National Environment Protection (Ambient Air Quality) Measure

Report of the Risk Assessment Taskforce

Appendix 6

Possible use of Health Risk Assessment in the Review of NEPM Pollutants Specified in 'Future Actions'

INTRODUCTION

The RATF has recommended the use of a four stage HRA framework for use within the standard setting process. This framework could be used to develop an air quality standard for $PM_{2.5}$ in the review of the NEPM particles standard in 2001, and for the reviews of ozone and sulphur dioxide standards in 2003. It should be noted that the Issues Identification phase of HRA may indicate that the existing standard is still applicable and hence there would be no need to use a HRA process.

If a HRA process is undertaken it should be noted that a quantitative health risk assessment may not be necessary for all the nominated pollutants. In some cases it may be that only the first two stages of the HRA framework (hazard identification and dose-response relationships) would need to be undertaken to identify appropriate health endpoints and threshold levels for effects. This approach would not require the development of detailed exposure assessment and risk characterisation models.

A number of case studies on the application of HRA in the review of standards outlined in the future actions of the NEPM are provided for discussion. The case studies outline the data required to undertake HRA and whether there are any specific models that may be applicable. A detailed review of the available models has not been undertaken, as this would pre-empt the formal review process. Issues that will need to be addressed in terms of both air quality and health data are highlighted.

As a number of the issues will be common across each of the pollutants general discussion of these is presented. Where issues are specific to a particular pollutant these are discussed separately.

Hazard Identification

This stage of a HRA process is critical, as it will determine the selection of health endpoints and the dose-response data to be used. This stage needs to be completed in consultation with key stakeholders and may best be done by a group with similar make up as the RATF (ie., engaging government, industry and community representatives). This stage must be completed (including consultation) before embarking on subsequent stages of a HRA.

There are several issues that need to be addressed in the Hazard Identification phase of a HRA process. One of the critical issues that impacts on the type of air quality data required for exposure assessment is the choice of an appropriate health endpoint.

The choice of health endpoint was strongly debated throughout the development of the Ambient Air Quality NEPM. The issue to be addressed is whether the more sensitive health endpoints such as reduction in lung function or 'cruder' endpoints such as increases in daily mortality should be used. One argument against the use of more sensitive endpoints is that they are treatable by fairly non-invasive methods e.g. use of brochodilators. The opposing argument is that these more sensitive endpoints should be used because they are indicators for effects that impact on the quality of life, affect sensitive sub-groups such as children, and therefore should be avoided.

In hazard identification the relative importance of controlled human studies and epidemiological data in assessing which health endpoints are used will need to be determined for each pollutant. WHO have recently published guidelines for assessing epidemiological

studies for HRA. These guidelines should be followed in the hazard identification stage of any review of the NEPM standards.

A further issue that needs to be addressed in the review of the NEPM standards is the identification of the sector of the population to be protected. Increasingly overseas there is a focus on ensuring the protection of the health of children. If this is to be adopted in Australia then the more sensitive endpoints, such as reduction in lung function or exacerbation of asthma will need to be assessed. If increases in daily mortality are to be used then the section of the population to be protected will be the elderly or critically ill.

As morbidity outcomes are more sensitive indicators of the impacts on public health they may be more appropriate to be used in the development of air quality standards. This will generally result in more conservative and protective air quality standards and their use may be strongly debated. The use of morbidity outcomes is a critical issue for the review of the SO_2 standard as it is not possible to set a SO_2 standard that will be protective of sensitive asthmatics.

It should be noted that the UK Department of Health concluded that as there were no local data for other health outcomes in the UK, only increases in daily mortality (all causes) and hospital admissions for respiratory disease should be used for quantitative risk assessment in the UK. A similar decision is likely to be needed in the Australian context given that to date the bulk of the Australian data on the health effects of air pollution is for increases in daily mortality and hospital admissions.

Dose-response relationships

Decisions on which dose-response relationships would be applicable in the review of the NEPM standards would need to be determined. There is insufficient Australian data for generation of local dose-response relationships, which means that overseas data will need to be used. Information generated from local studies will give an indication of the degree of uncertainty involved in the use of the overseas data.

Exposure Assessment

In conducting an exposure assessment for Australia exposure assessment models will need to be developed. WHO does not provide guidelines for conducting exposure assessment. The USEPA approach could be used and models are available however, these models are complex, require lengthy run times and are data intensive. The assumptions and default values incorporated into the models have been derived for the US situation and may not be applicable in Australia. This would need to be assessed before use. The exposure assessment approach used in the development of the Ambient Air Quality NEPM is not appropriate, as it does not take into account the differences between the pollutants.

Risk Characterisation

This stage combines the dose-response relationships and exposure assessment to produce an estimate of the potential number of people affected by the pollutant. Baseline health incidence data, such as average daily mortality statistics, will also be included in this estimation. A risk characterisation model would need to be developed for Australia. The USEPA model could be used but it must be kept in mind that the US model has been developed for specific purposes within the US and may not be applicable in Australia. No details on the modelling approach used in the UK have been provided.

Risk Management

To derive an air quality standard, the results of the risk assessment need to be assessed taking into account the results of economic and social impact assessment. As there is no acknowledged threshold for the health effects associated with some pollutants (eg $PM_{2.5}$), this will require assessment of an acceptable level of risk to the population which takes into account what can be feasibly achieved in terms of air quality within a given time frame and acceptable cost (both economic and social). The results of any risk assessment are only one of the inputs into the risk management stage.

CASE STUDIES

(For Discussion Purposes Only)

Particles - $PM_{2.5}$

Hazard Identification

There are an increasing number of studies which report associations between $PM_{2.5}$ levels and health outcomes, including daily mortality, hospital admissions for respiratory and cardiovascular disease, decreased lung function, increased bronchodilator use in asthmatics and asthma. For particles, both PM_{10} and $PM_{2.5}$, the bulk of the data on the health effects is derived from epidemiological studies although some data has been derived from controlled human exposure studies. There is a large database on the health effects associated with PM_{10} with much less data available for $PM_{2.5}$. There is still some debate as to the relative importance of the health effects attributed to PM_{10} versus $PM_{2.5}$. This issue is unlikely to be resolved before the review of the particle standard as there are only a small number of health studies that have used $PM_{2.5}$ and even less that have assessed the relative importance of the fine and coarse fractions of PM_{10}. This is also confounded by the fact that $PM_{2.5}$ is a subset of PM_{10}.

Dose - Response relationships

WHO have used meta-analyses to produce dose-response relationships for health effects associated with exposure to $PM_{2.5}$. These relationships could be used in the risk characterisation stage of a HRA, however the uncertainty associated with their use must be acknowledged. WHO provides guidelines for such usage and recommends, where possible, use of data from the country developing the air quality standards. At present there is not enough air quality data or information on the health effects of $PM_{2.5}$ to derive dose-response relationships specific to Australia.

The dose-response relationships for $PM_{2.5}$ recommended by WHO are for short-term (24-hour) exposures. The WHO does not provide dose-response relationships for long-term exposures.

The USEPA have also generated dose-response relationships that could be used in the review of Australian particle standards. The USEPA relationships have been derived for both short-term and long-term impacts on mortality, as well as morbidity indicators such as hospital admissions for respiratory disease. Dose-response relationships for PM_{10} have been derived for a wider group of health endpoints reflecting the larger database available for PM_{10}.

Both WHO and USEPA dose response relationships for particles have been derived from the results of epidemiological studies. The air quality data used in these epidemiological studies was the average of the ambient air monitoring stations with peak data excluded. It is critical

that the data used in the exposure assessment phase of any HRA be derived in the same way, as the dose-response relationships may not be valid at particle levels outside those used in the studies identifying the health effects.

Exposure Assessment

The limiting factor in applying HRA for a $PM_{2.5}$ review will be the exposure assessment stage due to the limited availability of $PM_{2.5}$ monitoring data in Australia. Whilst Sydney, Melbourne, Brisbane and Perth have reasonable databases this is not true for all other capital cities and larger regional areas. Nephelometry data could be used, as this is highly correlated with $PM_{2.5}$. To do this the correlations between nephelometry data and $PM_{2.5}$ data will need to be determined for each air shed on seasonal and site-specific bases. This would provide a substantial database for exposure assessment. This has already been done in several jurisdictions (Perth and Melbourne).

In Australia, several time series studies have used nephelometry data as a surrogate for $PM_{2.5}$. These studies have shown associations between nephelometry data and increases in daily mortality and morbidity.

As the dose-response relationships for $PM_{2.5}$ have been derived from epidemiological studies using an average of air monitoring data from existing air monitoring stations, the exposure assessment should reflect a similar estimate of exposure to the population. This is the approach adopted by the USEPA in their risk assessments for particles. In this averaging, data from peak sites should be excluded, as this data was not included in the epidemiological studies used to derive the dose-response relationships and it is unclear whether the relationships apply at these higher concentrations. An exposure model would need to be developed for the Australian situation. The USEPA model could be used but this would require acceptance of the assumptions and default parameters built into the model. Details of the USEPA approach are clearly documented in their "Risk Assessment for Particulate Matter" (ABT Associates, 1996).

Ozone

Hazard Identification

There are numerous studies that relate ozone concentrations with a range of health endpoints such as increases in daily mortality and hospital admissions, increases in emergency room attendances for cardiovascular and respiratory disease (including asthma), decreases in lung function and increases in respiratory symptoms. Both chamber and epidemiological studies have been conducted. It should be noted that the health effects associated with ozone have been observed in 'healthy' populations and are not isolated to sensitive subgroups. In Australia there are several epidemiological studies which relate ozone with mortality and morbidity outcomes.

Dose – Response relationships

Dose response relationships have been derived by WHO for decreased lung function, increases in hospital admissions for respiratory conditions, increases in respiratory symptoms and inflammatory responses in the lung. The dose-response data for decreased lung function and inflammatory responses in the lung have been derived from panel studies or controlled human exposure studies. The relationships for increases in hospital admissions and respiratory symptoms have been derived from epidemiological studies. It is unclear whether these dose-response relationships are linear especially at the low and high ends of exposure.

The USEPA have derived dose-response relationships for morbidity outcomes such as hospital admissions for respiratory disease and asthma, decreases in lung function, and moderate to severe pain on inspiration. As with the WHO relationships the USEPA admissions data has been derived from epidemiological studies and the relationships for decreases in lung function and pain on inspiration from controlled human exposure studies or panel studies.

In the review of the ozone standard it would be possible to use either of the WHO or USEPA dose-response relationships. They have been derived for sensitive health endpoints that would provide an assessment of the potential risk to children.

The UK Department of Health has derived dose-response relationships for increases in daily mortality and hospital admissions for respiratory disease. These could also be used in the review of the ozone standard. A comparison of the local studies should be made against the dose-response relationships derived by WHO, UK or USEPA before a decision is made as to which one is applicable in the Australian context.

Exposure Assessment

For ozone the approach to the exposure assessment will depend on the health endpoint chosen and how the dose-response relationships have been derived. As the health effects of ozone are dependent on the duration of exposure and the volume of air inhaled during the exposure, the amount of time spent outdoors and the typical level of activity are factors that should be considered in risk evaluation. For ozone indoor levels are much lower than those experienced outdoors and do not contribute significantly to total exposure. Time-activity data will need to be included in the exposure assessment and the approach taken will be more complex than that for $PM_{2.5}$. Time-activity data for Australia is not currently available for risk assessment and would need to be collected. It may be possible to use the publicly available data derived for California, however the uncertainty associated with its use would need to be clearly communicated. The USEPA exposure model could be used but it is very data intensive. Details of the modelling approach and limitations are provided in the USEPA documentation for the "Risk Assessment for Ozone" (Whitfield et al., 1996). Decisions on whether to use time-activity data in the Australian context will need to be made. It may be possible to collect time-activity data for Australia prior to the review of the ozone standard in 2003.

If data from epidemiological studies are solely used for the determination of the health endpoints and dose-response relationships, then an approach similar to that taken for $PM_{2.5}$ could be used. This would however introduce significant uncertainty in the resulting risk estimates. An assessment of the detail of available exposure models would be required and their applicability determined once the assumptions are outlined. For Australia an exposure model may need to be developed.

Risk Characterisation

In assessing the risk of exposure to ozone the contribution from background levels should be taken into account. This is done both in the US and the UK. It is critical that air monitoring networks be maintained so that an estimate of background ozone levels can be obtained. It should be noted that the proposed NEPM monitoring will not deliver these data and additional monitoring will need to be conducted. This is also true for PM_{10} and $PM_{2.5}$.

Sulfur Dioxide

Hazard Identification
Sulfur dioxide is generally identified as a threshold pollutant with acknowledgment that some sensitive asthmatics may not be protected. Data has been derived from controlled human exposure studies as well as epidemiological studies. One of the significant issues that will need to be considered in the review is the averaging period and the acute health endpoints to be used in the assessment (for example, is a 10min average associated with health effects, and can such an average be measured in Australia?).

Dose – Response relationships
Dose-response relationships derived from overseas epidemiological studies could be used however there would be some uncertainty introduced as to their transferability to the Australian context due to the low levels of SO_2 experienced in most urban areas in Australia. Another source of uncertainty in the transferability of the dose-response relationships is the confounding by particles. In general when SO_2 levels are high, particle levels will also be elevated. The reverse however is not always true, ie when SO_2 levels are low, particle levels can still be high.

The WHO has derived a dose-response relationship for changes in lung function in asthmatics. This relationship has been based on the results of controlled human exposure studies. They have also derived dose-response relationships for increases in daily mortality, hospital admissions and decreases in lung function but highlight the uncertainty in these relationships due to confounding by other pollutants.

The USEPA use the data from controlled human exposure studies to identify a threshold for effects and then apply a safety factor to derive a standard. They have not pursued a quantitative risk assessment approach for SO_2. The air quality standards in the US are set to be protective of asthmatics and others with hyperactive airways.

The UK Department of Health has derived dose-response relationships for increases in daily mortality and hospital admissions for respiratory disease. It should be noted that the SO_2 levels experienced in the UK are much higher than those experienced in Australia. Whether these relationships are transferable to Australia will need to be assessed.

Exposure Assessment
As SO_2 is generally considered a threshold pollutant the approach to modelling exposure will differ to that used for particles and ozone. An exposure assessment model would need to be developed to assess the percentage of the population exposed to levels above the threshold value. Generally the amount of monitoring conducted in Australia for SO_2 is not as extensive as for either particles or ozone. This is due to the fact that in the absence of industrial sources the ambient levels of SO_2 are low. This lack of data may be a problem in conducting an exposure assessment for SO_2.

CONCLUSION

HRA could be used in the development of an air quality standard for $PM_{2.5}$ and in the review of the ozone and SO_2 standards. The availability of appropriate exposure assessment and risk characterisation models for ozone and sulfur dioxide should be evaluated when standards for those pollutants are reviewed.

REFERENCES

1. ABT Associates (1996). A Particulate Matter Risk Assessment for Philadelphia and Los Angeles. Prepared for USEPA.

2. Whitfield R G et al (1996). A Probabilistic Assessment of Health Risks Associated with Short-Term Exposure to Tropospheric Ozone. US Department of Energy, Argonne National Laboratory, Argonne.