). Each population has sensitive groups at higher risk of developing ill health from exposure to air pollutants. These groups include people already sick, the elderly and children. Other groups often at higher risk are outdoor workers and vigorous exercisers who are more exposed to air pollutants.

Hazard identification was carried out in the development of the NEPM.

3.3.2 Dose response assessment

Dose response assessment involves evaluating toxicological and/or epidemiological data to determine the incidence of adverse effects in humans at different exposure levels. Dose-response relationships for the criteria pollutants have been derived by both USEPA and WHO, with very little difference in the relationships derived.

WHO (1999) recommends that in developing air quality standards, regulators consider the uncertainty in the dose (or exposure) response relationships. This is because differences in population profiles (such as age and health status), climate and geography can influence the prevalence, frequency and severity of health effects from air pollution. WHO recommends that dose-response relationships be modified where possible to account for national conditions when setting standards.

For some compounds such as carcinogens, risk assessment usually requires extrapolating dose-response relationships from animal studies or from occupational data where workers have been exposed to high concentrations of the substance. This extrapolation introduces considerable uncertainty in the quantified risk. For criteria air pollutants much of the health effects data have been derived from either population-based epidemiological studies or from

controlled human exposure studies. The use of these data in risk assessment is preferable to extrapolating from animal data or from high dose human data.

Dose response assessment was carried out in the development of the NEPM.

3.3.3 Exposure assessment

Exposure assessment estimates the frequency, concentration and duration of exposure in the past, present and future. It involves identifying air pollution levels, exposed populations, sensitive sub-groups and potential exposure pathways.

The complexity of exposure assessment in HRA depends on how the dose-response relationship is determined. Exposure assessment may be as simple as averaging ambient air monitoring data when dose-response relationships are obtained from epidemiological studies (eg USEPA for particles). On the other hand it may involve detailed modelling of personal exposure using time activity patterns for a population when dose-response relationships are obtained from controlled human exposure studies (eg USEPA approach for ozone). The air quality data should be representative of the population exposure across the airshed and should include both low and high concentrations.

Due to difficulties obtaining consistent air quality data across all jurisdictions, a low level of confidence in the exposure assessment led to the abandonment of HRA in developing the NEPM and the utilisation of other methods.

3.3.4 Risk characterisation

Risk characterisation details the nature of potential human health effects for the exposure conditions specified in the exposure assessment. This stage brings together knowledge about health impacts, dose response and exposure, to calculate the likely number of people affected in identified ways. These health effects range from mild symptoms, such as eye or throat irritation, to increased deaths depending on the concentration of the pollutant. The health endpoint to be considered must be identified in the hazard identification stage. This step puts the risk in perspective for risk managers and the public. The risk may be expressed, for example, as the annual number of attributable events (such as hospital admissions), or years of life lost.

3.4 Limitations and Uncertainties

HRAs are associated with varying degrees of uncertainty. Each stage should include identifying the uncertainty and variability in the data. Uncertainty analysis seeks to identify what is not known about the pollutant and its potential impact on the estimates of risk.

HRA does not provide certainty in outcome. It is a tool that may be used to guide the standard setting process, based on available science and in which uncertainties should be clearly identified. The availability of detailed toxicological data will improve risk estimates, however, even the best estimates will be subject to uncertainty due to variations in susceptibility in populations.

Uncertainty is inherent in all methods of standard setting. Transparency in standard setting processes enables the assumptions, default values and decisions in the process to be clearly enunciated.

HRA requires the use of default values and assumptions to take account of limitations and uncertainties in the data. Appendix 2 describes several frameworks and models with their defaults and assumptions. While many assumptions or defaults tend to conservatism, in the absence of definitive data their use is necessary to describe such uncertainties. Given that changes to inputs, defaults and assumptions can change the outputs of an HRA, it is essential that the uncertainties in the defaults are outlined and the assumptions clearly stated.

An analysis of uncertainty can be undertaken to identify what is not known about the pollutant and its potential impact on the estimates of risk. Key uncertainties include:

1. adequacy of the characterisation of the pollutant under consideration;
2. adequacy of measurement methods for pollutants;
3. the estimated dose-response relationship(s);
4. the transferability of such relationships to different geographical areas;
5. sensitive subgroups; and
6. omitted health effects (for some pollutants, there may be a focus on particular effects (eg increases in daily mortality), to the exclusion of other health outcomes eg headache, nausea).

Sensitivity analyses should also be undertaken to determine the magnitude of change in the outputs with alterations to the inputs (including defaults) or assumptions.

Variability, although distinct from uncertainty, may also affect the interpretation of risk assessment. Sources of variability include variability in exposure and susceptibility, which together may lead to a wide range in risk estimates in the population. Central estimates of risk, which do not address variations across a population, may be misleading (Holgate et al, 1999).

Other limitations and uncertainties relate to the lack of information on specific agents and in particular the lack of information on interactions between agents. This is a very difficult issue and cannot be easily taken into account in any standard setting process.

In summary, and as indicated previously, in order to ensure its usefulness and credibility in the standard setting process, HRA should:

- be transparent in its assumptions, modelling and outputs, so that uncertainties and variability can be identified;
- estimate the incidence and severity of potential effects;
- identify the population at risk, including any sensitive sub-populations requiring protection;
- use scientific data and expertise; and
- effectively involve the community. Input from all stakeholders is essential in this process.

While alternative approaches to standard setting may be used instead of HRA, the alternatives and HRA are not necessarily mutually exclusive. The alternatives may be used as a reality test on information provided by the HRA process.

4. RESPONSE TO TERMS OF REFERENCE

4.1 Term of Reference 1

Investigate the adequacy of current risk assessment models for their applicability in the NEPC context, and in particular their ability to guide the application of standards for the Ambient Air Quality NEPM.

4.1.1 Discussion

It was agreed early in RATF's work (with the concurrence of NEPC Committee), that the principal focus under this Term of Reference would be the potential for applying risk assessment in reviewing standards.

RATF has investigated nine current risk assessment frameworks and models for their applicability in the NEPC context. Frameworks and models may be distinguished as follows:

- *HRA framework* – an overview approach to HRA providing methodological guidelines and, often, criteria for selecting health outcomes and assessing dose/response relationships. Frameworks incorporate different degrees of complexity and detail depending on the purpose for which the risk assessment is required.
    - Frameworks can range from very detailed assessments including complex exposure analysis and modelling of the health impacts associated with various scenarios (eg. USEPA) to simpler identification of health impacts, identification of Lowest Observed Adverse Effect Level (LOAEL) and No Observed Adverse Effect Level (NOAEL) and dose response relationships. These are then subjected to judgement of an acceptable level of protection. The latter approach is taken by WHO and is used in setting air quality standards in the UK.
    - Frameworks generally require subsequent development of models for practical use, especially in exposure assessment and risk characterisation.
- *HRA model* – a detailed, data-intensive methodology specifically designed for a particular (stated) purpose in the HRA framework. All data input requirements are fully specified and encoded within the model, and the model outputs are generally in a specified format. HRA models require numerous inputs and assumptions and have inherent uncertainty. They can quantify risk. Model types used include:
    - Exposure assessment: may be as simple as an averaging of ambient air monitoring data (eg USEPA for particles) to a detailed modelling of personal exposure taking into account time activity patterns over a given population (eg USEPA approach for ozone);
    - Quantitative risk assessment: uses exposure assessment results and dose response relationships to estimate how many people may be affected in a specified manner by exposure to a specified pollutant.

The RATF has interpreted the term 'risk assessment models' as used in TOR 1 to mean 'HRA frameworks'. A generic HRA framework is provided in Figure 2. Further, the term 'model' has been used in this report as a component part of a framework.

The nine approaches reviewed by the RATF (Sgro, 1999) include:

- five frameworks (Canadian, WHO, UK, enHealth Council and the Assessment of Site Contamination NEPM);
- three frameworks that incorporate detailed models (USEPA, CAPCOA and Ricci-Beer); and
- one model (IEUBK).

Of the frameworks/models assessed only three are currently used in developing air quality standards – the USEPA, UK and WHO approaches. The essential difference between these frameworks is in the level of complexity for exposure assessment and risk characterisation.

The USEPA framework includes complex and data intensive models for exposure assessment and risk characterisation. Considerable resources have been spent developing time-activity profiles for the US population. This information includes time spent commuting, mode of transport, time spent indoors, time spent outdoors, and activity levels both indoors and outdoors. The information developed for some parts of the US may be appropriate for Australian conditions if climatic factors are similar (eg California). This would require careful assessment before such data were used in Australia. Time-activity data from colder areas of the US (eg the mid-west) would not be appropriate for use in Australia, as Australians on average spend much more time out of doors than mid-Western Americans. US exposure assessment assumptions are not always applicable to Australia and it therefore may be necessary to generate appropriate Australian exposure assessment models. In general, the USEPA approach is expensive and time consuming and the total adoption of their framework should be approached with caution. Nevertheless, the USEPA approach is considered to be transparent and technically robust, and specific elements which are considered relevant to Australian conditions could be used in HRA approaches in Australia. Associated costs relative to likely benefits may be a factor in deciding whether to use elements of the USEPA approach.

The UK framework utilises a risk-based approach to standard setting relying on expert panels for assessment of health effects at various air pollutant concentrations and risk characterisation stages. The four-stage framework is considered but not followed systematically and elements such as public involvement are not incorporated. Methods of population exposure assessment are also unclear. It is therefore not considered to be a suitable HRA framework for Australia unless agreement from key stakeholders can be reached that it is the most appropriate approach.

The WHO (1999) framework concentrates on the first two stages outlined in Figure 2, providing air quality guidelines protective of human health. WHO recommends countries complete the exposure assessment and risk characterisation stages using local data where appropriate. The hazard identification stage utilises expert international panels to make decisions on appropriate health end points and the subsequent generation of dose-response relationships. This approach forms part of the UK process.

If the WHO approach were adopted by NEPC, further work would be needed to develop exposure assessment methodologies and risk characterisation models appropriate for Australia. Australian health studies may also be needed to investigate the applicability to Australia of the dose-response relationships on which the WHO guidelines are based. A comprehensive public involvement process would need to be developed.

The enHealth framework, which is also similar to the WHO and USEPA, contains the four stages outlined previously, and provides a detailed methodology for hazard identification and dose-response assessment. Whilst it has primarily been based on the assessment of site contamination, the framework is generic. An exposure assessment methodology for criteria air pollutants has not yet been developed under the enHealth framework. As with the USEPA and WHO frameworks, the enHealth framework would require the development of Australian exposure assessment and risk characterisation models for criteria air pollutants.

The other models and frameworks were not considered as useful in developing ambient air standards. The Canadian framework requires a very different legal framework from those in

Australia for the definition of end points. CAPCOA applies to point sources rather than ambient air and is therefore not applicable. The approach taken and results from the Ricci-Beer model were difficult to interpret due to lack of transparency. IEUBK is useful for calculating blood lead levels in children and may be useful for setting ambient air quality standards for lead.

The Assessment of Contaminated Sites NEPM utilises a risk assessment framework that is consistent with the frameworks in the USEPA, WHO and enHealth approaches. The risk assessment models incorporated in this framework cannot be easily transferred to standard setting for criteria air pollutants because of difference in exposure assessment (heightened by extreme difference in mobility of chemical substances in transport media ie soil cf air). The exposure assessment model addresses site specific requirements, and is therefore not relevant to the development of ambient air quality standards.

It is important to note that while a generic framework can be applied to many pollutants, the detail and every stage may not be able to be followed. Models have been developed to meet specific needs and do not apply to all pollutants. Approaches, therefore, will be pollutant-specific, depending on how the dose-response data are obtained, whether there is an identified threshold for adverse effects or not, and whether effects relate to a biological marker (eg for Pb).

In developing air quality standards in the US, different approaches are taken for each pollutant. The approaches taken by WHO also differ with each pollutant. For example, air quality guidelines for NO_2 and SO_2 are developed from a threshold or no observed adverse effects level (NOAEL), while an assessment of the health risk from particles is left up to individual countries using dose-response relationships recommended by WHO. This approach requires an assessment of 'acceptable levels of risk' and the decision on what is acceptable varies from country to country. For Pb and CO, the air quality guidelines are set from levels of biological markers in blood (blood lead for Pb and carboxyhaemoglobin for CO). The presence of these biomarkers is related to total exposure to the pollutant. For Pb, estimating this exposure and identifying the component due to air alone can be quite complex, as Pb has many paths into the human body. In this respect the IEUBK model can provide useful information.

For the pollutants identified for assessment under the "Future Actions" associated with Ambient Air Quality NEPM, Appendix 6 provides a summary of the issues that would need to be resolved at each stage of the HRA process before any particular model could be selected. Discussion with key stakeholders would be required. For example, a key issue is the selection of the health endpoint(s) used in the development of the standards.

4.1.2 Conclusions

HRA is an important and useful tool to guide the review of ambient air standards. However, HRA will never provide exact information and the degree of uncertainty must be well communicated and debated by key stakeholders as stressed in Section 3.4. As noted in Section 3.2, in some circumstances the application of HRA may not be required.

A number of frameworks could be applied in Australia.

The USEPA approach provides a benchmark for a transparent and scientifically robust methodology for assessing the risk associated with exposure to criteria air pollutants and the implications of different standards. Its limitation is its inherent complexity and cost of

implementation that may prevent it being readily transferred to Australia. Some models within the USEPA framework may be able to be adapted for use in Australia; however, this requires consideration on a pollutant specific basis (see Appendix 6).

The WHO and enHealth frameworks require the development of exposure assessment and risk characterisation models. The WHO framework has been used for the generation of dose-response relationships, subjected to peer review and is utilised by many countries. It would be useful in reviewing the Air NEPM. The enHealth framework is currently in draft form and has been released for public consultation. A comprehensive module relating to air quality has not yet been developed. The enHealth approach should be reviewed when the framework has been finalised.

4.1.3 Recommendation

TOR1-1 *The HRA framework is a useful process for developing air quality standards. In utilising appropriate models under the framework it is essential that uncertainties and limitations are recognised and clearly stated. Recognising the inherent uncertainties associated with HRA, the efficacy of its application in particular circumstances may need to be debated by key stakeholders.*

4.2 Term of Reference 2

To assess the desirability and the viability of developing a standard methodology for risk based approaches.

4.2.1 Desirability of developing a standard methodology

A standard HRA framework, as described in Section 3.2, is desirable to apply a consistent, transparent, rigorous and well-documented approach to all pollutants.

For each group of pollutants or specific pollutant, the detail in the modelling approach used for exposure assessment and risk characterisation will vary. No one model applies to all pollutants.

NEPC could adopt as standard methodology the WHO framework, the USEPA framework or the enHealth framework (see Section 4.1.2). Each, however, would require considerable additional development.

An advantage of adopting either the WHO or USEPA frameworks is that many of the decisions about the assumptions (e.g. number of people and selection of susceptible sub groups of population) that should be made and the type of data that should be accepted have already been debated and documented, either as part of the framework (WHO) or as separate policy documents (USEPA).

4.2.2 The viability of developing a standard methodology for HRA

The viability of a standard methodology depends on:

- Developing and maintaining essential data inputs for the models;

- Developing and maintaining expertise in relevant government agencies (e.g. environmental and health) and ensuring that personnel in these fields carry out HRA collaboratively;
- Providing sufficient time to undertake all stages of HRA and necessary subsequent processes; and
- Funds being made available for development of the models within the frameworks to make them applicable to Australia.

Data required for HRA

Evaluating human health risks from air pollution requires information on exposure levels to various air pollutants, the number of people exposed (including sensitive groups), and the quantitative relationships between exposure and health effects. This requires the collection of information on toxicological and epidemiological studies, air quality data and exposure parameters such as population data to improve exposure estimates. It is important that the quality, reliability and consistency of the information collected for risk assessment be optimised.

The data requirements for air quality and epidemiological studies are discussed under Terms of Reference 4 and 5.

Exposure assessment is an important part of any risk assessment. Estimating exposure to air pollution can range from simply averaging the air quality data obtained from ambient air monitoring stations, to very complex analyses and modelling. The latter may involve population time-activity patterns, and personal exposure assessments (including assessing indoor air quality) as well as ambient air quality data to obtain an accurate assessment of population exposure to particular pollutants. Approaches can vary with the pollutant, the health outcome being assessed, and the type of exposure data used. For example, in the US national ozone standard, the exposure assessment involved an analysis of time-activity patterns, personal exposure, and estimates of both outdoor and indoor air quality. This complexity was deemed necessary as the dose-response data for ozone for the health endpoint under consideration was derived largely from controlled human exposure studies. This approach is extremely time and resource intensive and requires specific expertise. In contrast, for particles the exposure assessment involved averaging ambient air quality data from 'average' sites, as the health data was derived from population-based epidemiological studies.

The Air NEPM exposure assessment utilised ambient air monitoring data and interpolated these data to attempt to provide an estimate of exposure across the population. It used data from environment agency monitoring sites and interpolated the frequency distribution of air pollution exceedences. This approach did not provide an accurate estimate for exposure to the pollutants or data compatible with those in the epidemiological studies used to derive the dose-response relationships for the selected health outcomes, and so it was not pursued further.

Skills

RATF acknowledges that despite its own expertise and that accessed during its work, it took time to develop a reasonable collective understanding of both HRA and its place in standard setting.

HRA requires expertise in several areas including toxicology, epidemiology, air quality science, participative consultation processes and communication. Because of the science policy decisions implicit in the process, public involvement is essential. The scientific expertise

primarily resides within, EPAs, health departments, other government agencies, academia and consultants. Given the complexities inherent in HRA, it is critical that skills be developed and maintained by a core group of specialists. This may best be achieved significantly through government. A national approach would not mean that all governments need to replicate a full suite of HRA expertise, but there should be a 'critical mass' of expertise nationally.

Sequential Implementation

In the development of the Air NEPM, time pressures meant that some stages of the HRA and risk management phases were undertaken concurrently rather sequentially. It is critical that in the review of the NEPM, the steps occur sequentially. Iteration between steps may also be appropriate if new information comes to light during the HRA process.

Costs

As mentioned previously, each of the three potential frameworks – WHO, USEPA, enHealth – require more work on assessment of models before they could be used in standard setting in Australia.

While the USEPA HRA framework and associated models may provide a higher degree of certainty because of the extensive science policy work and development of comprehensive databases, RATF believes that it may be too costly for Australia to emulate. There is cost both in developing the policies and databases and in the infrastructure to maintain and implement the framework. All of the detail within the framework cannot merely be copied into Australia because of the different policy and legislative context in the USA, although elements may be used in particular cirumstances. For example, consideration could be given to adopting the California exposure models for the review of the ozone standard.

Costs would also be incurred under the WHO and enHealth frameworks to develop appropriate exposure assessment and risk characterisation models. Lesser costs may be incurred in utilising the WHO framework, however, due to the work already completed in the hazard identification and dose-response assessment stages, assuming the adoption of the same health end points is acceptable.

It would be desirable in principle to utilise an Australian framework such as enHealth, and further consideration should be given to that framework when it is finalised.

4.2.3 Conclusions

There are three similar standard frameworks available for use and it is desirable to utilise one of these frameworks for setting ambient air quality standards. The frameworks require either additional expense and infrastructure to be applied in Australia or development of appropriate exposure assessment and risk characterisation models. The WHO approach is likely to be less expensive than the USEPA or enHealth frameworks, assuming willingness to adopt its health end points and dose-response relationships. On these bases the RATF considers that the WHO framework is the most appropriate at this stage, but further analysis of costs is necessary.

Developing one standard exposure model for all pollutants and health outcomes is inappropriate. Specific pollutants require different models that should be reassessed against further developments when reviewing standards.

Developing an exposure assessment model for each pollutant will depend partly on jurisdictions having monitoring networks reporting on the concentration and distribution of air pollutants within airsheds as well as supporting the needs of the Air NEPM monitoring protocol to provide a measure of equivalent protection.

The viability of a HRA-based approach also depends on the availability and maintenance of expertise and on the sequential completion of all stages in the HRA process.

4.2.4 Recommendations

TOR2-1 *That NEPC adopt a standard HRA framework for use in standard setting. The details of the models used within the framework should be considered separately for each pollutant and will need to be developed further, including an agreed public involvement process, to make them applicable in Australia.*

TOR2-2 *That NEPC consider using the WHO framework in the review of the Ambient Air Quality NEPM, acknowledging that there may be a need in particular circumstances to develop exposure assessment and risk characterisation models. When the enHealth framework is finalised and the relevant documentation reviewed, consideration should be given to using the enHealth approach.*

TOR2-3 *The specific details of any models to be used in HRA will need to be finalised in consultation with key stakeholders at the time of the review.*

TOR2-4 *That it be recognised that adoption of a standard HRA approach will not be viable unless expertise to implement this approach is developed and maintained within a number of government agencies in Australia.*

TOR2-5 *That where an HRA framework is used in the review of ambient air quality standards, sufficient time is allowed to implement the steps in the framework sequentially, and where necessary, iteratively.*

TOR2-6 *That, in addition to the requirements of the Ambient Air Quality NEPM and in order to provide data for exposure assessments for future reviews of air quality standards, jurisdictions design and maintain their overall air monitoring networks such that estimates of the distribution of population exposure to criteria pollutants can be developed.*

TOR2-7 *That NEPC facilitate the development of guidelines for the operation and maintenance of air quality networks and a consistent recording and reporting system to be used by all jurisdictions.*

4.3 Term of Reference 3

To examine reporting protocols for risk assessment based approaches.

4.3.1 Discussion

The issues related to risk assessment that should be included in a reporting protocol were considered. In the consultancy brief for reviewing risk assessment models, criteria were

developed for comparing and assessing each model. These criteria provide the basis for a reporting protocol.

Any reporting protocol for risk assessment must provide information allowing all stakeholders to understand the inputs into the risk assessment process, the outputs of the assessment and how they are used in the risk management phase. The assumptions and uncertainties associated with each stage must be clearly documented and communicated.

The reporting protocol should include:

1. The criteria used to assess the health effects from exposure to air pollution;
2. Identification of sensitive populations to be protected (eg asthmatics, children, people with diseases);
3. Clear statement of the health endpoint being assessed and justification for selecting that endpoint, as well as other health points considered and rejected and the reasons why;
4. A clear description of how the exposure assessment was developed and the associated limitations;
5. A description of how the dose-response relationships were derived and associated uncertainties;
6. A description of all safety factors used and their derivation;
7. Any default parameters used in the risk characterisation and the uncertainty associated with their use;
8. An explanation of how the Precautionary Principle was applied;
9. An explanation of any statistical methods used;
10. How threshold and non-threshold pollutants are dealt with;
11. Characterisation of the uncertainty in the risk estimates; and
12. Criteria for risk acceptability.

Reporting against these criteria will increase transparency in the risk assessment process and help with stakeholder consultation throughout the standard setting process. Final reporting should acknowledge who was consulted, as is done in Summary and Response documents developed by NEPC in the NEPM development process.

The above criteria should be used as a basis for a reporting protocol but could be further developed at the time of the review of the Air NEPM.

4.3.2 Conclusions

A reporting protocol should be developed for communicating the results of any HRA based on the criteria outlined above. The protocol should allow for a clear understanding of the assumptions, limitations and uncertainties associated with the HRA process.

4.3.3 Recommendations

TOR3-1 *That NEPC develop a reporting protocol that will facilitate a clear understanding of the HRA process by all stakeholders.*

TOR3-2 *That the HRA reporting protocol include a standard set of criteria (as outlined in Section 4.3 of this Report) for reporting HRA outcomes.*

4.4 Terms of Reference 4 and 5

To review the adequacy of existing Australian epidemiological data and studies on the health effects of air pollution and recommend actions to address relevant inadequacies.

To review international epidemiological data relating health effects to air pollution and assesses the appropriateness of utilising such data in the Australian context.

These terms of reference are considered together as discussion on them is inter-linked.

4.4.1 Epidemiological Studies

Studies of the health effects of air pollution have shown associations between ambient air pollution levels and adverse health effects, including increases in daily mortality and hospital admissions. These studies come from various parts of the world with differing climates, pollutant concentrations and mixes, and socioeconomic status. Associations have been observed at air pollution levels below current air quality guidelines/standards. A detailed review of epidemiological study design and data requirements can be found in Appendix 3.

Investigating the health effects of air pollution follows a multi-disciplinary approach using epidemiology, controlled human exposure studies, and animal toxicology:

- *Epidemiological Studies* examine the relationship between air pollution exposure and health effects in the community. They can investigate acute or chronic (long-term) effects. Accurate estimation of exposure to a pollutant is usually difficult. Exposures are generally estimated from fixed monitoring sites and many pollutants occur as components of complex mixtures. The extent of potential confounding factors (eg cigarette smoking, health status), time considerations in air pollution effects (eg lags and latencies), individual variation in air pollution exposure, and exposure misclassification cause uncertainty in any observed associations with the health outcome (Lambert et al., 1992);
- *Controlled Human Exposure Studies* (or chamber studies) investigate mechanisms of injury and permit strict control of the exposures and the characteristics of the exposed persons. Ethical and practical considerations limit the use of controlled human exposure studies, and chronic effects cannot be readily addressed. Despite these constraints, such studies have contributed significantly to quantification of the relationship between respiratory function and air pollution (eg lung function to ozone exposure); and
- *Toxicological Studies* of animals can evaluate mechanisms of injury by pollutants using methods that cannot be applied to human subjects. Uncertainty is introduced from extrapolating animal models to humans.

Each approach has specific strengths and weaknesses in evaluating the human health effects of air pollution.

Epidemiological studies using routinely collected data on populations include *Time Series Studies* of daily mortality, daily hospital admissions and daily hospital emergency department (ED) attendances. These have fairly generic data requirements and are generally only practical in large cities (ie major capitals), over several years. Some *Time Series Studies* have been conducted in Sydney and Brisbane, and more recently in Melbourne and Perth.

Data requirements for epidemiological studies depend on the health outcome being assessed and the study design. Health outcomes used to investigate the effects of air pollution range from less sensitive indicators like daily mortality to more sensitive indicators such as lung function.

Studies on individuals (eg *Diary Studies, Cohort Studies*) require far more detailed data on health outcomes, confounders and, increasingly, exposures. Accordingly, they are far more expensive. Some of these studies have been conducted in Australia and more could be conducted (particularly in areas with populations too small to conduct broader time-series analyses).

The following sections aim to establish the adequacy of health data for epidemiological studies, specifically *Time Series Studies*.

4.4.2 Adequacy of Routinely Collected Health Data for Epidemiological Studies

To conduct epidemiological studies on the health effects of air pollution, a range of health data is required, including:

- daily mortality statistics;
- daily hospital admission and emergency department records;
- influenza data; and for some studies
- information on respiratory symptoms and medication usage.

This information is available from government health departments, or the Australian Bureau of Statistics, or may need to be collected for a specific study.

Daily Mortality Data

Death certificate data on all deaths of Australian residents is collected by the ABS and is available from 1964. Standard data definitions apply and the data is coded according to world-recognised classifications. These data are comparable to data used in overseas *Time Series Studies* of acute daily mortality and air pollution and are adequate for Australian studies.

Daily Hospital Admissions Data

All Australian States and Territories collect electronic data on admissions to public and private hospitals. Since 1993/94 the Australian Institute of Health and Welfare has compiled a minimum data set of admissions from all State and Territory health authorities for public and private hospitals in the National Hospital Morbidity Database (NHMD). Studies using these data must pay particular attention to changes in data definitions and data quality over time. While access to hospital services varies between countries, these data are comparable to data used in overseas *Time Series Studies* of the acute effects of air pollution on daily hospital admissions and are adequate for Australian studies.

Hospital admissions data are also available from State and Territory health authorities and are appropriate for use in epidemiological studies. Data are routinely available from 1992/93. Some jurisdictions have admissions data in electronic format prior to 1992/93. However, prior to use, studies using these data should evaluate the comparability of data definitions and data quality with more recent data. A summary of the available data is in Appendix 3.

Hospital Emergency Department Attendance Data

Some hospitals have collected electronic hospital Emergency Department (ED) attendance data in standard formats. Centralised systems to collect standardised ED data are under development in most States and Territories and moves are under way to consolidate these databases in a national minimum data set (similar to the NHMD database). Details of the State and Territory data are summarised in Appendix 3. Several Australian capital cities may

already have adequate hospital ED attendance data for appropriate time periods for *Time Series* studies. As State and Territory centralised hospital ED attendance databases are still in the early stages of development, studies using these data must pay particular attention to changes in data definitions and data quality over time, both within hospitals and between hospitals in the study region. While access to hospital services varies between countries, these data appear to be comparable to data used in overseas *Time Series Studies* of the acute effects of air pollution on daily hospital ED attendance and may be adequate for Australian studies.

General Practice Surveillance Data

Some local regions throughout Australia collect data on infectious diseases and other conditions (including asthma) from networks of local General Practitioners. Currently General Practitioner surveillance data in Australia is of limited use in air pollution epidemiology mainly due to the voluntary nature of such schemes and difficulties in defining the study population. However they have the potential to become an important data source in air pollution epidemiology.

4.4.3 Adequacy of Routinely Collected Confounder Data for Epidemiological Studies

There are a number of confounders that may reduce the ability to interpret the results of epidemiological studies. For *Time Series Studies*, the association between temperature, and more generally weather, and various acute health outcomes including daily mortality, daily hospital admissions and daily hospital ED attendance has long been recognised (eg: extremes of temperature, both hot and cold, cause increased deaths). Because of the potential for weather to confound the air pollution-health outcome relationship, its effects must be controlled in the analysis of *Time Series Studies* so that the independent effects of air pollution on the chosen health outcome can be determined. Other variables that can confound results are the presence of infectious diseases, aeroallergens and other chemicals.

Data on meteorological parameters, infectious agents and, to a lesser extent, aeroallergens are available with variable degrees of adequacy. Appendix 3 outlines where data on confounders can be accessed and considers the adequacy of the data.

4.4.4 Adequacy of Routinely Collected Air Pollution Data for Epidemiological Studies

Air pollution monitoring networks serve a range of purposes such as:
- evaluating the effectiveness of emission control strategies;
- monitoring ambient air quality; and
- assessing compliance with air quality objectives and standards.

Monitoring networks usually have not been designed specifically for measuring general population exposures.

The availability of appropriate air pollution data is critical for epidemiological studies. Air pollution data must be representative of population exposure to obtain the most accurate assessment of the risk posed by air pollution in Australian cities, therefore it is necessary to use the full distribution of air pollution data rather than peak data.

In the US, risk assessment is conducted as part of setting the National Ambient Air Quality Standards for criteria air pollutants. Although the air quality standards in the US apply everywhere, including peak sites, air quality data from peak sites are excluded from exposure assessment conducted as part of the risk assessment process. Only data giving an estimate of distribution of pollutant concentrations experienced by the general population are used. The

risk assessment process in the UK takes a similar approach where air pollution data monitored at peak sites are excluded from analyses.

In Australia, State environment agencies have conducted air pollution monitoring for many years. The extent of monitoring varies significantly between States, as does the location and mix of air monitoring stations. This lack of consistency in air monitoring data was one of the main reasons why the attempt at risk assessment during the development of the Air NEPM was not successful.

Time Series Studies require daily estimates of population exposure for at least five years at constant locations.

Minimum exposure data requirements for *Time Series Studies* are:

- sufficient fixed sites in the monitoring network to characterise the spatial distribution of air pollutants in the study region, ie sub regions within the airshed contain at least one monitoring site;
- sub-regional monitoring sites located to measure air quality representative of the sub-region, ie will provide a measure of the distribution of population exposure not peak data;
- each sub-regional monitoring site in the network operating at the same location throughout the study period (approximately five years);
- daily data from each sub-regional monitoring site available for at least 75% of days; and
- pollutants are not measured independently so that potential confounding can be assessed.

Studies of the chronic effects of air pollution require data on concentrations and composition of air pollution over long time periods. While these studies may not require data to the same degree of spatial resolution as acute studies, they require consistent data for longer time periods (ie at least 10 years). Databases of detailed historical daily air pollution data should be maintained for possible future Australian studies of the chronic effects of air pollution.

4.4.5 The Applicability of International Epidemiological Studies in Australia

In recent years there has been extensive international research into the effects of air pollution on health. As stated above this research has included epidemiological studies, controlled human exposure studies and toxicology. The contribution from each area varies significantly between pollutants. For example, the health effects of particles have been derived mainly from epidemiological studies whereas controlled human exposure studies and toxicological studies have contributed significantly to understanding the health effects of ozone. Controlled human exposure and toxicological study results transfer readily to many locations as they relate to a known dose of a particular pollutant and not to a specific pollutant mix. Therefore the results of these types of overseas studies could be utilised in Australia.

With epidemiological studies this is not so clear. For example, European studies of the effects of particles on daily mortality show differing results to those from the US. While associations between particles and increases in daily mortality are generally observed in Europe the results are less consistent and the effect estimates are generally lower than those observed in the US. The reasons for these differences are unclear but may be due to high levels of acid aerosols in the US or possibly using black smoke in Europe. Studies using black smoke as a measure of particles do not show a strong particle effect (UK Department of Health, 1998). Similar discrepancies are observed for ozone and daily mortality. The results of epidemiological studies vary both between and within countries, raising questions over the transferability of dose-response relationships from one country to another.

Notwithstanding differences in the strength of associations and the size of the effects estimates observed across studies, it is generally accepted that epidemiological studies have shown that ambient air pollution is associated with adverse health effects in a variety of locations worldwide. A detailed review of the health effects associated with the criteria pollutants is in Appendix 4.

It is not feasible to conduct sufficient epidemiological studies in Australia to provide a database to support the development of air quality standards on Australian data alone. The question therefore arises whether overseas data can be utilised in Australia. This is discussed below for each pollutant.

Ozone, Nitrogen Dioxide and Sulfur Dioxide

The health effects of ozone, nitrogen dioxide and sulfur dioxide have been widely studied overseas in epidemiology, toxicology and controlled human exposure studies. Epidemiological studies show that ambient levels of these pollutants are associated with increases in daily mortality, increases in hospital admissions for respiratory and cardiovascular disease, increases in emergency room attendances for respiratory disease (including asthma), decreases in lung function and increases in respiratory symptoms. These effects have also been observed in Australian studies although there is some evidence that the strength of the association may vary. The results of the epidemiological studies are consistent with those of the controlled experimental settings. Toxicological data support the results of the controlled exposure studies.

As the results of the Australian and overseas epidemiological studies are consistent with the results of the controlled exposure and toxicological studies, it is appropriate to use overseas data to support Australian studies.

Given the low SO_2 levels in most of urban Australia, it may not be possible to determine associations with daily mortality or hospital admissions using time series analysis. This would mean a strong reliance on overseas data for these health outcomes. In areas with higher SO_2 levels, such as Mt Isa, the population is insufficient for time series analysis, although other types of studies could be conducted.

Particles

An increasing body of literature reports associations between particles and adverse health effects. Most information comes from epidemiological studies that find increases in daily mortality, hospital admissions and emergency room attendances and exacerbation of asthma associated with daily changes in ambient particle levels. Much of this data comes from US studies. However, in recent years there has been significant research conducted elsewhere, particularly Europe and the UK. These studies, while finding associations, differ from the US studies in the strength of the association and the size of the effect estimates. Recent US studies (Samet et al, 2000) show variability in the results across twenty US cities. Preliminary results from the few Australian studies conducted to date indicate similar variability may be observed here but further investigation is required to clarify the type and nature of the relationships.

Unlike ozone and NO_2 until recently there has been little toxicological evidence supporting the associations observed in epidemiological studies. This situation is changing rapidly and toxicological evidence now provides some explanation of a biological mechanism for the effects observed in population-based studies. There still remains significant uncertainty around the biological mechanisms for the observed effects.

Australian studies show associations between particles and daily mortality and hospital admissions. However, Australian studies are currently insufficient to reliably establish specific Australian dose-response relationships. Therefore overseas data must be used in HRA and Australian studies used to support the overseas studies, while clearly identifying the uncertainties associated with using overseas data.

Carbon Monoxide and Lead

The health effects of carbon monoxide are related to the presence of carboxyhaemoglobin in the blood. This biological marker is related to the dose of carbon monoxide entering the blood stream. CO health effects have been identified through controlled human exposure and toxicological studies, and epidemiological studies. These results can be used in Australia.

The health effects of lead are also associated with a biological marker – blood lead levels. Much of the international literature relating to blood lead levels, especially in children, comes from Australian studies. The results of international studies can be readily utilised in Australia.

4.4.6 The Adequacy of Australian Studies on Air Pollution

In developing the Air NEPM, identified health effects and dose relationships were based almost entirely on overseas data, as there were very few local studies. There was debate as to whether the effects identified in overseas studies would be observed in Australia. Since then further work in Europe and Australia has allowed a better comparison of air pollution effects observed in different parts of the world and some indications of the transferability to Australia.

There are several published time series analyses of daily air pollution and mortality/morbidity in Brisbane and Sydney. Similar studies have recently been completed in Melbourne and Perth.

In general, the associations between adverse health effects and air pollution observed overseas appear in Australia (eg in Sydney and Brisbane) although the magnitude of the associations differ. For example, studies in Sydney and Melbourne show strong associations between ozone and daily mortality. This is not consistently observed overseas.

Similarly, although associations have been observed between particles and daily mortality and hospital admissions in Australia, they are not as strong, or consistent, as those observed in the US. The effect estimates also differ.

Sydney and Melbourne show strong associations between increases in daily mortality and NO_2. This association was not observed in Brisbane. Associations were also observed between NO_2 and increases in hospital admissions for asthma in Sydney. Overseas epidemiological studies have not revealed a consistent pattern with NO_2 and increases in daily mortality and morbidity, although some studies have found significant associations with these health outcomes.

For Pb and CO the situation is much clearer because exposure to them can be monitored by biological markers – carboxyhaemoglobin for CO, and blood lead levels for Pb. The health effects are related to the biomarkers and therefore the results of overseas studies are likely to be transferable to the Australian situation. However, for CO, recent epidemiological studies have found associations between ambient CO levels and increases in daily mortality

(cardiovascular) and hospital admissions for cardiovascular disease at levels below current air quality standards, based on currently acceptable levels of carboxyhaemoglobin.

The use of overseas exposure–response relationships for the above pollutants may lead to overestimates or underestimates of health effects in the Australian situation.

4.4.7 Overview

In general the results from the limited number of Australian epidemiological studies for particles, ozone and NO_2 are consistent with overseas studies with similar variability observed. How significant this variability is requires further investigation, and such studies are currently in progress. Only Sydney, Melbourne, Brisbane, Adelaide and Perth are large enough to conduct time-series epidemiological studies. Attempts to study smaller populations, for example Launceston, have failed to find statistically significant associations between air pollution and adverse health effects, possibly due to the lack of statistical power in the study. Different types of studies, for example diary studies of asthmatics, can be, and have been done in smaller population centres.

A national approach to obtaining data does not necessarily mean that all jurisdictions need to carry out the same data gathering exercises, however desirable this might be in terms of developing comparable data sets. As indicated above smaller cities may well have significant air pollution problems but lack the population to obtain sufficient 'power' in epidemiological studies. In addition, smaller jurisdictions may lack the resources to gather such data. However, the appropriateness of transferring the results of studies from larger cities (eg Sydney or Melbourne) to smaller cities with different climate and pollution profiles will need to be considered. Other forms of epidemiological studies (e.g.panel studies or cohort studies as discussed in Appendix 3) could be conducted in the smaller cities. Air quality and health data for these studies would be collected specifically for this purpose.

Limited opportunities to conduct some types of Australian epidemiological studies means some continuing reliance on overseas data to conduct risk assessments and set air quality standards. The Australian studies will provide information on whether overseas data realistically estimates potential health risk to Australians. Australian air pollution and health research should not just repeat overseas studies but should be targeted on particular questions, eg why do the results of Australian studies differ from those overseas and are these differences important? Such data can provide a basis to estimate the health risk to the Australian population from air pollution.

There are few Australian studies enabling an appropriate assessment of the transferability of overseas data. Similar associations have been observed in those Australian studies to those reported internationally. Several studies are in progress that will help clarify the relationships observed in Australia.

Studies conducted in areas with lower pollution levels have generally shown weaker associations than those in more polluted cities. As pollution levels in Australia are at the lower range of pollutant concentrations used overseas, differences between Australian and overseas studies may be partly due to the lower pollution levels experienced here. At lower pollution levels, where weaker associations are observed, these are more difficult to detect. The reason for differences is unclear, but may be due to statistical variability or regional factors. This requires further investigation before conclusions can be drawn. While obtaining local data is important, it will still be necessary to rely on overseas data to conduct risk assessments and to guide setting air quality standards in Australia.

Health research in Australia should therefore be targeted at specific questions, for example, confirming the associations between daily air pollution and hospital admissions, and investigating if the results of local studies differ from those overseas. A project being undertaken at Griffith University is using standardised methods to investigate morbidity and mortality effects resulting from all criteria pollutants (except lead) for major Australian cities (see Appendix 4).

4.4.8 Conclusions

RATF's view is that:

1. routinely collected health data are adequate for some types of Australian epidemiological studies;
2. air pollution data in some areas are inadequate for epidemiological studies;
3. there have been few Australian epidemiological studies and the results of these studies may need confirmation using different study designs and/or the application of different statistical tools;
4. the results of overseas studies will need to be considered in the development and review of air quality standards in Australia;
5. Australian epidemiological studies indicate that there may be some differences from overseas studies and the importance of these differences may require further investigation; and
6. the influence of different pollution mixes in different regions may warrant further investigation to ensure estimates of risk are applicable to all areas in Australia.

4.4.9 Recommendations

TOR4,5-1 *That overseas data be utilised in the development of air quality standards in Australia, provided that the uncertainties that flow from the use of such data are clearly identified.*

TOR4,5-2 *That targeted epidemiological studies be considered to confirm available results, to fill information gaps and to assess the transferability of overseas data to Australia.*

TOR4,5-3 *To support epidemiological studies for health risk assessment (HRA), air monitoring networks be maintained to provide air quality data which is representative of population exposure.*

4.5 Term of Reference 6

To consider the elements of any communication strategy required to implement a risk assessment based approach in the NEPC context.

4.5.1 Discussion

Early in its deliberations, RATF advised NEPC Committee that when considering the elements of a communication strategy, it wished to interpret this to include a broader sense of public involvement. NEPC Committee agreed to this approach.

Throughout this report the degree of uncertainty associated with HRA has been stressed. This uncertainty reinforces the need for stakeholders to be involved in the formulation and implementation of policy regarding the use of HRA in standard setting processes.

The benefits of public involvement

Effective public involvement in NEPC sponsored processes will add value through:

- subjecting recommendations and their supporting rationale to scrutiny and debate, and improving their content in the process; and
- gaining greater understanding and, ideally, ownership of the recommendations, modified where appropriate, being made to NEPC. Where differences of view remain, these should become better understood and more accurately taken into account by NEPC in the framing of policies and programs.

Lack of effective public involvement can lead to financial, temporal, social and political costs. These costs may be incurred through:

- significant stakeholder protest about outcomes and the conduct of the proponent . In developing the Air NEPM, stakeholder protest resulted in additional key stakeholder consultation;
- missing input that may save expense. If, for example, stakeholder feedback is that the uncertainty is too great to proceed any further along the HRA process in a particular circumstance, considerable expense and time may be saved through not carrying out work that will not be deemed credible by significant stakeholders.

In framing a public involvement program, the principles outlined in the NEPC Consultation Protocol need to be taken into account. In particular, the principles in the Protocol include the following:

- relevant consultation is an essential component of public policy development, implementation and review and that effective consultation will lead to more informed decisions and increase the effectiveness of environmental outcomes;
- conduct consultation in a transparent, accountable and timely manner, encouraging input from all interested parties;
- allow sufficient time for the consultation process;
- provide comprehensive, timely and accessible information, including use of the NEPC website where appropriate;
- establish clear and realistic timeframes for stakeholder input;
- stimulate constructive exchange of views; and
- regularly review and update contact lists for individuals.

The Consultation Protocol is oriented to the NEPM development process. Its principles are generally applicable to other processes.

In developing a specific public involvement program the following steps must be considered:

Active Stakeholder Identification

It is critical to ensure that all significant stakeholders feel sufficiently aware of the work of the RATF and that they have had adequate opportunity to comment upon it. It is not sufficient to rely upon stakeholders to identify themselves in response to advertisements that many will not see. An additional networking process to identify potentially interested stakeholders is required.

RATF commenced this process, and made considerable progress but more work needs to be done. The opportunity should be taken to further improve the database in advance of the upcoming review processes for the Air NEPM. Vigorous efforts were made to obtain email addresses for persons on the database to facilitate speed of communications and to reduce costs, and this should be continued.

Promulgation of Processes and Consultation Protocols

At an early stage, intending participants should be provided with a clear description of the elements of the process and the rules by which it will be governed. As noted above, NEPC has a consultation protocol, of which stakeholders should be made aware along with any specific matters relating to the particular process being undertaken.

Capacity Building

Until recently HRA has been seen as the domain of the technical expert, with relatively few other people in government, industry and community-based groups knowing much of the details and uncertainties associated with HRA models, in particular. In the past 12 months workshops and a conference have provided some initial opportunities for dialogue between HRA practitioners and those with expertise in other fields. However, it remains true that many stakeholders with a strong interest in the outputs of HRA still have little understanding of how those outputs are generated or of the level of uncertainty associated with them. In addition, those stakeholders least able to access government decision making processes may be the most affected by pollutants under consideration.

Unless stakeholders are informed of all issues involved and are able to participate in dialogue in a supportive environment, they may lack information upon which to form their views, or opportunity to advance those views. In such circumstances, public involvement programs will be of diminished effectiveness unless efforts are made to build the capacity of stakeholders to contribute. In some circumstances sufficient capacity may be able to be built through:

- posted written information;
- email or through the web, although it is important to note that many of the smaller community groups and interested members of the public do not yet have access to either email or the web; and
- public forums. There should be a concerted effort to maximise the opportunity for stakeholders to discuss rather than just read information.

All of these elements are addressed by the NEPC Consultation Protocol and are incorporated into NEPM development processes. RATF considers that not only should they be incorporated into the review of the Ambient Air Quality NEPM, but has utilised them in the consultation program for the RATF report.

It is the view of the environment movement representatives on the RATF, however, that in the current circumstance many stakeholders with a contribution to make to RATF's work are disadvantaged by a lack of knowledge of HRA. They therefore recommended conducting a one-day capacity-building workshop for 12-15 environmentalists active on air pollution issues. However, funding was not available for this. Due to the complexity of the issues involved in the HRA approach, assessment of the need for capacity building to optimise stakeholder input should be undertaken prior to commencing reviews for specific pollutants, in order to ensure that public involvement mechanisms provide maximum benefit.

Public Involvement Mechanism

The public involvement program should provide stakeholders with the opportunity to interact, on matters of substance, with those providing advice to NEPC. It must also provide clear feedback demonstrating that substantive inputs were properly considered and utilised, where beneficial.

4.5.2 Conclusion

The uncertainties inherent in HRA necessitate those uncertainties being communicated clearly in the process of involving stakeholders in the formulation and implementation of policy regarding the use of HRA in standard setting.

The RATF believes that its consultation program significantly enhanced the quality of this final report; in particular, it enabled the recommendations to be expressed more clearly. It allowed the particular circumstances of smaller jurisdictions to be more fully considered and addressed in the finalisation of the report.

Within a limited public involvement budget, RATF provided the opportunity for stakeholders to comment on its report to NEPC Committee via written submissions and through stakeholder forums in all States/Territories, except the Northern Territory where response was very limited. The forums were facilitated by members of RATF and thus provided direct interaction between stakeholders and RATF members. Broad stakeholder forums are a particularly useful form of public involvement where issues are contentious and/or complex, as they facilitate the interaction of many views and areas of expertise.

An analysis of issues raised in written submissions and in the forums and RATF responses to those issues are provided in Appendix 7.

4.5.3 Recommendation

TOR6-1 *That the following principles be adopted for public involvement processes with respect to standard setting for air pollutants, and that time and financial budgets be framed accordingly:*

- *active processes of stakeholder identification;*
- *clear promulgation of the processes to be followed and the consultative protocols that govern them;*
- *assessment of the need for capacity building to optimise stakeholder input, and implementation where necessary; and*
- *effective mechanisms for public involvement, recognising the value of multi-stakeholder forums where issues are controversial and/or complex.*

4.6 Term of Reference 7

To report to NEPC Committee within 12 months of establishment of the Taskforce.

The first meeting of the RATF was held in February 1999. NEPC Committee endorsed an amended schedule, enabling the RATF to finalise and deliver its report to NEPC Committee in the second half of 2000.

REFERENCES AND BIBLIOGRAPHY

Beer T and Ricci PF (1999) Environment International, Vol 25, pp887-98. A Quantitative Risk Assessment Method based on Population and Exposure Distributions using Australian air quality data

Holgate ST, Samet JM, Koren HS, and Maynard RL (1999),Air Pollution and Health, Academic Press, London

Lambert WE, Samet JM, and Dockery DW (1992). Community Air Pollution. In: Environmental and Occupational Medicine. Ed: Rom WN. Little Brown and Company, Boston

National Advisory Body on Scheduled Wastes (2000) 'On schedule eventually – A case study of problem solving through effective community consultation. Australian and New Zealand Environment and Conservation Council

National Environment Protection Council Act 1994 (Commonwealth)

Sgro F (1999) Report of Risk Assessment Methodologies Applicable to Ambient Air Quality in Australia (contains references to all frameworks and models reviewed)

UK Department of Health, (1998), Quantification of the Effects of Air Pollution on Health in the United Kingdom, Committee on the Medical Effects of Air Pollutants, Her Majesty's Stationary Office, London

WHO (1999), Guidelines for Air Quality, World Health Organisation, Geneva

WHO Working Group (2000), Evaluation and Use of Epidemiological Evidence for Environmental Health Risk Assessment: WHO Guideline Document Environmental Health Perspectives, Vol 108, pp 997-1002

ACRONYMS

CAPCOA	California Air Pollution Control Officers' Association
ED	Emergency Department
enHealth Council	Environmental Health Council (formerly National Environmental Health Forum)
EPA	Environment Protection Authority
HRA	Health Risk Assessment
IEUBK	Integrated Exposure Uptake Biokinetic Level (Lead)
LOAEL	Lowest Observed Adverse Effect Level
NEPC	National Environment Protection Council
NEPM	National Environment Protection Measure
NHMD	National Hospital Morbidity Database
NOAEL	No Observed Adverse Effect Level
RATF	Risk Assessment Taskforce
US EPA	United States Environmental Protection Agency
WHO	World Health Organisation

GLOSSARY

Biological marker	a biological change which reflects that environmental exposure to a particular pollutant has occurred.
Carcinogen	a chemical capable of causing cancer.
Ecological risk assessment	a set of formal scientific methods for estimating the probabilities and magnitudes of undesired effects on plants and animals of ecological value resulting from the release of chemicals, other human action or natural catastrophes

The Six Criteria Pollutants of the Ambient Air Quality NEPM

CO	Carbon Monoxide
NO_2	Nitrogen Dioxide
O_3	Ozone
Pb	Lead
PM_{10}	Particles with a diameter less than 10 micrometres
SO_2	Sulfur Dioxide