National Environment Protection (Ambient Air Quality) Measure

Report of the Risk Assessment Taskforce

Appendix 7

Issues Raised in the Consultation Program

BACKGROUND

The Risk Assessment Taskforce considered that stakeholder discussion of a draft report would enhance the quality of its final report and consulted with stakeholders prior to finalising its report.

There was significant interest in the draft report from stakeholders (two hundred and fifty copies of the draft report were distributed). Forums were conducted in all capital cities (except Darwin) between 23 August and 1 September 2000. One hundred and thirty-one individuals registered to attend these forums. Thirteen written submissions were received from government agencies, industry and conservation movement bodies, as well as risk assessment experts.

Amendments to the draft report have been made as a result of consultation outcomes.

This document presents a summary of issues raised during consultation on the draft report of the Risk Assessment Taskforce, and responses to those issues.

The issues are presented in a tabular format combining issues raised in the forums conducted in capital cities and issues raised in the written submissions received.

Many issues were raised in more than one forum and/or written submission, and in different forms. Style and expression differed from one forum and submission to another, and thus issues were raised in different ways having different connotations, contexts and emphases. As it is not possible in this summary to deal with all the subtleties emerging from such variations, an attempt has been made to group similar comments together. Similarly, an attempt has been made, where possible, to provide a single response which captures the essence of the issue.

The comments made in forums and submissions have been assessed entirely on the cogency of points raised. No subjective weighting has been given to any comment or submission for reasons of its origin or any other factor that would give cause to elevate the importance of any comment or submission above another.

Submissions are numbered, in order of receipt, as indicated in the list at the end of this Appendix. The origin of a comment appearing in the left hand column of the table can be traced by reference to the number(s) quoted at the end of the comment (for example, 10 refers to the Health Department of WA). Comments raised in the public forums are annotated with "(C)". The response appears in the right hand column. Please note that these responses have been developed by the RATF, and are not attributable to NEPC Committee or NEPC.

SUMMARY OF RESPONSES TO PUBLIC COMMENTS AND WRITTEN SUBMISSIONS

GENERAL COMMENTS

Comment	RATF Response
There are options for Health Risk Assessment (HRA): - not useful - useful, but... - should be used - imperative that it be used (C)	Agreed. Options are discussed in Report.
Congratulate RATF on extensive and detailed review of current air pollution related health risk assessment in Australia and overseas provided by the report's appendices. (6)	Noted.
Commend the RATF on the report. Appendices 3, 4, and 5 add value to the issues discussed in the report. (4,9)	Noted.
Believe that risk assessment approach offers best means of setting objective standards. (4,9)	Noted.
HRA has low credibility because of its (mis)use in cancer risk assessment in the USA (C)	Noted. The Report repeatedly acknowledges the need for transparency in the HRA process.
Risk Assessment should be driven by the concept of real adversity and how this is changed by intervention through air quality policy rather than through use of statistical concepts of risk (12)	Noted. Qualitative commentary on the outcomes of statistical analysis is required (Section 4.3.1).
"The product of risk assessment should not be in terms of predicted impacts rather than being expressed in purely statistical terms such as probability of binary outcome". (7)	Noted. Reporting protocol needs to ensure that commentary is provided to explain any statistical constructs.
Advocate application of risk assessment within context of NEPC Act. eg. s15, risk assessment useful to identify where regional differences are relevant and in ensuring measures are cost effective; s17 risk assessment necessary to ensure community are properly consulted. (7, 12)	Noted. Beyond RATF Terms of Reference. To be considered in specific reviews of standards or in the development of new NEPMs.
NEPC Act requires risk assessment to be carried out on alternatives to the NEPM proposed. "We understand that the brief for this report was confined only to Health Risk Assessment. This appears to indicate that the writing instructions for the RATF may have in fact been too narrow to cover the requirements under the Act". (12)	Noted. The RATF was established specifically to examine HRA in the context of ambient air quality standards.
Concern that the CSIRO were not consulted during the development of the public consultation draft. (4)	The draft report was developed and published in order to provide the basis for consultation.
Congratulate NEPC on making links between environmental, health and medical professionals and with consumer groups. This needs to be continued. (1)	Noted.
Recommend the involvement of the Australasian College of Nutrition and Environmental Medicine to provide advice on the health risks associated with various chemicals. (1)	Noted. Will place the College on NEPC Ambient Air Quality mailing list.

GENERAL COMMENTS

Comment	RATF Response
RATF membership does not include health related community groups. (C)	Agreed, although RATF included two community representatives and three health professionals (an MBBS; a PhD in environmental health and a PhD with a medical research background).
The standard setting process has been at an elite level to date, and confusing to members of the public – need to widen the debate (C)	Agreed. Need for full public involvement in the HRA process is identified in the Report (Section 4.5).
Consultation period too short given: - the technical nature of the document - the fact that it would be used as the basis for setting Australian air quality guidelines and standards. (10)	Noted. Reviews of air quality standards in the NEPM (informed by the outcomes of the Report) will incorporate appropriate consultation.
Need to empower stakeholders – the most vulnerable/least able to access government decision-making may be the most affected by pollutants under consideration (C)	Noted. Public involvement process provides opportunity for these issues to be raised directly during HRA process (Section 4.5.1).
Evaluation sheet for each session (C)	It was recognised at the final consultation forum (Perth) that it was an oversight not to have provided evaluation proformas.
Feedback from consultation sessions to participants (C)	This appendix (Appendix 7) comprises a summary of issues raised and responses. The final Report is expected to be made available publicly.
Report is a good starting point but needs to go further particularly in the: - assessment of models; - development of risk assessment expertise; - how risk assessment should be utilised in standard setting process. (3)	Report amended to: assess broadly the use of HRA for pollutants in NEPM "Future Actions" (Appendix 6); highlight health end points (Sections 3.3.1, 4.1.1, 4.3.1); discuss use of overseas dose response data (Section 4.4.5); outline decisions which need to be made to assist transparency (Sections 3.4, 4.3). Report refers to development and maintenance of HRA skills (Section 4.2.2)
Outline the next steps for the RATF, eg. - TORs take us to a certain point - the RATF has responded to the TORs - Where to from here - an addendum/extra report? (C)	Noted. The Report will be transmitted to NEPC Committee with suggestions for further actions.

CHAPTER 1 - INTRODUCTION

Comment	RATF Response
There is a lack of agreed HRA methodology, debate about the veracity of some approaches and the interpretation of results. (5)	Report amended to clearly identify appropriate models and the need for transparency in the use and reporting of models (Sections 2.1, 3.4, 4.3, 4.5).
There are many pollutants apart from criteria pollutants. (C)	Noted. The RATF was expressly established to consider the six criteria pollutants. Report amended to recognise that HRA is broadly applicable to other air pollutants (eg air toxics) (Section 1.5.2).

CHAPTER 1 - INTRODUCTION

Comment	RATF Response
Most HRA is done for air toxics and it should be emphasised that criteria pollutants are being discussed. (C)	The Report explicitly focuses on the application of HRA to criteria pollutants, and notes that the approach is applicable to air toxics.
If the ability to estimate incremental changes in risk for the range of possible standards for each pollutant is a requirement for HRA, a substantial research program is required. (9)	There is a need to examine Australian and overseas data prior to making decisions about incremental effects.
Section 1.3 mentions that one aim of risk assessment should be to provide estimate of incremental changes in risk for a range of standards - otherwise ignored in NEPC context. (7)	Noted. Decisions about incremental effects would need to be made on a case by case basis for specific reviews.
RATF report not clear about 'site specific' emissions. (C)	Report amended to clarify role of RATF (Section 1.5.2).
NEPM reads as if it protects all people. Previous NHMRC guidelines acknowledged that they did not protect all people all of the time, and NEPC standards should also acknowledge this. (C)	Noted. The NEPC Act is framed in terms of 'equivalent protection' for all people wherever they may live. Although air quality standards are set to protect sensitive groups it is acknowledged that the most sensitive sub-groups within the population may not be protected for some pollutants. For non-threshold pollutants e.g. particles and ozone it will be impossible to protect all segments of the population.
There is confusion regarding differences in standard setting and protection and risk due to ambient air pollution and hot spot pollution (C)	The NEPM explicitly applies to ambient air as acknowledged in the Report.
Was the lack of jurisdictional monitoring data critical in the development of the Air NEPM, given that dose response data for specific pollutants/populations should be sufficient, and that one can then generalise to remainder of population? (C)	The ability to perform a full HRA was restricted by the lack of monitoring data in some jurisdictions, in addition to other difficulties noted in the Report.

CHAPTER 2: STANDARD SETTING

Comment	RATF Response
Standard setting for criteria pollutants should be accompanied by discussion of: - general goals (prevented health outcomes in the long-term); - possible abatement strategies especially where standards are frequently or regularly exceeded. (6)	Noted. Report amended to include health outcomes in discussion on health end points (Section 4.3.1) Noted. Beyond RATF Terms of Reference
The methods listed for developing standards are not mutually exclusive - eg an Expert Panel could use HRA (C)	Agreed. See Section 2.
Explain what is meant by an Expert Panel (C)	Discussed in Section 2.
Why mention 'analytical limits' if not relevant for standard development? (C)	Noted. This was included for completeness in a review of means of setting standards (Standards cannot be set at a level below the analytical limit of detection because such a level could not be measured and enforced).

CHAPTER 2: STANDARD SETTING

Comment	RATF Response
ERA - recognise damage to built environment and crops (ie. anthropogenic activities) (C)	Noted. Report amended (Section 2)
HRA process can be applied to all pollutants (C)	Agreed, although the details of application differ.
HRA should not be seen as providing an objective answer but as an important input into standard setting process. Reliance upon expert judgement is a concern. HRA needs to be transparent and stakeholder participation is necessary.	Agreed. Stressed in the Report.
HRA is one approach for setting standards. Consideration should be given to other approaches such as ecological impacts, international best practice and stakeholder views. (8)	Agreed. Report does consider other means of developing standards (Section 2).
HRA is only one means of developing standards – only use HRA when it adds value (C)	Agreed. Noted in Report (Sections 2, 4.1.2)
HRA should be used as an input, amongst others, when developing standards (C)	Agreed. See Section 2.
There is debate over whether HRA is/is not important guide (C)	Agreed. This can be evaluated during the issues identification stage of the HRA process for specific pollutants.
HRA is only a tool - it is not the answer (C)	Agreed. This is clearly acknowledged in the Report (see Section 2).
Establish criteria for using HRA (eg availability of model(s) and data for a specified pollutant – if more data are required, what about the cost and time required to generate that data?)– if these are not met, then use other methods (C)	Noted. These issues will be considered during the issues identification phase of the standards development process (see Figure 1).
HRA may show that there is not a problem (hopefully identify this early in the process) (C)	Agreed. Report amended (Sections 2, 3.2).
Emphasise iterative nature of standards development process (C)	Agreed. Recommendation TOR2-5 now includes this.
Figure 1: Title refers to 'standard setting' - should be 'standards development' (as the NEPC itself sets the standards) (C)	Agreed. Heading changed.
Figure 1: After issues identification, recognise the need for decision making regarding the viability, cost and need to do HRA and/or use other processes (C)	Noted. These issues are taken up in the NEPC decision making process. Note that Figure 1 is a representation of the process, not a detailed description.
Figure 1: All methods of setting standards should be at the same level (ie no one method has automatic primacy) (C)	Agreed. Figure 1 modified.
Figure 1: Feedback loops– eg from HRA/other std setting processes to issue identification (C)	Agreed, but would make Figure 1 (which is a representation of the process, not a detailed description) too complex.
Figure 1: Indicate links between ERA and HRA (C)	Agreed, but would make Figure 1 too complex.
Figure 1: Before "Political Decision", should include a box describing 'acceptable' risk, particularly for criteria pollutants with no established threshold. (2, 9)	HRA outcomes need to be explained transparently. The actual decision on acceptability is inherently political.
Figure 1: Extend Public Involvement further down the diagram (C)	Agreed. Figure 1 modified.

CHAPTER 2: STANDARD SETTING

Comment	RATF Response
Figure 1: Public involvement panels should be extended down to "Political Decisions". (4)	Noted. The diagram attempts to focus on formal public involvement processes, which occur before political decision making
Figure 1: Have a dotted line around standards development, with an arrow to the (political) standard setting step (C)	Noted.
Figure 1: If the answer is NO from the political process, don't go back to the beginning - go back into the body of the diagram (C)	Agreed. Figure 1 modified.
Figure 1: Allow for the fact that HRA and ERA can be bypassed.	HRA may be bypassed if all agree on the need for a standard and the level at which the standard may be set (Section 3.2 and Figure 1). Otherwise one can 'skip through' some or all of the HRA steps very quickly, depending on data availability, level of agreement between stakeholders, and political requirements. Report has been amended (Sections 2, 3.2).
Instead of 'public', use 'community' "Public" includes everyone – including science, medicine etc (C)	Noted. In this Report both terms are equivalent.
Define public involvement to include education (C)	Discussed in Section 4.5.1
How are values of the community taken into account? (C)	Through public involvement (Section 4.5).
Empower community to give input (C)	This is done through public involvement and is recognised in the Report (Section 4.5).
How are models chosen? (C)	Model(s) will be selected on the basis of suitability for the pollutant in question, cost effectiveness and data availability. This would be determined at the time of review.
How are models used? (C)	Models are used to quantify exposure of the population to the pollutant(s) under consideration and the resulting risk.
"Acceptable risk" is determined by a political/social process (C)	Agreed.
Take individual differences into account in defining sensitive sub-groups. (C)	This is addressed in the Report (Section 3.3.3) and Appendices 4 and 6.
Should be clear as to what you are trying to avoid (eg number of deaths) in setting a standard (C)	This will be determined in the Issue Identification stage or Hazard Identification stage.
Highlight health end points (C)	The selection of health endpoints is acknowledged as a critical part of the HRA process. The Report has been amended to address this issue (Section 3.3.1).
Need consideration of cancer end point (C)	Agreed, if the pollutant under scrutiny causes cancer
Why was there no debate about the use of HRA when developing the contaminated sites NEPM, but there was for the air quality NEPM? (C)	Risk assessment has been widely used in contaminated sites assessment.
Indicate where the precautionary principle is used in standard setting (C)	Noted. The use of the precautionary principle is addressed in Sections 2.1 and 4.3.1.

CHAPTER 2: STANDARD SETTING

Comment	RATF Response
Reference to the Precautionary Principle is encouraging but definition is so qualified as to make it meaningless. eg. How is "serious or irreversible environmental damage" or "avoid where practicable" defined? (11)	The Report uses the definition specified in the Intergovernmental Agreement on the Environment.
Setting air quality standards on the basis of the Precautionary Principle in the face of uncertainty over the impacts of various levels of air pollution is likely to result in overstringent regulations. These will impose unnecessary costs on the community and industry. (13)	As mandated in the NEPC Act (and the Intergovernmental Agreement on the Environment) consideration will be given to the precautionary principle in establishing new NEPMs as well as an analysis of economic and social impacts of any proposed standards.
Uncertainty of data must not be used as a reason under the Precautionary Principle for the establishment of overstringent air quality measures. (13)	Noted.
HRA could be used for other 'atmosphere' related issues, like noise (C)	Agreed.
Strict standards are of little effect if there are no credible systems in place to monitor them. In the absence of such networks, the Precautionary Principle should prevail (when defined stringently) (11)	Noted. Where monitoring results are used in the standards setting process, this factor should be acknowledged. Otherwise, outside Terms of Reference.

CHAPTER 3 - HEALTH RISK ASSESSMENT

Comment	RATF Response
Health Risk Assessment is consistent with a rigorous scientific assessment of air quality standards, and is supported. (13)	The extent to which HRA will be applied (eg. qualitative/quantitative) will be determined at the time of review for a given pollutant.
Figure 2: Agree with the general framework, but it fails to give adequate emphasis to importance of determining, ranking and prioritising health end-points. (4)	Noted. Report has been amended (Section 3.3.1)
Figure 2: Words in the diagram have different meanings to different people – define them (C)	Agreed. Terms explained in Section 3.3
Section 3.2 (third paragraph) Agree with statements made, but differences between individual susceptibility and population susceptibility should be made explicit. (4)	Agreed. Text amended (see Section 3.3).
Define purpose of HRA and how it is different to public interest in local effects and individual risks (C)	Noted. This will be addressed through the proposed reporting protocol. The impact of local air quality is an issue for environmental agencies.
If everyone agrees on a standard up front, why go through HRA? (C)	Agreed. Report amended (Section 3.2).
Agree with the view that HRA offers useful guide in standard setting but uncertainties need to be stated. Where appropriate other approaches should be used. Data gaps may make HRA and ERA inappropriate. (8)	Agreed. R eflected in the Report.

CHAPTER 3 - HEALTH RISK ASSESSMENT

Comment	RATF Response
Both hazard identification and dose-response assessment can be taken to refer to clinical assessment and a study of the changing symptoms that an individual manifests. Approach cannot be used to set standards on the basis of population-based risks. (4)	Agreed. The hazard identification stage will identify appropriate end points to allow the setting of population based standards.
Need to prioritise pollutant effects and pollutants (C)	Agreed. NEPC will determine the pollutants for which standards will be set. Pollutant effects will be prioritised as part of the HRA process which will include public involvement (Section 3.3.1).
Efforts should be made to address data gaps, particularly regarding monitoring data and epidemiological studies. Could consider broadening the scope of chemicals monitored to include potential confounding effects. (2)	Noted. The Report addresses these issues (Sections 4.4.2-8)
Report confirms lack of reliable data for HRA but this does not preclude derivation of guidance values by completing the first two steps of HRA. Adequate site specific data are not essential for setting generic exposure guidelines which are based on the hazard presented by the substance and the dose response. (10)	Noted. Addressed in Report.
Accuracy of the data input and of the relationships between the health impacts and different pollutant concentrations will be crucial for a reliable outcome of the Health Risk Assessment Process. (13)	The Report clearly acknowledges the need to stipulate the level of uncertainty associated with the assessment, and to report this in a transparent manner.
The degree of uncertainty must be explicitly identified. (13)	Agreed.
HRA should quantify uncertainties. (4)	Agreed, where feasible. Section 3.4 outlines in detail requirements for transparency.
Need for on-going review of standards as changes occur in technology/ emissions management/exposures/ information about effects (C)	Agreed. This is explicitly acknowledged in the Report (see Section 1.4) (see also Air NEPM Future Actions, which require a review of NEPM standards).
Need to use sensitivity analysis to consider variations in standards and in averaging times. (C)	Noted. Addressed in Report (Section 3.4).
Adequate procedures are required for deriving meta-analytical effect estimates. (6)	Noted.
Report notes that Australian studies lack methodological transparency. The Proceedings of the International Clean Air and Environment Conference (CASANZ, 1998) provides further elucidation of these studies. (9)	Noted.
Report has not sufficiently addressed the difficulty that was faced in the development of the Air NEPM ie. how does one undertake the exposure assessment and how does one undertake the dose-response assessment? (4,9)	The Report identifies an appropriate way forward for future reviews of air quality standards. References quoted in the Report also deal with this matter.

CHAPTER 3 - HEALTH RISK ASSESSMENT

Comment	RATF Response
Section 3.3.2 – In the development of the Air NEPM, two types of dose-response assessments were carried out. The dose-response carried out for the NEPM as part of the health review was based on individual clinical dose-response, and did not produce quantified dose-response relationships that could be used in health risk assessment. (4)	Disagree.
Section 3.3.3 – "The discipline of undertaking the exposure assessment highlighted anomalies in the Australian air quality data. We note that the report says that the low level of confidence was not in the exposure assessment, it was in the data that had to be used to perform the exposure assessment. The same data would have to be used in any wide-ranging investigation". (4)	Noted.
Section 3.3.3 (paragraph 2): Sentence requires clarification. It implies that averaging air monitoring data constitutes an exposure assessment. (4)	Noted. Report has been amended.
Section 3.3.3 (paragraph 2): The paragraph does not deal with the difficulties of determining an appropriate metric for exposure assessment. There needs to be agreement on metric to be used. (4)	Noted.
Although it is noted that it is expensive and time consuming to obtain Australian exposure assessment data, information could also be used to refine water and soil contamination guidelines and be extended to a broader range of epidemiological data such as skin cancer correlated to sun exposure. (2)	Noted. Outside RATF Terms of Reference.

CHAPTER 4 - TERM OF REFERENCE 1

Comment	RATF Response
Different models will give different results, therefore need to use one model - a consistent framework is required for consistent outcomes. (C)	HRA model selection should be determined in the HRA process according to the pollutant and with public involvement. Different models are required to address different health outcomes.
HRA should be 'built in' for national standard setting processes (C)	The extent to which HRA is applied will be determined in the issues identification stage.
HRA is only one means of developing standards – only use HRA when it adds value (C)	Agreed. Noted in Report (Sections 2, 4.1.2)
There is a need for review mechanisms for standards (C)	Agreed. Addressed under the Air NEPM 'future actions' which require a review of all its standards after 7 years.
HRA is already built-in to state standard setting processes (C)	State governments evaluate pollutants on a case by case basis. HRA may be used as appropriate.
HRA is a repeatable/consistent/objective process (C)	HRA is not always applied repeatably or consistently; it needs to be applied on a case by case basis. It is an objective process.

CHAPTER 4 - TERM OF REFERENCE 1

Comment	RATF Response
Transparency and repeatability are important (C)	Agreed. The need for 'transparency' is repeatedly acknowledged in the Report. The HRA process can not be 'repeated' per se (see previous response).
HRA should not be the basis for making fine distinctions (C)	Agreed. The Report clearly addresses uncertainty and variability (Section 3.4).
Does the Recommendation answer the TOR – did RATF investigate models? (C)	Models were evaluated by independent consultant (Appendix 2) and further reviewed by RATF.
It would appear that this Term of Reference has not been met given that the report advocates possible frameworks and not models. (4, 9)	Noted. The Report draws a distinction between frameworks and models. Models are subject to updating and therefore need to be assessed when standards are reviewed.
Support the recommendation. "Consideration should also be given to extending this to the development of the Air Toxics NEPM". (13)	Noted. The Report acknowledges the broad applicability of this approach (Section 1.5.2), however, the focus was on the criteria pollutants in the Ambient Air Quality NEPM.
Recommendation - "where appropriate" – should specify criteria for 'appropriate' (eg health data availability) or for 'not appropriate' (eg insufficient CO monitoring data for use in a HRA model for determining risk from CO pollution). (C)	Agreed. Recommendation changed.
Recommendation – could be framed in terms of when the use of HRA is NOT appropriate – ie in circumstances A, B , C … (C)	The HRA process as outlined in Figure 2 is always appropriate, however, the extent to which it will be applied will be determined on a case by case basis. Where the need for a standard and the level at which the standard should be set are agreed, HRA may not be necessary.
For pollutants with a threshold - could stop at stage 2 of HRA process. For those without a threshold - use all steps of HRA process (C)	Agreed. At all stages during the HRA process there are opportunities to evaluate the need for qualitative or quantitative response, and decision points allowing the bypassing of certain steps.
USEPA has quality control through community representation - WHO has least public involvement and so does not have this quality control (C)	Noted. This is discussed in the Report. The Australian application of HRA should include public involvement.
RATF has assumed cost intensity of US approach (C)	Noted. The high costs of the USEPA approach are openly recognised by the USEPA. These costs were discussed by USEPA officials with the RATF (Perth, December 1999).
Why not use USEPA model? (C)	This is discussed in the Report and will be evaluated at the time of any review. The USEPA models are scientifically robust and have been developed for use under US conditions. Their models are data intensive and it may be the case that the required data are not available in Australia. Report has been amended (Section 4.2.2).

CHAPTER 4 - TERM OF REFERENCE 1

Comment	RATF Response
Report assumes sound risk assessment approach would be unduly costly. S34 (ii) of the Intergovernmental Agreement on the Environment implies that proper resourcing is required. WHO procedures are premised on a lack of resourcing and they have been unable to consult widely. (7, 12)	Different frameworks may be equally robust but the cost of implementation may vary. RATF considers that technically the USEPA approach is the most transparent and technically robust, but costs should be taken into account. Specific elements of the USEPA approach could be utilised where relevant and practicable in Australia. The WHO approach sets out guidelines for the first two steps of the HRA framework only, and has been developed in consultation with experts worldwide. Should WHO be used for particular pollutants, there would be a need to develop HRA steps 3 and 4 for Australia.
Use scientific data from USEPA (eg. data on ozone exposure) (C)	Noted. Report amended (Section 4.2.2) Consideration should be given to all relevant international studies and where appropriate US data should be used.
Ricci and Beer model approach superior to other approaches in terms of population and air quality 'cells' approach. "I think the crucial process is to find or develop a framework and corresponding models which are technically sound and then work on improving the transparency by developing explanatory notes etc. Given that the Ricci and Beer model is being developed in Australia specifically for air quality assessment, there is an opportunity to revise the approach iteratively , according to public comments and other inputs." (2)	Advice to RATF is to the contrary (Appendix 2).
Section 4.1.1 – Ricci/Beer have published extensively to increase transparency of model (ref. list supplied). No attempt seems to have been made to obtain later material. (4)	Noted. The relevant documents appear not to have been available to the author of Appendix 2. The Report will reference this material.
Section 4.1.1 – Draft enHealth framework is not strong in its applicability to air issues particularly the choice of averaging times is unique to air quality assessments and adds degree of complexity. (4)	Noted. Report indicates that the enHealth framework should be further considered when finalised.

CHAPTER 4 - TERM OF REFERENCE 2

Comment	RATF Response
Prioritise criteria for doing HRA so that one can ensure that if HRA is chosen as the means of developing standards, it is done on the basis that HRA is feasible (relevant models and data are available), and the outcomes will be meaningful. (C)	Agreed. This will be done through the issues identification phase of any review.

CHAPTER 4 - TERM OF REFERENCE 2

Comment	RATF Response
Support the recommendations in the report. Particularly those recommendations "covering the establishment of standard HRA framework that can be tailored for each pollutant, the recommendation that sufficient time be allowed for each sequential step, and those covering the collection of average air quality data on a consistent basis across jurisdictions. (13)	Noted.
Important for stakeholders to have input into selection of assessment models and for rationale and limitations of models selected to be stated. (8)	Noted. The Report clearly states the importance of public involvement in all stages of the HRA process (eg Section 4.5).
Section 4.2.2 (2nd dot point) - 'developing and maintaining ...' (C)	Agreed. Text amended.
Section 4.2.2 (last dot point) – need to communicate realistic timelines and budgets to politicians (C)	Noted.
Section 4.2.2 (first paragraph in Section "Data required for HRA") – Discussion fails to note complexity of air quality standard setting eg. appropriate averaging times, selection of appropriate metrics for exposure and risk assessments. (4)	This is discussed throughout the Report and in Appendix 6.
Section 4.2.2 (last paragraph in Section "Data required for HRA") is incorrect. "The model does not interpolate percentiles, it interpolates the actual frequency distribution of air pollution exceedences". (3)	Noted. Report amended.
Section 4.2.2 (last paragraph in Section "Data required for HRA") – Implies deficiency in the exposure assessment for the Air NEPM. Difficulty lay with high uncertainty of dose-response relationships. (4)	Noted. Although the RATF acknowledges the uncertainty in the dose-response relationships, it also believes that exposure assessment is a critical issue for consideration in HRA. The lack of data and appropriate models made such an assessment difficult. This is discussed in the Report.
Section 4.2.2 (last paragraph in Section "Skills") – CSIRO should be included in list of expertise. (4)	Noted. Report amended to include "and other government agencies".
Section 4.2.2 (last paragraph in Section "Sequential Implementation") – strongly agree that steps should be undertaken sequentially, not concurrently. (4)	Noted.
Section 4.2.2 (last paragraph in Section "Costs") – concern about the adequacy of enHealth framework. (4)	Noted.
Section 4.3.1 – First use of the term health endpoint. Is vitally important topic and should be discussed earlier. (4)	Noted. Amendments made throughout Report. See also Appendix 6.
Essential data inputs: ▪ NEPM ambient monitoring data ▪ monitor for specified health outcomes ▪ need to quantify impacts in particular airshed(s) (C)	Addressed in Report.

CHAPTER 4 - TERM OF REFERENCE 2

Comment	RATF Response
RATF focuses on final two stages of HRA (and is different to enHealth framework). RATF confuses Health Impact Assessment and HRA) (C)	The RATF recommends a four stage HRA process which is entirely consistent with the enHealth HRA framework. The RATF does not address health impact assessment.
First step in improving exposure assessment would be to show that air monitoring station data are representative for the region and the appropriateness of using such data to estimate individual exposure. The need for this information is noted in Recommendation 6 in Section 4.2.4 and Recommendation 1 in Section 4.4.9. (10)	Agreed, however, HRA in standard setting will provide a measure of population risk not individual risk.
Assessment of current air monitoring regimes required; the exclusion of 'peak' data; and the limited number of monitoring stations may detract from usefulness of air quality data for exposure assessment. (8)	For HRA it is critical that the data used for exposure assessment matches the data which have been used in the derivation of dose-response relationships.
Averaged metropolitan health statistics cannot be simply extrapolated to smaller areas without allowing for local variations in pollution sources and concentrations as well as variations in health status of the local population. (11)	Agreed.
Averaging of monitoring data should be used cautiously because many daily continuous sources tend to be point or line sources. (11)	Agreed.
Does estimation of average exposure have to be done for every airshed? – probably not necessary for standard setting purposes (C)	There may be implications regarding transferability of data to other airsheds. See Section 4.4.7.
A small number of monitoring stations would make it difficult to optimise the system to get average values – need information beyond what the NEPM can deliver. The real objective of monitoring is to obtain accurate exposure data. (C)	Agreed. It is acknowledged in the Report (Section 4.2.3) that there is a need for further monitoring beyond that required by the Air NEPM.
The scale of operation may be strategic or local – this will affect the design of the system, determining whether "average" or specific (accurate) data are obtained. (C)	In setting ambient air quality standards regional air quality is assessed, not local air quality. Environmental agencies manage local air quality.
The geographic placement of monitors will determine the 'average' values (C)	Agreed. The use of "average" in the draft report was open to interpretation. Report amended (Section 4.4.4).
Peaks are not always omitted from epidemiological studies – in Europe, there are two types of studies – those which use averages, and those which include peaks (C)	Noted. Discussed in the Report (Section 4.4.4) and Appendix 4.
Extremes (peaks) are included in responses used as indicators (eg hospital admissions) (C)	For time series studies peak data are not used in the exposure assessment. This is discussed in the Report and the USEPA reference cited in the Report.
Need complete set of data to develop dose response function – eg for SO2, there are many chamber studies, but cannot average these across the population. (C)	Noted. This is discussed in the Report, Appendices 4 and 6. This would be addressed through choice of exposure model.

CHAPTER 4 - TERM OF REFERENCE 2

Comment	RATF Response
Timing of monitoring network implementation will affect availability of data (C)	The Air NEPM requirements for monitoring networks are a sub-set of total jurisdictional monitoring requirements. RATF have recommended that jurisdictions establish and maintain their monitoring networks so that they extend beyond NEPM monitoring requirements. The acceptability of individual airshed data as being representative across the airshed will need further consideration.
People living closer to sources will continually experience semi-permanent gradient of pollutant concentrations. Respiratory disease rates tend to be higher in populations closer to main arterial roads. (11)	Noted.
Consider the possibility of mobile monitoring equipment that could be rotated to specified cities, in order to extrapolate from existing data and to estimate pollution levels. This may assist in overcoming financial constraints to collecting reliable air monitoring data. (11)	Noted. Such an approach may be useful for compliance monitoring. In HRA there is a need to acknowledge limitations in exposure data, and to encourage studies which will improve such data.
Current air monitoring regimes underestimate particulate emissions from traffic sources. RATF report does not seem to take into account long term adverse health effects eg. from traffic emissions. (11)	Noted. It is expected that long term effects will be taken into account when reviewing standards in the Air NEPM.
Need to ensure compatibility of monitoring instruments (eg TEOM vs Hi-Vol for particles) to ensure comparability of data (C)	Noted. This needs to be addressed by environmental agencies and the Peer Review Committee.
Under-estimation in TEOM measurements at higher PM concentrations needs to be allowed for, possibly by cross-calibrations (eg. Hi Vol Samplers). (11)	Noted. This needs to be addressed by environmental agencies and the Peer Review Committee.
If monitoring is stopped, then there is no ability to determine trends (C)	Agreed.
Abatement strategies depend on sources of pollutants (eg point or diffuse) – specify source types and strategies (C)	Agreed. This is a management issue for environmental agencies.
There is need for liaison between EPAs and Health Departments - routinely collected data are OK (C)	Agreed. Such liaison is routinely undertaken and the need for development of adequate government expertise is specifically noted in the Report (Section 4.2.2).
Exchange of information (regarding best practice for HRA) between NEPC and others – eg NRA (C)	Agreed.
Recommendation 1: "…will need to be different…" - replace with "are to be considered separately for each pollutant…" (C)	Agreed. Report amended.
Recommendation 1: "…to Australia" replace with "…in Australia" (C)	Agreed. Recommendation amended.
Is there a need for an Australian framework? (C)	Highly desirable
Australia should develop its own data for an Australian model (C)	Agreed, where feasible.

CHAPTER 4 - TERM OF REFERENCE 2

Comment	RATF Response
Recommendation 2 suggests using the enHealth framework which is geared towards land and water issues and does not address issue of averaging times in air quality standard setting. (4, 9)	Noted. The enHealth HRA framework is a generic HRA framework. Should the final enHealth framework include appropriate models for air quality, then as suggested in the recommendation, it can be re-evaluated.
Recommendation 2: Recommends two frameworks - conclusion mentions three (C)	Noted. Report amended.
Recommend a national framework of enHealth , WHO (C)	Noted.
Recommendation 2: WHO is only half a framework – steps 3 and 4 are missing, and says nothing about development and acceptance of air pollution standards (C) (4)	Agreed, this is noted in the Report (Sections 4.1.1 and 4.1.2)
Problems with WHO model: - important quality control steps omitted - tendency to make decisions based on dose response relationships not clinical indicators or symptoms - dose term often assumes unrealistic exposure conditions - application of factors of safety "The end product of WHO processes are standards which are highly conservative of public health and which are very difficult, if not impossible for industry to meet". (12)	The WHO framework provides details in the hazard identification and dose-response phases. The type of endpoint chosen is specific to each pollutant. The applicability of specific models to be used in the review of the Air NEPM would need to be assessed at the time of the review.
Recommendation 2: "quite clear" (C)	Noted.
Recommendation 2: requires explanation (C)	Noted.
Recommendation 2: Split into 2 parts to separate WHO from enHealth. Recast the recommendation to reflect the difficulties of using each framework (C)	The issues related to the use of the WHO and enHealth frameworks with respect to the risk characterisation and exposure models are the same.
USEPA approach is flexible - use for all pollutants (C)	Noted. The USEPA framework, as with the other frameworks discussed in the Report, is flexible and applicable to all pollutants. For each pollutant, a different approach is used, and the individual models under the framework differ.
The USEPA framework is transparent in its documentation – need to look at assumptions (in order to assess its utility in particular circumstances in Australia) (C)	Agreed. The relative merits of the USEPA framework and incorporated models are discussed in the Report (Sections 4.1.1 and 4.1.2) and in Appendix 6.
Advocate USEPA model. Provides quality control through use of community involvement and it is more flexible so it can be applied to all pollutants. (12)	Agreed. The relative merits of the USEPA framework and incorporated models are discussed in the Report (Sections 4.1.1 and 4.1.2) and in Appendix 6.
Recommendation 3: Sharpen up, with more detail with an example – (eg PM2.5 – problems of dose response data) - link to pollutants nominated in Future Actions (C)	Noted. Recommendation 3 has been clarified, and Appendix 6 has been expanded.
Recommendation 3: should have been done as part of Term of Reference 1-has the RATF done its job? (C) (4)	Noted. Recommendation 3 has been clarified, and Appendix 6 has been expanded. Report has been modified throughout to refer to the expanded Appendix 6.

CHAPTER 4 - TERM OF REFERENCE 2

Comment	RATF Response
Recommendation 3: NB changing issues – any assessment done now may not be of any (or certainly of reduced) value in 2005 – need to revisit as appropriate (C)	Agreed. Assessments will need to be conducted when NEPC reviews standard(s).
Recommendation 3: RATF should recommend a strategy for reporting on the utility of using HRA, on a pollutant specific basis (C)	This will be done through the issues identification stage of any review and the decision as to whether to use HRA will be taken at that stage.
Recommendation 3: "specific models" – which models – clarify/specify in Recommendation (even though already in text) (C)	Not practical to specify models in the recommendation. Model(s) will be determined at time of review of standard(s).
Recommendation 4 has resource implications that need to be made explicit. (4, 9)	Report outlines HRA expertise required in generic terms. Resource implications are discussed broadly.
Recommendation 4: replace "environmental standards" with "use this approach" (C)	Agreed. Recommendation amended.
Recommendation 4: "Governments"? – all governments, only some, or a central organisation? – national capacity is the key (C)	Agreed. Development of a national capacity is the key issue. Text (Section 4.2.2) and Recommendation amended.
Recommendation 5: Add 'including consultation/involvement' to the end of the Rec (C)	Noted. Public involvement is an integral part of the HRA process.
Recommendation 5: The steps are sequential and iterative (C)	Agreed. Report (Section 4.2.2) and Recommendation amended.
Need to take account of lead time required to develop data for HRA (C)	Noted. Report recognises need for data availability (Section 4.2.2).
Recommendation 5: Should it refer to 'fully implement'? (C)	Noted. Implied in Report.
Recommendation 6: Assumes that HRA will happen – not necessarily so. (C)	This will be determined in the issues identification stage in the review of standards.
Recommendation 6 - use of the term 'average' is ambiguous and meaning of recommendation is obscure. (4)	Noted. This is discussed in Appendix 6.
Recommendation 6: Distribution of exposure (temporal and spatial), rather than average exposure (C)	Noted. Recommendation amended.
Recommendation 6: Suggest that "Distribution of population exposure" may have been intended. (4, 9)	Noted. Recommendation amended.
Recommendation 6: Modelling can assist in estimating average exposures (C)	Agreed. Addressed in Report (Section 4.2.2).
Recommendation 6: Need to look at both average population as well as groups at risk • acknowledge sensitive sub-populations • need range of exposures (C)	Noted. Recommendation amended.
Recommendation 6: Assumes the need for epidemiological data, and it assumes the need for epidemiological data for the whole population. Panel studies may well be sufficient. (C)	Noted. Addressed in Report (Section 4.2.1) and Appendix 3. Epidemiological data form a large part of the health literature for criteria pollutants.
Threshold pollutants – average exposure not relevant to concentrations below the threshold. (C)	Noted. Discussed in the Report (Section 4.4.4) and Appendix 4.

CHAPTER 4 - TERM OF REFERENCE 2

Comment	RATF Response
Recommendation 7: Reads as if all monitoring networks should be consistent with each other, but NEPM monitoring is only a subset of total monitoring – therefore overall networks may not be totally consistent (C)	Agreed. See Section 4.2.3.
Recommendation 7: Relates to issues in addition to NEPM monitoring (C)	Noted. See Section 4.2.3.
Recommendation 7: Refer to Peer Review Committee (PRC) (C)	The RATF understands that the PRC will assess jurisdictional monitoring plans for compliance with the NEPM. Any additional requirements (eg for HRA) will not be assessed by the PRC.
Many Recommendations for TOR2 require resources – quantify them so that NEPC Committee can take these into account in making decisions about standard setting (C)	Noted. Have addressed resource requirements in a broad sense for criteria pollutants covered by Air NEPM Future Actions (Appendix 6). Further requirements consequent to the RATF recommendations will be examined by NEPC Committee. Detailed evaluations should occur at the time standards are to be reviewed.

CHAPTER 4 - TERM OF REFERENCE 3

Comment	RATF Response
Reporting on risk assessment outcomes is important to make HRA transparent and inform stakeholder input into broader standard development process (8)	Agreed. See Section 4.3.
Reporting should maximise access to information. (8)	Agreed. See Section 4.3.
Consultation protocol - NEPC should write it in lay terms (C)	Agreed.
Publish outcomes of HRA in both scientific and lay terms (C)	Agreed.
Criteria should also include: - extent to which population is protected (cf end points) - pockets of high exposure - criteria for risk acceptability – difficult – maybe make individuals aware of the risks associated with their activities - description of models - the results of HRA (C)	Agreed. All points covered in Report (Section 4.3.1).
Choice of health end-points is so important, it needs to be an integral step in the framework or explicit guidance needs to be provided. Inadequate to include it in the reporting protocol. (4,9)	The decision on 'health endpoint(s)' is made in the hazard identification stage. Details of the decision making process will be reported as per the reporting protocol.
Criteria suggested should include description of the models used for risk assessment. (8)	Agreed. See Section 4.3.
Report any health end point(s) which were considered and rejected and why they were rejected. (C)	Agreed. This will be done in the hazard identification phase of any HRA (see Section 4.3.1), and be reported under the protocol.

CHAPTER 4 - TERM OF REFERENCE 3

Comment	RATF Response
Should 'criteria for risk acceptability' be in the reporting protocol list. (C) "The HRA process is designed to produce consistent reliable information, on which decision-makers can make their decisions. The question of what level of risk is acceptable is one for the decision-makers to make, and should not form part of the outcome of the HRA process." (13)	Noted. It is included to ensure transparency and openness at all stages of the process – although it can be regarded as part of the risk management phase of any standard setting process.
Communication is a priority issue for HRA. Require protocol to acknowledge consultation process - who was consulted on what issues (C)	The NEPM development process requires the publication of a "summary/response" document which details who was consulted, comments made and resultant changes/responses for all NEPMs. This is addressed under TOR6.
Communication process - involve local government authorities, interested groups. (C)	Agreed, as per NEPC consultation protocol and acknowledged in Report (Section 4.5).
Recommendation 1 – amend to "That NEPC in consultation with health agencies develop…" (C)	Noted. "All stakeholders" includes health agencies. NEPC has previously consulted relevant stakeholders when developing its protocols.

CHAPTER 4 - TERMS OF REFERENCE 4 & 5

Comment	RATF Response
If it is not possible to do the epidemiological work, then it is not necessary/possible to do HRA (C)	The RATF acknowledges that it will not be possible to conduct epidemiological studies in all Australian cities. The Report (Section 4.4.5 and Appendix 4) clearly acknowledge that reliance on overseas data for setting air quality standards in Australia will continue.
Should be clear about what risk is being assessed, in order to design studies (C)	The health endpoint will be determined in the issues identification stage in any risk assessment.
Consider uncertainty in HRA given that errors in measuring individual exposure may lead to underestimation of pollution. eg exposure data based on readings from nearby fixed site monitors. (6)	Noted. This issue has been addressed in the Report (Section 4.2.2).
Epidemiological studies with any statistical power (such as meta-analyses) are very difficult in Australia due to low population densities. (11)	Noted. Appendix 3 discusses the data requirements for epidemiological studies. Some Australian cities are well placed for epidemiological studies.
Power of studies is important (eg Launceston has the particulates, but not the population) – references for power of studies in the Appendix? (C)	Agreed. Report amended (Section 4.4.7).
Support recommendations for adequate air quality monitoring and local epidemiological studies of associations between health impacts and air pollutants. (8)	Noted.
Review and continuation of epidemiological studies could be facilitated through enHealth's recent commitment to research on environmental justice and the proposal for a national health database. (8)	Noted.

CHAPTER 4 - TERMS OF REFERENCE 4 & 5

Comment	RATF Response
Criteria for assessing 'adequacy' of epidemiological studies are not included in Terms of Reference. (7, 12)	Noted. Limitations of epidemiological studies discussed in Appendices 3 and 4.
Appropriate criteria for assessing studies are to be found in s15 and s17 of the NEPC Act and against these criteria there are significant deficiencies in Australian observational studies on which RATF should report. (7, 12)	Outside RATF Terms of Reference.
Draw out long term effects – recommend long-term studies for Australia (C)	Appendix 4 provides a discussion of long term health effects. It should be recognised that long term studies are difficult to perform, requiring significant information about confounders not required for short term studies.
It is necessary to consider and assess long-term effects on human health eg - time series studies not able to properly record long-term effects on human health; - recurrent cumulative exposure may enhance morbidity eg. chronic bronchitis. (6)	Agreed. This issue would be considered at the outset of any HRA process – it was considered in the Report and the difficulties noted (Section 4.4, Appendices 3, 4). Consultation on future NEPMs should clarify the issues.
Chronic health effects should be emphasised more strongly in the report as these would occur at lower pollutant levels than acute effects. (2, 9)	Noted. The Report addresses the need for data for lower pollutant levels and chronic health effects (Section 4.4.7).
Report seems to suggest that peak data should be dismissed outright. Peak data would be useful in Diary studies, reduce the need for controlled human studies at higher pollutant levels, and assist with reducing the uncertainty in exposure assessment by increasing statistical power. (2, 9)	There was no intention to dismiss peak data. There is a need to obtain "representative" data for use in HRA, as well as the distribution of exposure. Report has been amended (various sections). Peak data are useful for certain studies.
Use overseas dose/response relationships in Australia as differences in exposure and population are not of major importance (C)	This issue is discussed in Section 4.4.5 and Appendix 4.
Overseas work - there could be different mixtures of pollutants having different synergistic effects - need to validate the results for Australia (C)	Noted. See Section 4.4 and Appendices 4 and 6.
"Supports the recommendations that there be further studies to assess the applicability of overseas data to Australia, and that where overseas data is used, the degree of consequent uncertainty be clearly identified." (13)	Noted.
Acknowledge synergies between pollutants (C)	Agreed. See Report (eg Section 4.4.3).
More information required on confounders. "How are geographical confounders assessed in Cohort Studies, eg. climatic conditions, local drinking water and food quality, concentrations of non-monitored air toxics/ aeroallergens/radiation and other environmental factors?" Monitoring for potentially confounding chemicals could provide basis for future air quality standards. (2)	Addressed in Appendix 3.
Make a recommendation regarding confounder data (eg indoor/outdoor) (C)	Confounders are identified and discussed (Section 4.4.3 and Appendix 3).

CHAPTER 4 - TERMS OF REFERENCE 4 & 5

Comment	RATF Response
Recommendation 1 - recognises tension between monitoring to obtain data for airshed monitoring (NEPM) and data for epidemiological studies, but need to state it more clearly (C)	Noted. See Section 4.2.
Recommendation 1: differently achievable at different concentrations (C)	Noted.
The monitoring system gives ambient levels - for epidemiological studies, need local levels eg CO exposures near freeways – an overall network may not be the answer (C)	Noted. The type of data needed for an epidemiological study is dependent on the type of study being conducted e.g. panel study vs time series study. This is discussed in Sections 4.2.2 and 4.4.2 and Appendix 3
Commission special monitoring for epidemiological studies (C)	Noted. The type of data needed for an epidemiological study is dependent on the type of study being conducted e.g. panel study vs time series study. This is discussed in Sections 4.2.2 and 4.4.2 and Appendix 3.
Recommendation 1: Puts pressure (resources, $ and staff) on small jurisdictions (C)	Noted. Report amended (Section 4.2.2).
Recommendation 1: Fails to note the important role of air pollution modelling to ensure monitoring data is useful for epidemiological studies and risk assessment where populations may not be well covered by the monitoring. (4)	Noted. The ability of models to predict ambient levels of air pollution will be pollutant specific. The merits of models vs air monitoring data will need to be assessed at the time of any review.
Recommendations 1 and 2: Possibility of nationally funded monitoring for data for epidemiological/HRA requirements – a national program does not have to mean that every jurisdiction does the same thing, but it can mean a coordinated approach with different studies being conducted in different cities to obtain sufficient data for standard setting (more cost effective) (C)	Noted. See Section 4.2.2.
Recommendation 2: Minimum populations are required for epidemiological studies (C)	Noted. Addressed in Appendix 3.
Recommendation 3: Are data from (say) Brisbane transferable to (say) Hobart (C)	This would need to be assessed at the time of any review. See Section 4.4 and Appendix 4.
Air monitoring data and health data are very patchy. (11)	Noted. See Report and Appendices 3 and 5.
Australian Standard methods are adequate to obtain data, but there are problems in measuring particulates (C)	There could be an issue measuring particles with TEOMs.
Particulates are increasingly implicated in carcinogenesis. (11)	Noted.
Include HighVol data (C)	Appendix 4 discusses inclusion of HiVol data in Australian context.
Need to respond to new information regarding air pollution and health effects (C)	Agreed. This will be addressed during the issues identification and hazard identification stages of any HRA.
Are there more definable end points for non-Pb pollutants? (C)	Discussed in the Report (eg Appendix 4).
Lead has a bio-indicator (blood lead levels) - the effects of other pollutants are more vague (C)	Addressed in Report (Section 4.4.4).

CHAPTER 4 - TERMS OF REFERENCE 4 & 5

Comment	RATF Response
Lead air standards need to take into account a build up in surficial soils over a number of years increasing the presence of lead and therefore additional level of conservatism needs to be built into the standard. (2)	Noted. IEUBK takes this into account.
Define the cities in which time series studies can be conducted (C)	Noted. This cannot be answered directly as population mortality, hospital admission rates and air pollution data need to be considered.
Negative studies are not published as much as positive studies, leading to possible bias. (C)	Noted. Report amended (Section 3.3.1).
"Zero" may mean no data rather than zero effect (eg hospital admissions after pollution event) (C)	Noted.
There is a new national electronic database for hospital admissions (C)	Noted. See Section 4.4.2.
Standards can affect the choice of monitoring regimes. (11)	Noted.

CHAPTER 4 - TERM OF REFERENCE 6

Comment	RATF Response
Support in principle "that the establishment of effective air quality standards requires in turn an effective communication and public consultation process." (13)	Noted.
Inclusive and appropriate approach to public involvement is relevant not only to HRA but other NEPM development. A protocol on public/stakeholder involvement should be prepared. (8)	Noted. The approach recommended by RATF is consistent with the NEPC consultation protocol, which is implemented for each NEPM.
Should RATF specify a minimum approach for consultation? (C)	Covered by the NEPC Consultation Protocol.
How is promulgation to be managed? (C)	To be determined for each program.
Some recommendations as part of Term of Reference 6 could be made as to how clear communication of risk results might be achieved. (3)	Noted. See Section 4.5.
It is noted that more than just a 'communication strategy' is recognised by the RATF report but it does not recognise the differences in capacity of key stakeholders. A training workshop and other means of capacity building should be addressed in the RATF report. (8)	Noted. This is addressed in the Report.
Capacity of stakeholders and of researchers/HRA practitioners/communicators should be enhanced. (C)	Noted. See Section 4.5.
Funds should be provided for: - publicising - supporting community groups - information packages/newsletter for schools/community groups (C)	Noted.
Consultation adds credibility as well as capacity building (C)	Noted. Addressed in the Report

CHAPTER 4 - TERM OF REFERENCE 6

Comment	RATF Response
Use stakeholders to consult with their constituencies – enhances credibility, efficiency and is cheaper (C)	Agreed, to be done in partnership with the agency developing standards.
Are stakeholders and the public the same? (C)	Yes
Stakeholders should include Local Government (C)	Agreed.
Evaluate effectiveness of consultation (C)	Agreed. See Section 4.5.
Evaluation of consultation programs – develop performance indicators (C)	Noted.

APPENDIX 2

Comment	RATF Response
'Subjective health effects' – consider the possibility of double-blind testing to determine whether they are subjective and what is the individual range of tolerance. May provide useful information on susceptible sub-populations and confounders. (2)	Noted.
Disappointed that no effort was made to contact the authors of the Ricci and Beer report. (3, 4)	Noted. However, it is the understanding of the RATF that one of the authors did have discussions with the consultant who prepared Appendix 2, and was present at the Perth risk assessment conference.
p 5, second to last paragraph: 2 to 3 orders of magnitude uncertainties in risk estimates can only be true for estimates of NOEL and LOEL. At high risks it cannot be the case. (4)	Noted. Uncertainty needs to be clearly stated in any HRA process.
p 10, last sentence: Sentence is generally correct but in particular cases HRA process itself can set standards provided there is a pre-arrangement to do so. (4)	Should it be used in a standard setting process, HRA is one input.
p 22, paragraph 3: Why review a model that is not designed for air quality issues? (4)	Noted. The enHealth framework is generic.
p 31, paragraph 1: Ricci/Beer model used linearisation in their method. (4)	Noted, however, this may not be appropriate for all pollutants.
p 31, last 3 lines: It is worth noting this difference between theory and practice. (4)	Noted.
p 32: Unable to find these tables and values in current version of WHO Air Quality Guidelines on the internet. (4)	Noted. This Appendix comprises a consultant's report. RATF is not in a position to modify that report.
p 39 last paragraph: Disputes Reviewer's claim that the Ricci/Beer model "tends to shroud model transparency within multiple layers of mathematical complexity". Nature of the problem is highly complex and cannot be effectively dealt with using crude models, though political need means that modelling must be transparent and easily understood. "This represents a genuine challenge that will not be met by simply dismissing the more complex models on the grounds that they are too mathematical".	Noted. Transparency is critical in any HRA process. This Appendix comprises a consultant's report, and RATF is not in a position to modify that report.

APPENDIX 2

Comment	RATF Response
p 40: Ability to estimate incremental changes in risk not been used as a criterion for the evaluation of other models but it should be. Few could comply. (4)	Noted. This Appendix comprises a consultant's report. RATF is not in a position to modify that report.
p 41: Ricci/Beer is one of few models to be published in international scientific literature (Ref. provided). (4)	Noted. Reference now included in Report.
Table 7-7, p41: Under "Model Inputs" report states that Data quality guidelines were not included. This is incorrect. Substantial effort went into data quality assurance. (3)	Noted. This Appendix comprises a consultant's report. RATF is not in a position to modify that report.
Table 7-7, p42: The report states "Hardware/Model/ Run Times – No information. "The model runs on a standard desktop PC. It is highly efficient. On a typical Pentium workstation the model analyses PM10 exposure in Melbourne at 5 separate concentration levels, over 3 years of data in 40 seconds. Result files can be loaded easily into a spreadsheet for viewing/charting". (3)	Noted. This Appendix comprises a consultant's report. RATF is not in a position to modify that report.

APPENDIX 3

Comment	RATF Response
Information is available from databases managed by : - Commonwealth and state Departments of Health. Other contacts include: - ASH - AMA - Health Care consumers - medical schools - institutions where HRA is being taught	Noted. See Appendix 3.
Data collection could be helped by the Australian Institute of Health and Welfare, which has data collection protocols (C)	Noted. Discussed in Appendix 3.
List of references provided on the link between health risks and tobacco smoke. The references provided do not adequately address this issue. (1)	Noted. Outside RATF Terms of Reference
Networking in Australia and overseas - the "Cochrane Collaboration" (C)	Noted.
Section 3.1: Occupational history would be more useful for chronic studies and confounding issues. Other useful information would include "usual workplace" and "residential history". (2)	Noted., occupational exposures generally occur at higher levels and for prolonged periods of exposure.
p 12, paragraph 4: Database created by Walsh constitutes a database on exposure, even if not on personal exposure. p 12, last paragraph: May be material missing from between the last and second to last paragraphs. (4)	Noted.

APPENDIX 4

Comment	RATF Response
Could the lack of association between NO2 and daily mortality in Brisbane (p 10) be attributed to lower NO2 concentrations, thereby pointing towards a potential threshold for NO2? (2)	Noted. Discussed in Appendix 4.

APPENDIX 6

Comment	RATF Response
Appendix 6 describes a possible methodology not a case study. Method parallels the one used by Ricci/Beer and fails to meet requirements of quantifying incremental risk. (4)	Appendix 6 amended to clarify the intention of the case study, which is to indicate what might be required to undertake HRA, and apply to three criteria pollutants as examples. The Appendix is not intended to be definitive, nor does it aim at quantifying incremental risk.

LIST OF THOSE WHO MADE SUBMISSIONS

SUBMITTER ID	SUBMITTER
C	*Comment raised in public consultation*
1	Canberra ASH
2	CH2M Hill Australia
3	Mr Sean Walsh
4	CSIRO Atmospheric Research
5	NSW EPA
6	The Urban Transport Institute
7	Queensland Mining Council
8	Conservation Council of WA Inc
9	Clean Air Society of Aust & NZ
10	Health Department of WA
11	Mr Ian Wood
12	Minerals Council of Australia
13	Australian Institute of Petroleum