Review of the report

HEALTH RISK ASSESSMENT OF ATMOSPHERIC EMISSIONS EXPANSION OF WAGERUP REFINERY TO 4.7 MTPA

prepared by ENVIRON Australia Pty Ltd and Benchmark Toxicology Services for Alcoa World Alumina Australia Dated 19 April 2005

prepared by

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Executive Summary

The HRA was an initial screening assessment of potential for risks arising from direct toxic actions of air pollutants in predicted Wagerup emissions.

1. The scope of the HRA did not include investigation of health complaints reported by residents of communities around Wagerup, but was relevant to them in an indirect way. Odour was not included in the scope of the HRA.

The HRA is a useful screening or initial assessment. It has been carried out correctly, within its limited scope. The methodology is consistent with initial assessments as defined by Australian authorities (enHealth 2001, 2002).

The measurement of predicted risk levels was based on calculation of measures described as *Hazard Index* (HI) and *Incremental Cancer Risk* (ICR). The final conclusions of the HRA are given in qualitative terms. However, being based on quantitative methods, the conclusions are regarded as semi-quantitative.

A prudent, conservative, and highly health-protective approach was taken in the HRA.

Review of Air Quality information and the Criteria selected shows that inputs used to calculate the measures of risk were conservative and appropriate.

Air Quality data and information for the areas surrounding Wagerup is valid and extensive, and its quality has been independently reviewed.

Choice of methods was appropriate, although other approaches and the limitations of the methods have been discussed in this review. Comparison of predicted GLCs with published health guidelines was carried out on a comprehensive selection of pollutants.

The major criticism is some lack of clarity and readability in the HRA which may lead to confusion or unnecessary concern. Choice of some overseas criteria and methods is criticised, because applying overseas criteria developed for overseas contexts is not always appropriate. In this case there were no technical difficulties apparent.

The lack of information about context e.g. the relative importance of Wagerup emissions compared to general background levels, and overall intake of chemicals which may be important for health, is a criticism of this HRA.

The HRA presents useful and almost certainly correct assessments, on the levels of risk contributed by the predicted Wagerup emissions. The HRA conclusions are that low, very low, or *de minimis* risk of health effects on any residents can be foreseen.

Given the low levels of GLCs predicted (in comparison with published standards, goals and guidelines) and review of the information presented, these conclusions are considered to have been supported by the evidence put forward in the HRA.

On the basis of the evidence and results in the HRA this review concludes that all levels of foreseeable risk are essentially the same, and the term *de minimis* is preferred.

Conclusions are therefore reassuring on the matter of future air quality and the *de minimis* nature of any health risks, taking into account the limitations of this HRA.

Some further investigation of health complaints or health effects may be necessary or desirable, because there are as yet unresolved questions regarding “health effects” and health complaints in the community. Careful preparation will be needed to determine what types of health study or Health Impact Assessment are feasible or appropriate, if resolution of these questions for the community of Wagerup is to be achieved.

Finally, it is recommended that effort is made to enable readers and particularly the residents and community groups to understand what this HRA has concluded, so that the value of it is accepted as part of the engagement process between Alcoa and the local communities.

1. Introduction

1.1 Review procedure, methods and comment

This review was commissioned as part of the environmental review procedures (Environmental Review and Management Plan – ERMP) relating to the Wagerup expansion proposal of Alcoa World Alumina. The ERMP included the provision for review of the documentation and main reports, including those for Air Quality information and Health Impact.

This review is of the document entitled HEALTH RISK ASSESSMENT OF ATMOSPHERIC EMISSIONS EXPANSION OF WAGERUP REFINERY TO 4.7 MTPA dated 19 April 2005 which was prepared by ENVIRON Australia Pty Ltd, referred to in **this review** as the "HRA".

It has been prepared by Dr John A. Bisby, registered specialist in Occupational Medicine, whose qualifications and experience are included as Appendix 1.

This review is based on the main documents provided and listed below, and on other material sought from various public sources, including technical and medical libraries and internet sources; on information in possession of IHC; and on the consultant's knowledge and experience in the fields of medicine, epidemiology, toxicology, air pollution, odour, and regulatory inspection.

The HRA and other documentation was received and reviewed. References, sources, criteria and standards were reviewed. Comment was developed on the methods, content and conclusions of the HRA for inclusion in this review.

The reviewer was requested to clarify the issues for a readership which would include all stakeholders, including in particular the Community consultation group members and residents of the areas surrounding Wagerup who were the focus of the HRA.

The need for understandable explanation stems from a statement from the Wagerup Refinery Unit 3 Scoping documentation (Sept 2004), page 50:

Alcoa is committed to ensuring it understands and addresses the needs of all key stakeholders of its Wagerup operations including local neighbours and community groups and employees, through an effective and ongoing engagement process.

During preparation for this review, it was concluded that this statement requires that documentation such as the HRA and associated Air Quality reports or Toxicology assessments, and any future epidemiological research such as is proposed in the ERMP, provides information pertinent to this community consultation or engagement process. Information must be either originally in a format which is understandable by stakeholders, and in particular local neighbours and community groups and employees, or clear explanation and summaries of such information must be developed and provided to the stakeholders. This need became a criteria for review of the HRA.

Technical language is unavoidable in such a review (and in a Health Impact Assessment), but wherever possible matters have been explained with the aim of being understood by a non-technical reader. The reviewer apologises for remaining technical terms which cause any doubt or ambiguity, and stands willing to clarify further if required.

This present review of the HRA is referred to as "this review". Quotations from the HRA and other documents are provided in *sans serif italicized* text.

Chemicals, compounds, and materials present in Wagerup emissions (and dealt with in the HRA) are referred to as "pollutants". There is no distinction implied between a chemical

in the emissions (e.g. polycyclic aromatic hydrocarbons) and the same chemical where it occurs in the environment from non-emission sources.

1.1.1 List of documents

1. HEALTH RISK ASSESSMENT OF ATMOSPHERIC EMISSIONS EXPANSION OF WAGERUP REFINERY TO 4.7 MTPA, ENVIRON Australia Pty Ltd, 19 April 2005.

This was received by IHC (Dr Bisby) Friday 22 April following an incomplete draft received 17 April 2005.

Other background or associated documents were requested as necessary to complete the review, and the following were received from Alcoa:

2. ENVIRONMENTAL SCOPING DOCUMENT, Wagerup Refinery Unit 3 EPA Assessment No. 1527, 15 September 2004
3. Wagerup Air Quality Review (CSIRO report C 0936), May 2004
4. Health Risk & Toxicological Assessment of Emissions from the Upgraded Alcoa Pinjara Alumina Refinery, 14 November 2003, (Toxikos 2003)

Two primary source documents relating to Health Impact Assessment in Australia have been used and referred to in this review:

5. Health Impact Assessment Guidelines September 2001. ISBN 0 642 50365 6. Publication approval number: 2971. Referred to in this review as (enHealth 2001).

6. Environmental Health Risk Assessment – Guidelines for Assessing Human Health Risks from Environmental Hazards. IBSN: 0 642 82091 0. Publication approval number: 3096. Referred to in this review as (enHealth 2002).

Relevant extracts from these Commonwealth of Australia publications are included as Appendix 2.

1.1.2 Content of this review

Most readers will require certain questions to be answered about the HRA document:

- What is an HRA?
- What is the purpose of an HRA?
- Is this a complete or partial Assessment of Health Impacts?
- Are the conclusions of the HRA supported by the information and data presented in the HRA?
- Is there more to consider in terms of health impact?

In addition, the question of "readability" was addressed, meaning the accessibility of the information to the non-technical reader, in terms of understanding the concepts involved and the conclusions put forward.

2. Discussion

This section comments on the HRA content and the methods used, results and conclusions.

2.1 HRA methodology

The Environmental Scoping Document of 15 September 2004 sets out the process and procedures to be carried out to complete the Environmental Review and Management Programme (ERMP). It calls for a Health Risk Assessment with the additional qualification that a **Quantitative** Health Risk assessment would be done.

Quantitative in the general sense means assessment of the size of any identified risk. This does not necessarily result in the type of mathematical calculations which feature in the HRA, and quantification may be done in terms of broad levels of risk. In the final conclusions of the HRA, quantification is done in very broad terms of risk being "low", "very low" or "*de minimis*".

Methodology chosen for the HRA is similar to that forming the basis of the previous Environ report, prepared by Toxikos in 2003, entitled Health Risk & Toxicological Assessment of Emissions from the Upgraded Alcoa Pinjara Alumina Refinery, 14 November 2003. Some explanation provided in that report is important in understanding of the HRA.

In section 4.1 of that report it states that the screening assessment "*does not address actual risks*". The precise meaning of that statement is not clear, but it correctly cautions the reader about the overall limitation of the methodology used and interpretation of the results.

This is perhaps the most important limitation of any HRA which considers emissions from one source and compares the effect of those with guidelines or safety limits for human exposure. Such a comparison is not "*addressing actual risks*" because the actual exposures which any person has, and which may impact on their health, will come from many sources in real life. The concentration of any of the Wagerup emissions at any resident's location (residents are called "*receptors*" in the HRA) will always be only a part of the air which the resident breathes in. Similarly, Wagerup dust fall which occurs on a resident's location will only be a part of the dust falling on that location. Health risks depend on real-life exposures, i.e. what is actually breathed in, or gets onto the skin, or is swallowed in food or drink.

All or almost all the pollutants considered are chemicals which may be present in any residential environment, or present to some extent in normal diets, or arise from everyday activities. Wagerup emissions or pollution from Wagerup add to everything else in the actual environment in which people live.

The "Ground Level Concentrations" derived from the Air Dispersion modeling done by CSIRO and others does not show the actual exposures for persons, or actual concentrations in any residential location, only the expected concentrations due to the Wagerup emissions. Where there is no other source of the particular chemical, or the contribution from Wagerup to the total is dominant, then the predicted Ground Level Concentration (GLC) may indicate something close to the actual exposures or location concentrations.

2.2 Objectives for the HRA

Central issues for this HRA are:

- whether the Wagerup emissions could contribute amounts of any pollutant which would alter the total levels at any residential location;

- whether such a balance could be tilted so much that a health impact or risk to health would be created.

The ongoing air monitoring program which measures actual levels of pollutants (Ground Level Concentration) at locations, plus the work on Air Dispersion Modeling which can predict future levels, can answer the first question with reasonable certainty.

The HRA can partly answer the second, and if it is applied with large safety margins, can do so with reasonable certainty.

The HRA states that the "*approach taken is considered to be conservative (i.e. health protective) in most cases.*" The reason for adding the phrase "*in most cases*" is not clear.

No exceptions to the "*conservative*" approach are stated, i.e. for the 27 pollutants considered, and none were identified during this review. As far as can be determined, the approach taken was "*conservative*" and therefore "*health protective*" in all respects.

The present HRA is stated (page 2) to be a "*screening-level assessment in that it makes generally conservative default assumptions regarding the potential magnitude of exposure and uses conservative toxicity criteria*".

As a "*screening-level assessment*" is not further defined, this has been given consideration in this review. As with the Toxikos report in 2003, the present HRA, which uses the same methodology, is not a full "Health Impact Assessment" as defined in the Australian Government documents enHealth 2001 and 2002, or as understood in the general sense of that term.

It is therefore not a "Quantitive Health Risk Assessment" as would be done to assess health risk to individuals, or in this case to individual residents or the community in the areas around Wagerup. As explained in enHealth 2002, such a full Health Impact Assessment is not required or recommended, until and unless an initial assessment shows that such a full assessment is justified.

2.3 Use of the measures of Hazard Index and Incremental Cancer Risk

2.3.1 Exposure to individual pollutants – the use of HI and ICR measures

The comparison of predicted GLC for areas against some health protection guideline level (otherwise called an air quality standard or criteria) is a widely accepted method for consideration of the risk arising from an individual pollutant. This has been done in the HRA for the selected 27 pollutants of concern.

The initial basis for quantitative risk assessment in the HRA is the calculation of ratios of predicted exposure to exposure standards which are considered by various authorities to be without risk to health to almost all exposed persons. This is the cornerstone of risk assessment, accepted by authorities such as the National Environment Protection Council (enHealth 2001).

The detailed work done, involving calculating the measure called a "*Hazard Index*" (HI), is firstly one of reductionism. That is to say, it:

1. considers each individual pollutant which is a contributor to total emissions
2. finds predicted Ground Level Concentrations (GLCs) from Air Quality Dispersion modeling; GLCs of pollutants are used as a guide to human exposures
3. calculates a measure of risk to residents due to each pollutant (the HIs)

then at a further stage, moves to looking at the totality of all pollutants:

4. adds (sums) the HI risk of each pollutant to arrive at an HI representing total risk, and
5. draws overall conclusions about "safety" of the total emissions to residents.

The reductionist approach is used widely, and has been adopted as a common method of assessing air quality risks. Within limitations it is informative and valid. There are uncertainties in the method, but the prudent use of conservative values and assumptions at each step provides certainty, particularly when any potential risks to human health are very small, or (to use the phrase in the HRA) *de minimis*.

When assessment shows Hazard Indices (HI) and "*Incremental Cancer Risk*" (ICR) to be very low, they can be reasonably certain about identifying the absence of risk, or *de minimis* risks attributable to that pollutant.

This ability to identify very low or *de minimis* risks with more certainty than their ability to identify any increased risk, is due to the large safety margins included in the calculations, otherwise referred to as the built-in conservatism.

The method used in the HRA for individual pollutants is therefore appropriate and consistent with guidelines as set out for Australia in the enHealth documents (enHealth 2001, 2002).

2.3.2 Exposure to multiple pollutants – the use of HI

It is always the case that real-life exposure is to multiple pollutants, rather than to one. At the further stages identified above (4 and 5), the reductionist approach attempts to turn towards a more holistic approach, to recognize that risk to health may occur from the totality of exposures. Thus in stages 4 and 5 above, HI for individual pollutants were added together to provide a "total" HI, representing the risk from exposure to combinations or the total of pollutants. These "total" HIs are then used to produce conclusions for individual receptor locations and contour maps of the Wagerup area.

This process of arriving at the final HI requires critical comment and much more explanation than is provided in the HRA.

The overall HI is presented as a simple, one-number measure of total risk representing the likelihood of health effects of any type from combined exposures, in this case to 27 pollutants.

It appears to be "scientific" because it is based on calculations and computer-generated numbers. However, there are serious doubts as to the medical or scientific merit in such calculations or use of them. In reality, it is not possible to arrive at one simple numerical measure covering all types of risk from multiple pollutants. Calculations of Hazard Indices for total pollutants produces only pointers to risk, despite the use of what appear to be exact numbers.

To add ratios representing very different types of pollutant with very different types of biological action and target organs and arrive at an overall risk index such as the HI has little if any real meaning or relationship to the realities of human health. Such artificial measures are cautioned against by enHealth. When used, they need very precise explanation, including explanation of their limitations and the approximations being used, if confusion and misconception are to be avoided.

An additional complication when considering actual risk or real-life health outcomes for individual residents, is that measures such as the HI represent only a small fraction of the true total risk profile for individual residents, because they are based only on the contribution of the Wagerup emissions.

The HRA, and all other references including the enHealth documents, stress the unavoidable uncertainties in this process. In the current HRA, the calculation of HIs and use of them in contour maps and in the final step before arriving at the conclusions, should be accepted, but only with the above caution and a commitment to fully explain the concept and its drawbacks to readers.

Discussion of the conclusions of the HRA provides further information on this issue.

2.3.3 Validity of measures

The validity of any of these calculations, or how much an HI or ICR can be considered to reflect a real-life assessment of risk, depends on two issues:

1. how much of any real risk comes from the pollutants being studied and how much from other exposures, and other factors involved in causing health effects;
2. the validity of the two components of an HI or ICR, which are the Air Quality guidelines selected and the GLCs used for the geographical locations.

Health effects (whether they are acute, chronic, non-malignant or cancer) are always caused by many factors in which the environmental exposures may play a major or minor part. These are not part of this HRA and are not reviewed further in any detail. The role of other contributors to environmental exposures, other than the Wagerup emissions, is also not part of this HRA and is also not reviewed further.

The GLC information used in the HRA is derived from the work done on Air Quality for Wagerup. This has been extensive, and its validity and reliability for use in Health Impact Assessment is accepted by all parties and has been independently reviewed for the ERMP.

This review does not include further comment on the Air Quality data (either the published monitoring data or the predicted GLCs from modeling). However, the reviewer has been using and assessing such data for over 30 years in Government and industry work and considers the volume and quality of information available as equal to any previously done in the Australian context.

2.3.4 Confusion of terms

Unfortunately, the HRA and its Appendix A contain conflicting explanations of the Hazard Index measure. Appendix A of the HRA refers to calculation of "*Hazard Quotient*" for individual pollutants, and "*Hazard Index*" as the measure calculated for total or combined pollutants. The main HRA does not refer to "*Hazard Quotient*" calculations, and it would appear that the term "*Hazard Index*" has been used to cover "*Hazard Quotient*" and "*Hazard Index*" as defined in Appendix A. This review has assumed that the Appendix states the matters more correctly.

2.4 Choices in the HRA approach

Certain choices were made by Environ and BTS during their preparation of the HRA. To provide a review of the HRA requires consideration of those choices, because the overall conclusions may depend on these choices. The choices identified were:

- the overall methodologies to be used
- 27 compounds were selected for further study from a potentially very large number identified in Wagerup emissions
- screening level of HRA was done for inhalation route of absorption (pathway) only
- Arsenic and Cadmium were selected for further consideration of other routes of absorption, on which a HARP computer model methodology was run.

Finally, the results were interpreted into broad conclusions and further choice was made on how to express those conclusions. Comment is provided on these choices.

2.4.1 Choice of methodology

The methodology adopted is explained on pages ii-iii of the HRA, and further on pages 2-4, and is discussed above.

The four broad Steps adopted for the HRA are the standard method of approaching health risk assessment, although not exactly as set out in the Australian guidelines on "Health Impact Assessments" (enHealth 2001, 2002).

The title adopted of "*Health Risk Assessment*" is perhaps too broad, as the actual content and scope of this work undertaken is much more limited than would justify such a title. Other terms are used in the text as alternatives, including "*Health Screening Assessment*" (p 3). Further comment is added on this in the final summary of this review. The main concern about titles and terms is that they should not unintentionally mislead readers into placing more weight on any particular assessment or report than it can actually bear.

2.4.2 Selection of pollutants to be included in the HRA

A background document explaining the process for selection was provided and reviewed. The procedure for selection was adequate, and a previous review (Toxikos 2003) of Wagerup emissions by other consultants arrived at a virtually identical selection. The 27 pollutants selected for further review appear to be the most relevant, and none of potential significance from the full listing have been omitted. If subsequent investigations reveal that allergy is possible or likely, then the full list of compounds present in emissions may need further review from the perspective of identifying potential allergens which may be candidates for allergy testing.

2.4.3 Analysing for inhalation route of exposure only

The overall level of pollutant involved (based on ambient monitoring and modelling) justifies the consideration of the inhalation pathway only, and discounting of other pathways. One exception to this approach would be any future exposure assessment in relation to Wagerup workers, in both refinery and RDA areas.

There is some discussion in the HRA of pollutants settling on soil and being taken up by vegetables and hence introduced into diet (as is quoted in relation to Arsenic). This seems quite unrealistic in the present case, based on the nature of the pollutants and the levels of pollution (e.g. particulates) predicted at receptor sites. Some realistic explanation of background levels normally present in soils would have been useful to the reader's understanding (e.g. of Arsenic in soil). It would also have supported the decision to address inhalation routes of exposure rather than all routes.

Similar comment applies to concepts of exposure pathways through drinking water, or contamination of skin. Pollution levels predicted are just too low for any such pathways to have any significance for health, taking into account the natural background levels of these pollutants in all residential areas (in Wagerup surroundings and elsewhere). The CSIRO report on Air Quality notes that the presence of elements in emission dust samples and in soils was "*not vastly different*", indicating that deposition of particulates of Wagerup emissions will be unlikely to change the composition of local soils or dust samples.

2.4.4 Choice of references, reference documents and sources

The HRA quoted a wide range of sources and authorities for methodologies, standards, and guidelines. These include Australian Government (Commonwealth and State) such as NEPC, etc; World Health Organisation (WHO Europe and WHO); California State

Government, United States Government (US EPA ATSDR), Texas State Government; Netherlands Dutch RIVM; and Canadian Governments.

Emphasis is said to be placed on Australian NEPC and US EPA, but in the assessment of individual compounds, equal weight has been given to whatever prime source was chosen. The enHealth document is identified (correctly) in the HRA as a key reference, although in practice US EPA approaches and other sources such as Texas and California have become dominant.

The choice of authorities and references may have been set by others and, if so, was appropriate. However, selection of such a smorgasbord of references and authorities can lead to confusion and misunderstanding because international authorities, national authorities and regional authorities may have adopted approaches, philosophies or procedures which differ considerably.

It could be considered that in Australia, only Australian guidelines and standards should be used in Health Impact Assessments. This is the view expressed in enHealth documents. The advantage is that discussion of appropriate criteria, standards and consequential decisions, are facilitated by a common understanding of context, and a common set of definitions and criteria for both exposure and health effects. A disadvantage would be where the situation in terms of pollutants or findings is unique or has not been dealt with in the Australian context. This is not the case in terms of Wagerup, where every pollutant considered has a long history in the Australian context. The more general concepts of emissions, pollution control and health impact assessments are also well documented in the Australian context.

The enHealth 2001, 2002 documents provide guidance on methodologies, procedures and references for uses in the Australian context. Appendices 3 and 5 of enHealth 2001 provide multiple references to Australian documentation, with appropriately limited reference to WHO, UK Government and Canadian Government references, but provide no references to, for example, Texas or California State standards, methods or guidelines.

enHealth 2001 identifies 27 key factors influencing or potentially impacting on health, and therefore potentially of importance in Health Impact Assessments (its preferred term) of which only three, Air, Diet and Water, are addressed in the HRA, and only one (Air) is addressed in any depth for all but two pollutants.

In the event, with all indicators of (air quality) risk pointing to lack of risk for residents, choice of authorities or methods is probably not important in a technical sense. Any reasonably valid method would have come to the conclusions arrived at in these circumstances. However, for future management of the health impact issues, and risk communication, preference for Australian authorities, references and standards would be recommended to improve common understanding, and avoid confusion arising from conceptual differences.

2.4.5 Use and adoption of air quality criteria or standards

Use or reference to criteria or standards cannot be separated from consideration of the context of the particular criteria or standard. The main objection to using overseas standards or criteria is that lack of context.

In terms of management of emissions, the legislative position in Australia in both the workplace and environmental contexts, is that employers or operators of industrial operations are required to minimize emissions and exposures to persons (workers and others affected by their operations) to the extent that is reasonably practicable. These duties are found in Occupational Health and Safety Acts and Environmental Protection

Acts and associated Regulations and guidelines at Commonwealth and State levels. The meaning of "reasonably practicable" has been defined in law. This duty to minimize emissions is over and above any requirement to meet a particular standard, or emissions license conditions.

This context needs to be taken into account when selecting criteria for use in an HRA or any Health Impact Assessment. It is a prime reason for using Australian referenced criteria, because criteria from different contexts may eventually mislead or confuse during discussion or management of environmental quality.

In Australia there are certain pollutants for which environmental criteria or standards are available, and these have been used, correctly, in the HRA. Where ambient community criteria are not set, then criteria could be derived by dividing workplace or occupational standards by a safety factor. This has been the basis for ambient goals for decades in Australia, and will be one major source for future ambient criteria. Workplace standards are known as National Occupational Exposure Standards (NES), and overseas by other terms, the best known of which are Threshold Limit Values (TLVs) from the USA.

There are several important linkages between occupational pollutants and community air pollutants, e.g. in the way they are derived, and in which pollutants are of importance. The source of pollutants in both scenarios is anthropogenic (industrial) activity, including pollutants from fixed plant and operations such as Wagerup and from vehicular emissions.

In the present case, Australian NES are available for all the pollutants selected for assessment.

Issues of measurement, sampling frames, and others make selection of any criteria problematic. The problems of using criteria from many overseas sources are no less than the problems of deriving (where necessary) Australian criteria.

2.4.6 Selection of Arsenic and Cadmium for further "hotspot analysis"

The enHealth 2002 guideline carries the following comment:

10.2.3 Use of subjective terms *The use of the term 'hot spot' can result in misleading perceptions of concentrations and the term should be used prudently.*

The Air Quality data presented do not lead to the conclusion that any "*hot spot*" analysis is or was required. The choice of the California methodology for hotspots (i.e. using OEHHA criteria and sources) is also questionable.

The negative side of further investigation of other routes of exposure for Arsenic and Cadmium is that a lingering impression is created that these matters remain uncertain. The actual data presented in the HRA and the information made available mean that it is certain that there is no significant risk from these materials as they arise from Wagerup emissions which would require further analysis. Although it could be debated (and the reviewer might not have had access to all information available), it seems likely that choice of the Australian enHealth approach overall would not have required such further hotspot assessments.

The HRA further assessment on Arsenic and Cadmium is reported as follows (p 33):

ENVIRON (2004) applied the HARP program as part of an assessment of the Pinjarra RDA and found that exposure by other than inhalation pathways was likely to be significant for arsenic and cadmium.

The application of the computer program HARP is not described in any detail and therefore could not be reviewed. However, no justification for the above statement regarding "*significant*" exposure to Arsenic and Cadmium could be found in the HRA. On the basis of the other evidence presented and from the background papers, in particular the

CSIRO report, no hot spots in relation to arsenic and cadmium were evident. Nor is there evidence of any probable "*significant*" exposure to arsenic or cadmium.

The HRA also provides more comment on Arsenic and Cadmium in sections which, on review, were considered to be confusing and open to misunderstanding. This is discussed in the following section.

2.5 Results presented in the HRA

Tabulated Air Quality Standards are correctly set out.

Results, in the form of calculated HI and contour maps of risk (HI contours), are presented in standard formats.

The calculation of Hazard Indices and production of contour maps appear to have been done using standard techniques.

The Appendix A of the HRA contained extensive Toxicology comment and information about individual pollutants. Given the overall conclusions of the HRA, it was considered that almost all this information was not relevant to the levels of exposure presented in the results. Review or detailed assessment of its content was therefore not relevant.

Information presented in Appendix A concerning the health complaint called Multiple Chemical Sensitivity was reviewed. Its relevance to the HRA was unclear, and its publication appears to be the result of a request to Dr DiMarco of BTS for comment, i.e. it was not initially considered to be necessary in the HRA. This particular complaint is not referred to in the body of the HRA, and none of the exposure assessments carried out relate to it as far as can be determined. No comment on Multiple Chemical Sensitivity is therefore necessary at this time, or in relation to the HRA.

2.5.1 Incremental carcinogenic risk (ICR)

Given the context of using US criteria and references (which are mostly not included in Australian enHealth references), it may be helpful to provide further explanation. A major part of the problem stems from theories about cancer causation (which largely remain theories at the present time).

In particular, it stems from the probably erroneous theory put forward in the HRA that "*one molecule creates some risk of cancer*" (referenced on page 10 of the HRA), and on the other hand recognising that decisions cannot be based on such a theory. Thus regulatory authorities have (all) dismissed the "one-molecule theory" and adopted the practicable (and probably "true") position that there is some type of threshold for cancer effects, as there is for non-malignant effects.

This threshold is then defined as the *de minimis* or negligible risk level, and may be assigned a measure, such as risk of one additional case of cancer arising in a population of one million persons over their lifetimes (70 years).

One million persons in the current Australian context can be expected to develop about 270,000 systemic cancers from which they will die, and about 400,000 cancers in total (with many not dying of their potentially fatal cancers due to treatment). This is based on current epidemiological information for the Australian population. What the *de minimis* risk means is that instead of that population developing 270,000 fatal cancers, they will experience 270,001 fatal cancers over the next 70 years. This explanation is simplified in terms of the underlying epidemiological concepts, but represents a correct representation of the application of *de minimis* risks.

To communicate this level of risk requires two messages, one purely scientific in terms of probabilities, aimed at scientists and health experts who need to work with that type of information, and a more meaningful message to all the stakeholders in the issues who need information on which to base their decisions and considerations. For this second (and most important) group, a *de minimis* risk means in real life and in plain language, that "*there is no risk*" from the assessed exposures.

The most commonly quoted reference used in Australian and overseas documents is the set of principles of causation originally developed by Bradford Hill. Bradford Hill set down what should be considered as relevant when trying to establish whether exposures to humans are likely to have been the cause of health effects which they later suffer. Because the drawing of appropriate conclusions in this HRA, and interpreting what they mean, depends so heavily on these concepts, these principles have been discussed in more detail in Appendix 3.

2.5.2 Comment on inclusion of non-relevant information

The HRA is weighted with information about toxicology of individual compounds and toxicological theories which bear no obvious relationship to the matters addressed in the HRA. As examples, neither the phenomenon of "*Hormesis*" (page 13) nor the "One-Molecule Theory" of carcinogenesis, both of which are discussed in the HRA, is of any practical assistance in arriving at the conclusions of the HRA. The one-molecule theory is presented in the HRA on page 10 and in the Appendix A, as follows:

By convention, exposure to even one molecule of a genotoxic carcinogen is assumed to incur some small but finite risk of causing cancer

The implication that this concept is in some way accepted by authorities, either within Government or the medical or scientific community, is incorrect. This "theory" is explicitly contradicted by practical acceptance of concepts such as *de minimis*, considered in detail below, and by the various Regulatory instruments dealing with carcinogens. Even in purely technical and theoretical discussions, the notion that one molecule "causes" a human cancer has been discredited for two decades.

The concept of Hormesis is not further used or addressed in the HRA and inclusion of any discussion of it is therefore not relevant to this HRA.

2.5.3 Use of broad qualitative estimates in conclusions

The HRA, despite using apparently precise mathematical calculations, which give an impression of quantitative risk assessment, uses very broad qualitative measures in its overall conclusions. This issue is only important for future management and community understanding of the issues. It is discussed at length in enHealth 2001 and 2002, which recognise and promote the use of initial appraisal or screening approaches, before attempting full Health Impact Assessments and state:

The level of risk can be described either qualitatively (i.e. by putting risks into categories such as 'high', 'medium' or 'low') or quantitatively (with a numerical estimate or probability density distribution).

Current risk assessment methods do not enable accurate quantitative estimates of risk for low levels of exposure to environmental hazards. Numerical estimates of risk will rarely be feasible because of limitations in toxicological and exposure data which will be reflected in the uncertainty assessment, but quantification may be possible for some components such as exposure assessment. Clearly defined qualitative categories can enable reliable and effective risk management decisions.

Estimates do not have to depend on the use of numbers to be useful; ordinary language may be used to indicate the level of risk. A finely divided ranking system can give a relatively accurate indication of quantity without using numbers (ACDP, 1996). Clearly defined qualitative categories can enable reliable and effective risk management decisions.

Numbers may give a misleading implication of accuracy, especially when based on poor or uncertain information. The generation of a precise value in QRA should not be mistaken for accuracy (IEH, 1999b). The problems are compounded where results are interpolated over several orders of magnitude and where information on the mechanisms of tumour induction is limited.

While qualitative risk conclusions can avoid the false sense that the extent of the risk is known precisely, the use of terms such as 'high', 'medium' or 'low' may have different interpretations to different groups and they should be clearly defined. This is often best achieved by being put in context or compared to other risks relevant to the community. If comparisons do not directly relate to alternative options, they should be used cautiously, especially if like is not compared to like or if comparisons are being used to imply acceptability.

2.6 HRA Conclusions

The final conclusions in the HRA are that risk is **low** (for Acute health effects – HI), **very low** (for chronic health effects – HI), and ***de minimis*** (for incremental cancer risk – ICR).

These terms are qualitative conclusions or semi-quantitative, in contrast to the rather technical quantitative approach using extensive mathematical measures in the body of the HRA. There is inadequate explanation of these qualitative terms. (How low is low? What does *de minimis* really mean?)

In this review, these HRA conclusions were considered in detail. Results and information presented in the HRA were re-assessed to see if the wording of the Conclusions was appropriate. To some extent, because of the nature of the evidence, this will always be a matter of opinion.

However, in this case, this review concludes that for all categories, the risk levels are in real terms at the same or very similar levels. In other words, one term could have been used in the conclusions to describe all the risk levels.

The reasoning behind this conclusion follows. The concept of adding (summing) into one Hazard Index is described in the earlier Toxikos 2003 report as leading to "*grossly overestimating risk*". No indication is provided as to how much any risk is being overestimated by this technique, and because of the nature of these toxicological risk assessments, none can be. Overestimation of risk is another way of saying the approach is "very conservative" or providing a large "safety margin". This review considers that the HRA did adopt a most conservative approach.

The general rule of thumb for interpreting the final measure of risk used (HI) is that was described as follows (Toxikos, 2003):

- *values less than one* (sometimes called unity) *represent no cause for concern;*
- *values greater than one but less than 10 generally do not represent cause for concern because of the inherent conservatism embedded in the exposure and toxicity assessments; and*
- *values greater than ten may present some concern with respect to possible health effects.*

As all results presented in the HRA are below unity, all the terms used in the HRA conclusions effectively mean what is called *de minimis*.

2.6.1 Discussion of de minimis

A risk which is *de minimus* means a risk so low that it has no impact, and therefore should not be a priority for action to try and lower it further.

It comes from the legal principle (applicable in Australia and elsewhere) "*de minimis non curat lex*", which is often translated as "the law does not deal with trifles".

However, any translation should be flexible, and "trifles" could be more appropriately translated for present purposes as "a risk so low that it has no impact".

The term *de minimis* has been preferred in this review, because:

- firstly, it is used in the HRA in its final Conclusions (for ICR)
- secondly, unlike other terms such as "no cause for concern", "acceptable" and "negligible", it has been fairly well defined
- thirdly, when applied to a risk situation it also incorporates notions of progress towards management of the issues, or action required, whereas terms such as "no cause for concern", "acceptable" and "negligible" are less helpful.

A further comment and background on *de minimis* is provided at Appendix 4.

2.6.2 Impact on health

The conclusions in the HRA, in summary, are that the current and future exposures arising from Wagerup emissions will not create any risk of health effects. In other words, they are what A B Hill described as being "*too small to be of any practical importance*" and are defined in the HRA as *de minimis*

However, although the HRA, using one particular approach, concludes that there will be no effects from the Wagerup emissions on residents, the reality at present is that the existence of health complaints and suggestions of actual health effects from various sources (e.g. as repeated in the CSIRO report) remains to be resolved. These health complaints and implied health effects, on the information available, seem very vague and as yet not fully investigated.

In the documentation provided, only one health disorder is dealt with in any detail: that of the complaint known as MCS (Appendix A). Whether this type of complaint is prevalent in the areas, compared to other sections of the Australian community, has not been tested. No further information is provided in regard to the incidence or investigation in residents around Wagerup in the HRA. MCS is a complaint arising in many urban areas and in country residents in Australia (author's experience). In terms of other complaints, no information is discussed in the HRA. Although many serious health effects, disorders and diseases are mentioned in Appendix A when discussing individual pollutants, none is identified as being present in residents.

The issues of consistency and of plausibility have not been addressed in the HRA. This refers to whether a finding that there is or is not any causative link between exposures and health effects can be confirmed or supported by other evidence. Other approaches to Health Risk Assessment or any further Health Impact Assessment studies may address these issues. For example, information from other similar industrial operations may be available, or from studies on workers exposed at similar levels, or say up to 100 times higher. These alternative approaches could assist with understanding of the conclusions of the present HRA

Other gaps in present knowledge relate to the further criteria set out by Hill (Appendix 3).

2.6.3 Odour issues

The potential for odours and perceptions to lead to complaints about air quality and about health effects is not addressed in the HRA. It would appear from the background documentation that odour is the epitome of a "short-term event" reported from Wagerup areas over the past two decades, and it is a major component of complaints from residents.

Odour is usually strongly linked to claims of health effects in the community context in Australia. It needs to be addressed in the context of any HRA for the following reasons:

- it may have major impact on future perceptions about any health risk arising from Wagerup emissions;
- various "health effects" symptoms and even signs which are interpreted as health effects are anxiety-mediated and are triggered by odour;
- irritancy is addressed, in some detail in the HRA and in the CSIRO report. Irritancy and odour are, in practice, closely linked in terms of "health surveys" and health records. Odour is often reported as "irritating" (e.g. in doctor's clinical notes and by claimants). Odour can lead to nausea, and even vomiting, mediated by psychological or emotional mechanisms. Odour is linked to "fear" and anxiety (and panic attacks), to occurrence of headache, and to other anxiety-mediated symptomatology and reported signs, e.g. dizziness, memory failure, and a feeling of inability to function mentally ("brain fog").

2.6.4 Understanding the HRA

The main criticism of the HRA is that despite the fairly clear-cut conclusions, and sound risk assessment, it may fail to clearly explain matters to readers and may generate confusion and misconceptions. This problem of definitions, understanding and readability, is returned to several times in this review. This is because understanding and confidence in the overall conclusions is not possible without clarity of definitions, and precision in the words used.

In this section these problems are illustrated by specific examples taken from the HRA, together with critical comment.

The actual scope of work of the HRA is explained on pages ii -iii, including setting out the limitations of the HRA. However, the confusion of concepts for the reader and difficulties in understanding, which is an overall criticism of this HRA, is well illustrated. It reads (para 2 on page iii):

The potential health effects arising from the predicted short-term (acute; 1-hour and 24-hour averages) and long-term (chronic; annual averaged) exposure to non-carcinogenic compounds, and potential carcinogenic risks were considered in the HRA assessment by comparing the exposure concentrations predicted by the modelling with health protective guidelines for ambient air developed by reputable authorities such as the National Environment Protection Council (NEPC), World Health Organisation (WHO) and the U.S Environmental Protection Agency (USEPA).

In one long sentence, which would have been better split into several, are contained many complex ideas, and ambiguities. As examples, "*potential*" and "*risk*" are used interchangeably, "*health effects*" and "*carcinogenic risks*" are mentioned as if they are separate concepts, and the term "*exposure concentrations*" is introduced but not used elsewhere in the HRA (except in relation to toxicology tests on rats exposed to formaldehyde).

Similarly, in explaining the method for assessment of carcinogenic risk the HRA states:

To assess the potential health effects associated with exposure to carcinogens, the incremental carcinogenic risk (ICR) was calculated to provide an indication of the incremental probability that an individual will develop cancer over a lifetime as a direct result of exposure to potential carcinogens.

Mathematical calculations of ICR are provided. However as these merely provide "*an indication*" of a "*probability that an individual will develop cancer*", then the reader may well question the necessity or meaning of such precise calculations, but obtain an impression that some residents may be at risk of cancer (from the Wagerup emissions). Such calculations are **not** about any "*individual*" or real-life persons and their risk of developing cancer, and this should have been emphasised.

Explanation of what the "*incremental*" part of ICR means is not provided for the general reader, and it is not a concept which can be intuitively understood. An attempt at explanation is given on page 27:

The expression of the incremental carcinogenic risk values presented in Table 9 are best explained by way of example, with the incremental carcinogenic risk calculated for Receptor 16 for the baseline emissions scenario of $3.68x10^{-7}$ (0.000000368) which can also be interpreted as a risk of 1 in 2,717,391.

This is not an adequate explanation, albeit correct in a narrow technical sense.

The immediately following section in the HRA contains similar problems:

An increase in the incremental carcinogenic risk compared to the baseline incremental carcinogenic risk is predicted to result form the Wagerup refinery expansion at all receptor locations, with an increase in the incremental carcinogenic risk ranging from approximately 33% (Receptor 2, Upgrade Case 6) to 160% (Receptor 15, Upgrade Case 7). However, while the predicted percentage increases in the ICRs is significant, the absolute maximum increase at any of the receptors is 0.26×10^{-6} at Receptor 16, the closest receptor to the refinery and the RDA.

This explanation is also potentially misleading. Whilst mathematically correct, it may well be interpreted as indicating an actual increase in risk of cancer, which is incorrect.

If the quoted percentage increases 33% to 160% are misunderstood, this could lead to completely unnecessary concern for readers, and particularly for residents living at the quoted receptor sites.

Whilst increases in these largely meaningless numbers have been recorded, they are not "*significant*" in any health sense. The words "*absolute maximum increase*" are unclear as to what they mean.

The impression for the average reader is that the closer one lives to the refinery, the greater the risk of developing cancer. This would be a completely wrong conclusion to draw from the information provided. Although it might generate deep concern amongst residents, it may be particularly concerning to workers within the Wagerup operations. The reality is that these calculations (and the conclusions of the HRA) do not indicate **any** cancer risk arising from impact of current or predicted Wagerup emissions.

A further example relates to the paragraph explaining the results of the further Arsenic assessment, which states:

*However, the results presented in Section 5.4 indicated that **arsenic exposure via inhalation is the major contributor to the predicted ICR** and as such this requires further evaluation. The HARP program was utilised assuming a particulate deposition velocity of 0.003 m/s (approximately an order of magnitude greater than recommended in the CALPUFF user manual for fine particulate emission) and this indicated that **the inhalation exposure pathway was likely to account for approximately 75% of the carcinogenic exposure to arsenic**. The remaining 25% of **the exposure** was predicted to occur **as a result of soil ingestion (14%), vegetable ingestion (8%), dermal absorption (2%) and drinking water (1%).** It should be noted that there is a great deal of uncertainty associated with this and that the assumptions inherent in the HARP are designed to err on the side of health protection in order to avoid underestimation of risk to the public (OEHHA, 2003). Further, there is a great deal of uncertainty and actual variability in much of the data used for this assessment (e.g. **amount of local vegetables produce consumed**; particle size distribution of particulate containing arsenic). Therefore, the potential alternative exposure pathways presented above should be considered as broadly indicative only. At the **maximally affected receptor** (ie. Receptor 16, Upgrade Case 7), the **ICR attributable to arsenic** via inhalation exposure was $0.28x10^{-6}$. Assuming that **this accounts for 75% of the potential ICR attributable to arsenic, then the potential total ICR associated with arsenic would be approximately $0.37x10^{-6}$ and the total ICR for all compounds would increase from $0.63x10^{-6}$ to $0.72x10^{-6}$ at this location** which is less than the reference value of 1×10^{-6}. Therefore, the alternative exposure pathways for arsenic, are not expected to have a significant impact at the maximally affected receptor (i.e. Receptor 16) and will have a lower level of impacts at the less affected receptors.*

The bold emphasis on certain phrases above has been added during this review to emphasise the problem of reader perception and the potential for misunderstanding.

This wording is considered difficult to understand, and potentially quite misleading. As a rapid check on perception, this section was submitted to two other reviewers (within IHC) on April 26, who were asked to interpret what the HRA was trying to convey to readers on this topic. Both found these paragraphs to contain ambiguities and uncertainties which they could not resolve. Overall, it was judged to leave the reader with the impression that there were serious doubts and fears about a cancer risk from arsenic exposure at the residence known as receptor 16 and therefore to a lesser extent at others. It was agreed that this was **not** what the HRA was **intending** to convey to readers. It was considered that attempts (in the form of caveats) had been made to try and reassure readers that in truth the risk was *de minimis*, particularly in the last sentence of the above paragraph. However, the preceding sentences were likely to raise more concern than would be allayed by the final sentence. Overall, such loosely worded sections are not providing readers with clarity and realistic assessment.

Another example is the confusion over the calculating of "*Hazard Quotient*" and "*Hazard Index*" discussed in a previous section of this review.

Occasionally in the HRA there is comment on health issues which is potentially misleading or incorrectly presented. An example is the use of the term "*Potentially sensitive*" on Page 7, referring to what are better defined as "*special populations who may be at greater risk of adverse health effects*" (as defined in enHealth 2001).

"*Sensitive*" is ambiguous term. In a health or medical context, it usually refers to conditions caused by the allergic-response process, e.g. a person is sensitized to a substance (pollutant). This refers to developing an allergic response to the substance which is provable by objective tests where patch testing, prick testing or blood testing for IgE levels can be undertaken. This is a common health issue in Australia (and elsewhere) in terms of health conditions such as dermatitis and asthma, hay fever and anaphylactic shock, and the general condition of "atopy". "*Sensitive*" is preferably reserved to have this meaning, which is not what is intended in the HRA. "Vulnerable" is an alternative and preferable term, commonly used to convey the intended meaning of a subgroup of a population which, because of some personal or group characteristic, is or may be more susceptible to the adverse effect of some exposure (in this case to pollutants).

2.6.5 Interpretation of receptor location conclusions and contours

In the HRA, comment about risk at various locations is made, and extensive mapping of contours of risk are provided.

The future use of these contours (and receptor location conclusions) may require further explanation than is provided in the HRA.

Contours and receptor location comments cannot be interpreted as showing areas around Wagerup which are more or less "healthy" or "safe" to live in.

In summary, as an indicator of a broad range of risk, these measures are useful as initial screening assessments of emissions, but not as pointers to real-life risks.

3. Summary and conclusions

3.1 Scope and limitations of the HRA

- The present HRA could perhaps be described as a "limited or initial screening assessment of potential for risks arising from direct toxic actions of air pollutants". The HRA is limited in its scope and ability to represent a full "Health Impact Assessment", as defined by Australian authorities (enHealth 2001, 2002). This is not a fault of the HRA, which did not claim to present a full or comprehensive Health Impact Assessment.
- The most important technical limitation of this HRA is that it considers emissions from only one source when comparing with guidelines or safety limits for human exposure.
- Another major limitation unavoidable in this type of HRA is that it only considered **direct toxicological** mechanisms for causing health effects, and only considered **physical** health effects.
- The HRA does not deal specifically with health matters or health complaints, nor with their causation, which are probably of central interest to the local communities seeking information about health risk assessment.
- Odour was not included in the scope of the HRA. No Health Impact Assessment which ignores odour is likely to be addressing the issues which trigger health effects complaints. There is information in the background documents suggesting this will be addressed separately, but no further or detailed information was available at the time of this review. It seems highly likely that odour will need to be addressed as a mechanism involved in health effects and health complaints (i.e. integrated with all considerations of air pollutant effects through toxicity mechanisms) to achieve better understanding of Wagerup emissions.
- Australian Government guidelines provide that any Health Impact Assessment should consider benefits as well as health (and other) risks and should provide information in context. This was not included in the scope of this HRA.

3.2 Results and conclusions of the HRA

- The HRA, from consideration of air quality information and air dispersion modeling in particular, presents valuable, and almost certainly correct assessments, on the levels of risk contributed by the Wagerup emissions.
- The quantification, or measurement of risk levels, provided is related to calculation of the measures described as "*Hazard Index*" (HI) and "*Incremental Cancer Risk*" (ICR). The final conclusions of the HRA are given in qualitative terms. However, being based on quantitative methods, this reviewer would regard them as at least semi-quantitative.
- Review of both Air Quality Standards or Criteria selected, and the Air Quality Data (the information about Ground Level Concentrations predicted for the area), shows that:
    - Criteria used to calculate the measures of risk were conservative and appropriate.
    - Air Quality data and information used in the HRA is valid and extensive, and its quality has been independently reviewed. The air pollution information gathered for the areas surrounding Wagerup would appear to be comprehensive.
    - It does appear that in <u>all</u> cases, a very prudent, conservative, or highly health-protective approach has been taken in the HRA.

- Choice of methods was appropriate, although other approaches and the limitations of the methods have been discussed in this review. Selection and use of the air quality data and health guidelines criteria data was appropriate and conservative.
- Comparison of predicted GLCs with published health guidelines is the standard approach for this type of HRA and was carried out on an agreed an comprehensive selection of pollutants.

- The HRA states that the conclusions are: "*considered more likely to over*-(estimate) *than under-estimate the potential health risks associated with atmospheric emissions from the Wagerup refinery and the RDA* (abstract)". Given that the ADM and predicted emissions are a reasonably true representation of the future true measured GLC, then this review agrees with the results and conclusions and this statement regarding over-estimation rather than under-estimation.
- Results of this HRA are reassuring on the matter of air quality and the *de minimis* nature of any health risks, taking into account the limitations of this HRA.
- The HRA is also valuable in pointing out that a full Health Impact Assessment which investigated the same direct toxicologically-mediated health effects is probably not justified.
- However, some further investigation of health complaints or health effects may be necessary or desirable. Consideration of the outcomes of this present HRA suggests that very careful preparation will be needed to determine what types of health study or Health Impact Assessment are feasible or appropriate, if resolution of these questions for the community of Wagerup is to be achieved.

3.3 Criticisms and omissions

- The major criticism is that the HRA may, because of lack of clarity and readability in some parts, lead to confusion or unnecessary concern in some readers. This is detailed in the section on "Understanding the HRA" (2.6.4 above), and numerous examples are provided. The overall problem is that any lack of clarity and readability may detract from the valuable work done and conclusions reached. The recommendation made at the end of this review relates to this issue.
- Choice of overseas criteria and methods is criticized, only because all relevant guidelines and criteria can be sourced in Australia, and all such methods, guidelines Standards and criteria should be used within the Australian context including the Australian regulatory context. Applying overseas criteria which are developed for overseas contexts can lead to difficulties. In this case there were no technical difficulties apparent.
- Given the low levels of GLCs predicted (in comparison with published standards, goals and guidelines) the further calculations undertaken (of totaled HI) are criticized as being largely unnecessary. However, any fault in this relates to the concern about readability and comprehension rather than any concern relating to the validity of the conclusions.
- The lack of information about context, e.g. the relative importance of Wagerup emissions compared to general background Air Quality levels, and overall intake of chemicals which may be important for health, is a criticism of this HRA.
- The large volume of toxicological information about pollutants, provided mostly in Appendices A and B, is not relevant given the levels of exposure revealed by the HRA.

This non-relevant information (which is all in the public domain), detracts from the objective of giving relevant and "in context" information to readers.

- The HRA states in conclusion to the section on (page 3) entitled Overview of the Screening Assessment Approach that:
  The results of the HRA are able to be used to assess the relative change to potential health risks associated with an expansion of the Wagerup refinery, and identify the individual sources and compounds exhibiting the highest contribution to potential health risks in order to help define atmospheric emissions management strategies.

  These claims probably overstate the case. It has not and cannot "*identify the individual sources and compounds exhibiting the highest contribution to potential health risks*", nor would it change or influence in any significant way "*atmospheric emissions management strategies*".

  The HRA as performed is a useful screening or initial assessment. It has been carried out correctly, and has come to conclusions which are almost certain to be correct. However, given the:

  - limitations of this screening assessment (recognised in the HRA)
  - omission of odour in the assessment (and other omissions outlined in this review)
  - as yet unresolved questions regarding "health effects" in the community
  - and the continuing complaints of "health effects" from individuals,

  it is unlikely the HRA can do much more than confirm its conclusions, which essentially are that on the basis of the evidence considered, no risk of health effects on any residents can be foreseen.

3.4 Recommendation

Finally, it is recommended that effort is made to enable readers, and particularly the residents and community groups, to understand what this HRA has concluded, so that the value of it is accepted as part of the engagement process between Alcoa and the local communities.

4. Appendices

Appendix 1: Professional details for Dr John A. Bisby

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Qualifications

MBBS London University 1964; LRCP MRCS (UK Conjoint Board) 1963

MSc Occupational Medicine (London School of Hygiene & Tropical Medicine) 1973

Diploma in Industrial Health (UK Conjoint Board) 1973

Fellow, Faculty Occupational Medicine, Royal College of Physicians, UK (FFOM)

Fellow, Faculty Occupational Medicine, Royal Australasian College of Physicians (FAFOM)

Current consulting and professional activities

Consultant with International Health Consultants (IHC) Pty Ltd. Registered specialist in Occupational Medicine (Australia). Major areas of interest: Occupational Medicine, Environmental Health, applied toxicology, major hazards control, industrial hygiene, ergonomics, and epidemiology. Presently consulting with Australian and international companies and Government bodies. Member Scientific Committee on Accident Prevention, International Commission on Occupational Health (1996 –).

Former positions and activities

1996-98: Member, Carcinogens Scheduling Expert Working Group, National Occupational Health & Safety Commission Australia.

1991-98: Associate Professor in Occupational Medicine and Environmental Health, Department of Public Health & Community Medicine, The University of Melbourne; Director of the Australian Petroleum Industry epidemiology program (Health Watch).

1992-96: Council member, Faculty of Occupational Medicine, Royal Australasian College of Physicians.

1992-96: Member, Social Issues Committee, Royal Australasian College of Physicians.

1978-95: Consultant, RAAF Specialist Medical Reserve.

1991-94: Technical Director, Altona Clean Air Project

1989-90: United Nations (UNDP) project in Bangkok on *Safety and Health in the Construction Industry* for 11 Asian countries.

1982-89: Executive member, Australasian College of Occupational Medicine.

1987-88: Expert member, Victorian Government committee Lead Regulations and Code.

1986-88: Vice President, Australasian College of Occupational Medicine.

1977-88: Expert and Technical Consultant Member of ILO (International Labour Organisation) meetings on airborne contaminants, chemicals, accident and health statistics and Control of Major Hazards.

1981-87: Board Member, International Commission on Occupational Health (ICOH).

1986: Member, ILO Petroleum Committee.

1985-86: Chairman, Specialist Education and Rural Industries Committees (NOHSC - WorkSafe Australia).

1984-86: Commission Member, National Occupational Health and Safety Commission, (NOHSC - WorkSafe Australia).

1975-86: Co-ordinator to the Shell Group in Australia, responsible for advice on Occupational Health and Safety for employees, Safety aspects of the Group's operations in relation to customers and the community, and Environmental Affairs.

1983-85: Member, National Labour Consultative Council Committee on Occupational Health & Safety.

1977-81: Member, National Health and Medical Research Council Carcinogens (Standing) Committee.

1973-75: Specialist in Occupational Health, Division of Occupational Health and Pollution Control, New South Wales Health Commission. Appointed Inspector of Factories (medical) NSW Government.

1967-72: General Medical Practice UK and Australia.

1964-67: Hospital medical and surgical practice, UK.

Publications have included papers and reports on:

Agricultural chemicals safety, Pesticides and organophosphate poisoning, Air Pollution, Lead Absorption in Children, Lead and Carbon Monoxide absorption in Traffic Police, Occupational Health and Safety Practice in Australia, Further Education in Occupational Hygiene, Use and structure of Material Safety Data Sheets, Industrial Solvent Exposure, Hygiene Standards and Legislation, Occupational Cancer Legislation for Australia, Health Promotion in Industry, Epidemiology of work-related diseases and accidents, Epidemiology in the Australian Petroleum industry, Mortality and cancer incidence, Retrospective Exposure Assessment for Benzene, Leukaemia risk associated with low level benzene exposure, Disaster management.

Appendix 2: Primary Australian references

Relevant extracts and comment from these Commonwealth of Australia publications are reproduced solely to further understanding of the HRA and this review.

The following are extracts of:

> ***Health Impact Assessment Guidelines*** **September 2001.** ISBN: 0 642 50365 6. Publication approval number: 2971. Referred to in this review as (enHealth 2001).

Preface to *Health Impact Assessment Guidelines*

The critical link between human health and our surroundings is highlighted in the National Environmental Health Strategy (1999). In particular, it calls for greater attention to the impacts of developments – "...health considerations should form part of any impact assessment for developments or decisions that could have health consequences." There is overwhelming evidence that development can have a beneficial effect on health and wellbeing; through the creation of employment, promotion of economic advancement and providing circumstances which can improve living standards. Development can also have adverse effects, however, through problems such as noise, water and air pollution, and increased risks of injury and disease transmission. Development may also impact on the social and emotional status of individuals and communities through, for example, alienation and dis-empowerment. Some community members may be particularly susceptible to both the physical and social impacts, such as children and the elderly. Health Impact Assessment (HIA) is a process that systematically identifies and examines, in a balanced way, both the potential positive and negative health impacts of an activity. These Guidelines specifically address the use of HIA when conducting Environmental Impact Assessment, further developing the National Health and Medical Research Council *National Framework for Environmental and Health Impact Assessment* (1994) in the light of experience in implementing HIA in Australia and overseas. In this planning context the outcomes of HIA provide the ideal starting point for efforts to maximise positive health impacts and prevent or minimise negative impacts. Rectifying problems during planning is usually the preferred approach; rather than having to deal with them once a development is under construction or in place. By ensuring that immediate and future human health can be protected, the possibility of sustainable development is strengthened by HIA. For proponents the Guidelines will assist understanding of what needs to be done and promote a more balanced approach by ensuring positive impacts are given appropriate consideration. For the wider community HIA can help to ensure our surroundings are best able to enhance health for all into the future. Maximising the economic and other benefits of development while managing the adverse impacts is an important but often difficult balance to strike. These Guidelines are intended to assist with the achievement of that balance. The current consideration given to human health in Environmental Impact Assessment (EIA) is often unstructured and confined to negative impacts. An EIA may not properly recognise the positive effect on health that development can have, for example financial status. Health is determined by many factors including genes, age, a person's social and economic circumstances, lifestyle and access to services, as well as environmental health factors such as air and water quality, housing, etc. HIA seeks to ensure both the positive and negative impacts on health (as viewed from a wider perspective than just physical illness or injury) are effectively considered during impact assessment.

What is health impact assessment?

Health Impact Assessment (HIA) is defined by different agencies in different ways, but there is a general consensus around a broad definition, published in 1999 as the 'Gothenburg Consensus Paper' by the WHO Regional Office for Europe. That definition is: *"a combination of procedures or methods by which a policy, program or project may be judged as to the effects it may have on the health of a population."* HIA may thus include assessment of high level policy and programs as well as individual developments, and encompass the vast array of assessment techniques used for each. In its broadest form, HIA seeks to predict the health impact of a policy, program or project (including a development) usually before implementation, and ideally early in the planning stage. It aims to facilitate the reduction or avoidance of negative impacts on human health and enhancement of the positive impacts, and in so doing promoting sustainable development (SD) – human health being central to the concept of SD.

These Guidelines are intended to assist (health professionals) to better understand the rationale for HIA and the processes involved.

What is meant by 'health' and what are its determinants?

It is useful when examining the scope of HIA in general, and of these Guidelines in particular, to consider what health is and what are its determinants. The WHO definition of health is: *'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'.* This definition is very broad. While it helps to identify what might be included as 'health' it is less helpful in setting boundaries around what should be considered and what may be ignored. A more specific approach is to examine the key determinants of health and consider which are susceptible to change and by what means. As outlined above, the approach described in these Guidelines is sometimes referred to as *environmental* health impact assessment as it focuses mainly on the environment (natural and built) in attempting to improve and maintain health. Nevertheless, HIA may also need to address other issues, such as lifestyle, an important determinant of health, which may be readily impacted upon by developmental change. Overall, it is important to note that health is influenced by a very broad range of factors.

Principles to be addressed when undertaking Health Impact Assessment

Overall The Charter of (Environmental Health) Entitlements and Responsibilities for Individuals, Communities, Business and Government will be observed throughout the HIA process (NEHS 1999).

The Community Community consultation is a critical and integral part of the HIA process. People and communities are part of the "environment" and rely on the quality of the environment for their survival and maintenance of good health and wellbeing. The public has a right to know the actual or potential effects of a proposed activity on their health and their environment, and should be consulted on the management of risks. The community is also a rich source of local information that can only be tapped through its involvement. The protection and, where possible, the improvement of public health should be fundamental to HIA.

Scope, relevance and timeliness of the Health Impact Assessment The scope and detail of the HIA should be in proportion to the scale of the potential health impacts of a proposed development. Scoping should identify only those impacts which have significant potential to occur. The level of risk assessment should be in accord with the nature, scale and significance of the actual or potential effects of the proposed activity. Where there is insufficient information or uncertainty about the risks to health, this should be clearly stated. Both positive and negative health impacts should be considered. Human health should be safeguarded i.e. likely health problems should be remedied before they can occur (once they have been identified as a possible concern). The additional financial cost is likely to be less for both industry and governments if action is taken at the design stage.

Integration of Health Impact Assessment and Environmental Impact Assessment HIA should be explicitly integrated into the assessment of effects on the environment (i.e. into EIA) to ensure that any actual or potential impacts or risks to public health are adequately addressed in the development approval process.

Monitoring and review Where appropriate, monitoring should be carried out to assess whether modification to the proposal has actually been implemented, evaluate the HIA process, and assess the outcomes, i.e. whether anticipated or unanticipated health impacts have occurred. Environmental and health controls, as conditions in approvals, should be reviewed regularly.

Screening Screening is the process of determining whether or not a proposed development warrants impact assessment. It is commonly governed by statute. Screening for health issues is carried out as an integral part of the overall screening process. It is usually, if not invariably, undertaken by the agency responsible for determining whether a development needs to be assessed, and if so, to what extent. All proposed developments that are required to undergo EIA should be screened for possible health impacts, as well as for other impacts. While this may not ensure every project likely to impact on health is detected, it will identify most, if not all, of those likely to have health impacts that are significant. If health authorities wish to apply HIA more broadly they would need to make other arrangements outside this framework to identify the projects or issues of significance. Screening is, firstly, a process of filtering out those projects that do not require HIA because: the health effects are expected to be negligible; or the health effects are well known and readily controllable though measures that are well understood and routinely applied, and so require no specific investigation or analysis. Identifying these early in the HIA process allows scarce resources to be applied to assessment of those projects with the most significant likely health impacts.

Assessing the health impacts (risk assessment) The risk assessment process should identify the impacts that a proposed development is likely to have on health. These effects could be negative, resulting from

exposure to a hazard, or positive such as improved recreational opportunities or job opportunities. This is an aspect overlooked by the typical assessment that does not fully consider human health, and is one reason to include a broader view of health in the impact assessment process. Assessment of risk may be done by assessment against health-based guidelines, it may be a quantitative assessment, or use qualitative techniques, or it may use a mix of these approaches.

Risk assessment using health-based guidelines and objectives Health-based guidelines and objectives assist in consistently and reliably assessing health risks, ensuring safety in the situation to which they are relevant. Guidelines and objectives have been developed for environmental and occupational hazards, including noise, pollutants, radiation and microbiological agents. Guidelines are prepared by national and State/Territory agencies as well as international bodies such as the WHO. They provide a straightforward means of predicting impacts, but they do not exist for every possible environmental health hazard. Ideally, predicted levels should have insignificant or little effect if they fall below the levels as specified by the guidelines or objectives. Guidelines should, however, be used critically. Reasons for caution include: most guidelines are developed to protect against specific types of health effects. They do not necessarily guarantee protection from all types of adverse effects, and reflect the science at the time of publication; they do not necessarily address the social, community or psychological dimensions of health and well-being effectively; they may apply to occupational exposure and are not directly applicable to public health; they may not identify positive effects on health; and they may not fully account for factors such as the age and sex of a person. For instance, children, the elderly and pregnant women may be more susceptible to some environmental health hazards. If no regulatory standards or objective criteria are available, other modes of evaluation are used. Other approaches that can be used to assess a project's potential effects on health include risk-based analyses that may be quantitative or qualitative. Whatever method is used will also need to address the concerns expressed by stakeholders and the public, as well as any other risks that are identified.

Quantitative risk assessment The basic risk assessment process is set out in Figure 2, which was taken from a draft of *Environmental Health Risk Assessment – Guidelines for Assessing Human Health Risks from Environmental Hazards*. Given that positive effects are also to be included, risk assessment may not be the ideal term but it is used for the sake of uniformity with the 1994 NHMRC publication6 and similar risk assessment frameworks. *Environmental Health Risk Assessment* provides a methodology for assessing risk from chemical hazards in considerable detail; reference to this document is recommended for those undertaking such assessments. The intent when dealing with risk should not be to reduce it at all costs or to reduce it to a negligible level, but rather to balance the benefits and costs to the community of reducing the risk. There is economic cost to the proponent (money and time) and to the health authority (the opportunity cost of the assessment activity) and these should be offset by the health or economic gains that result from the project's improved consideration of health issues.

The precautionary approach The NHMRC framework document suggests that when the scientific basis for a risk assessment is still in the early stages of development, decisions should err on the side of caution. This is often referred to as a precautionary approach.

What is meant by the precautionary approach? Definitions of the precautionary approach vary, but the most widely internationally accepted is that described in Principle 15 of the Rio Declaration on Sustainable Development (UNCED, 1992). This states: *"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."* In Australia, some jurisdictions have included this concept, variously referred to as the 'precautionary approach' or 'precautionary principle', in agreements and legislation. In February 1992, the Intergovernmental Agreement on the Environment included the following as part of a commitment to sustainable development: *"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 risk weighted consequences of various options."*

The precautionary approach is not intended to be a device to inhibit development. However, proponents may need to consider and discuss health risks that are uncertain as well as those that are well defined, including an indication of the degree of uncertainty and where the uncertainty is thought to lie. A precautionary

approach is limited in its utility by the uncertainty as to its meaning and application. Caveats that apply to its use include: Implementation of a precautionary approach should start with an objective risk assessment, identifying at each stage the degree of scientific uncertainty; All the stakeholders should be involved in the study of the various management options that may be envisaged once the results of the risk assessment are available; Regulatory measures taken should be proportionate to the risk which is to be limited or eliminated; measures based on a precautionary approach should be able to establish responsibility as to who should furnish the scientific proof needed for a full risk assessment; and measures based on a precautionary approach should always be of a provisional nature, pending the results of scientific research performed to furnish the missing data and performance of a more objective risk assessment.

Health Impact Assessment

The process of estimating the potential impact of a chemical, biological, physical or social agent on a specified human population system under a specific set of conditions and for a certain timeframe.

The following are extracts of:

> ***Environmental Health Risk Assessment – Guidelines for Assessing Human Health Risks from Environmental Hazards.*** IBSN: 0 642 82091 0. Publication approval number: 3096. Referred to in this review as (enHealth 2002).

The level of risk can be described either qualitatively (i.e. by putting risks into categories such as 'high', 'medium' or 'low') or quantitatively (with a numerical estimate or probability density distribution). Current risk assessment methods do not enable accurate quantitative estimates of risk for low levels of exposure to environmental hazards. Numerical estimates of risk will rarely be feasible because of limitations in toxicological and exposure data which will be reflected in the uncertainty assessment, but quantification may be possible for some components such as exposure assessment. Clearly defined qualitative categories can enable reliable and effective risk management decisions.

Estimates do not have to depend on the use of numbers to be useful; ordinary language may be used to indicate the level of risk. A finely divided ranking system can give a relatively accurate indication of quantity without using numbers (ACDP, 1996). Clearly defined qualitative categories can enable reliable and effective risk management decisions. Numbers may give a misleading implication of accuracy, especially when based on poor or uncertain information. The generation of a precise value in QRA should not be mistaken for accuracy (IEH, 1999b). The problems are compounded where results are interpolated over several orders of magnitude and where information on the mechanisms of tumour induction is limited.

While qualitative risk conclusions can avoid the false sense that the extent of the risk is known precisely, the use of terms such as 'high', 'medium' or 'low' may have different interpretations to different groups and they should be clearly defined. This is often best achieved by being put in context or compared to other risks relevant to the community. If comparisons do not directly relate to alternative options, they should be used cautiously, especially if like is not compared to like or if comparisons are being used to imply acceptability.

In many instances, situation-specific health risk assessments may not be necessary as the nature and magnitude of the risks will be quite apparent, there may be no population at risk, or decisions on risk management may be made on other grounds. In such cases, the significant resources required for a detailed risk assessment would be better directed to risk management steps (ANZECC/NHMRC, 1992, p. 20). The level of risk can be described either qualitatively (i.e. by putting risks into categories such as 'high', 'medium' or 'low') or quantitatively (with a numerical estimate or probability density distribution). Current risk assessment methods do not enable accurate quantitative estimates of risk for low levels of exposure to environmental hazards. Numerical estimates of risk will rarely be feasible because of limitations in toxicological and exposure data which will be reflected in the uncertainty assessment, but quantification may be possible for some components such as exposure assessment. Clearly defined qualitative categories can enable reliable and effective risk management decisions. It should be recognised that, as a consequence of testing limitations (for example, not every square metre of a contaminated site nor every item of food in the marketplace will be tested), situation-specific health risk assessment is a screening process where there may be low rates of false negatives and false positives. 'Risk assessment is based on probabilities rather than

absolutes and this should be reflected in decision making' (*ibid*, p. 34). Uncertainty is usually caused by inadequate knowledge but can also relate to:

• parameter uncertainty (measurement errors, random errors, systematic errors);

• multiple uncertainty (errors arising from the incorrect models or reality); and

• decision–rule uncertainty (not knowing how to interpret predictions) (Finkel, 1990)

Variability occurs when a single number is used to describe something that actually has multiple or variable values such as bodyweight or susceptibility to adverse affects, or something that varies over time such as the population of an area. Variability occurs as a result of differences between the characteristics of different people or populations. Uncertainty arises as a result of lack of data. Both uncertainty and variability need to be considered in risk assessments.

Key Principles in Environmental Health Risk Assessment

There are a number of key principles for environmental health risk characterisation (EPA NSW, 1998; US EPA, 1995):

1. Actions should always adequately protect public health and the environment, putting these responsibilities before all other considerations.

2. Risk assessments should be transparent. The nature and use of default values and methods, assumptions and policy judgments in the risk assessment should be clearly identified. Conclusions drawn from the evidence should be separated from policy judgments.

3. Risk characterisations should include a summary of the key issues and conclusions of each of the other components of the risk assessment, as well as describing the likelihood of adverse health effects. The summary should include a description of the overall strengths and limitations (including uncertainties) of the assessment and conclusions.

4. Risk characterisations (and risk assessments) should be consistent in general format, but recognize the unique characteristics of each specific situation

5. Health risk assessment must be undertaken with an appreciation that the health risk assessment is often part of a larger assessment that encompasses ecological risk assessment.

6. To protect public health and the environment an appropriate degree of conservatism must be adopted to guard against uncertainties.

7. Ensure that comparisons have been made against environmental health criteria that have been endorsed by the relevant Commonwealth, State or Territory environmental health agencies.

8. Where there are no Environmental Health Criteria for a particular agent refer to the administrative authority at the relevant Commonwealth, State or Territory level.

9. Ensure that human health risk assessments are undertaken, where necessary, according to methods in this document, or its revisions as published from time to time

10. When deriving environmental health criteria use toxicological data or exposure criteria from agencies or organisations relevant to the State or Territory (e.g. local or Commonwealth health agencies such as NHMRC, or the enHealth Council) or to which Australia is party (e.g.World Health Organization).

11. Ensure that human health risk assessments are undertaken using national toxicological assessments (e.g. NHMRC) or WHO assessments or, where neither has been made, methods agreed to by the administrative authority for contaminated sites at the relevant Commonwealth, State or Territory level.

12. The risk assessor's knowledge of the peer-reviewed scientific literature relevant to risk assessment and the practical aspects of risk assessment should be up-to-date.

13. Variations in risk assessments as a result of particular statutory requirements, resource limitations, and other specific factors should be explained as part of the risk characterisation. For example, a reason will be required to explain why certain elements are incomplete.

Appendix 3: The environment and diseases: association and causation*.

* A. Bradford Hill, *The environment and diseases: association and causation*. Proc Roy Soc Med, Sec Occup Med 58:272 (1965).

Bradford Hill set out the issue and gave as an example that:

"some form of respiratory illness is associated with a dust in the environment. In what circumstances can we pass from this observed association to a verdict of causation? Upon what basis should we proceed to do so?"

He then set out the principles on which cause and effect have been analysed since that time. His principles have dominated thinking on the issue in the UK, USA, and Australia.

The problem he defined is exactly the question in relation to future emissions at Wagerup – will they, or could they possibly, cause health effects or the health complaints reported?

Because health effects happen to all humans, in any place or time, they will happen to residents in the receptor areas defined in the Wagerup studies. Experience suggests that in a proportion of cases, these health events will be associated by the sufferers with events in their lives, including events such as local air, water, or soil pollution. The question to be answered is whether that association could actually be causation (cause being air pollution effect being the health events).

Bradford Hill said:

"The "cause" of illness may be immediate and direct, it may be remote and indirect…the decisive question is whether the frequency of the undesirable event B will be influenced by a change in the environmental feature A."

B in the current context is a health effect on a resident, and A is exposure to Wagerup emissions.

Bradford Hill went on to say that firstly, the "play of chance" should be excluded, before testing further using his principles. This means that the health events observed or reported must be firstly defined as unexpectedly high, rather than being expected in that population.

At any stage, for any disease or health effect, there is a normal level of incidents in any population (e.g. cases of asthma, allergies, cancers, rashes or bronchitis, or reported symptoms). Before investigating whether any particular events are abnormal, and possibly due to pollution, it is necessary to be sure that there really is a increased health problem in a particular area or population group, e.g. residents around Wagerup.

Bradford Hill's principles for testing whether causation, or only association, is involved are:

(1) ***Strength:*** *"First upon my list I would put the strength of the association."* Translating this into the Wagerup situation, the question is whether any particular health effect is occurring more, and by how much more, in the residents, than in other similar groups in WA or Australia generally.

(2) ***Consistency.*** Have such increases in health effects been repeatedly observed by different persons, in different places, circumstances and times? This might include situations around other Alumina smelters or similar operations.

(3) ***Specificity*****:** Are any observed health effects specific to residents, or are specific types of disease increased in this area? However, as Hill remarked, "*We must not, however, over-emphasize the importance of the characteristic…We must also keep in mind that disease may have more than one cause*".

(4) ***Temporality*:** As Hill put it, "*which is the cart and which the horse?*" This is a question which might be particularly relevant with diseases of slow development. In the present context, the question might arise as to whether a particular environment leads to the health effect (e.g. asthma) or do families or individuals with a tendency to asthma seek to live in this environment? As Hill said, "*this temporal problem may not arise often but it certainly needs to be remembered*". No epidemiologically complete or validated information appears to be available relating to health complaints or health effects which have been reported. Some environmental health investigations in Australia have needed to consider the past medical records of residents to investigate this aspect of cause.

(5) ***Biological gradient*:** Hill provided an example: "*The dustier the environment the greater the incidence of disease we would expect to see. Often the difficulty is to secure some satisfactory quantitative measure of the environment which will permit us to explore this dose-response. But we should invariably seek it*". In a more general sense, this revolves around the question of whether there is a dose-response curve, i.e. are those most exposed, showing most effects? In the present Wagerup situation, the Air Quality information and the HRA suggest that (not surprisingly) the workers in the Wagerup operation, particularly in the RDA areas, are likely to be most exposed. What then is the past experience within the operation which has now been going for many years? As explained in relation to the calculations of risk, the most important finding is that all risks to residents in reality fall into the one category of *de minimis* (low, very low), there being no significant difference between exposures or risks at the receptor or residential sites identified. In health assessments, insignificant differences in risk rating (as worded in the HRA conclusions) are more likely to mislead rather than inform.

Biological gradient may be an issue for further investigation. The problems of compiling retrospective exposure indices is particularly difficult. However, there is some information about complaints and geography from background papers, and this and potentially future collection of information could give some clues to any dose-response gradient: In particular, the coupling of health information from exposure and recorded effects in workers within the Wagerup operations over past decades may be informative.

Further investigation, particularly of health complaints or health effects, has not been considered in the HRA, but potentially could be useful if, for example, medical records of residents who have moved away from exposure could be reviewed for 'before and after' effects. In regard to Hill's criteria of ***Analogy*** (see 9 below), where he suggests that *"In some circumstances it would be fair to judge by analogy"* there may be some prospects for comparison of exposures (e.g. to irritants or allergens in persons with asthma or infections etc) of persons moving in and out of the area.

(6) ***Plausibility:*** Hill said "*It will be helpful if the causation we suspect is biologically plausible. What is biologically plausible depends upon the biological knowledge of the day. In short, the association we observe may be one new to science or medicine and we must not dismiss it too lightheartedly as just too odd. As Sherlock Holmes advised Dr. Watson, "when you have eliminated the impossible, whatever remains, however improbable, must be the truth."*" Hill linked this with his next principle, ***Coherence***.

(7) ***Coherence:*** *"On the other hand the cause-and-effect interpretation of our data should not seriously conflict with the generally known facts of the natural history and biology of the disease".* In modern words, where there is reasonable knowledge about levels of exposure which can or cannot cause health effects, this must be given high weighting in coming to any judgment about causation. This is where the 'health guidelines' from various authorities, which form the core of the present HRA, are most useful.

(8) ***Experiment:*** "*Occasionally it is possible to appeal to experimental, or semi-experimental evidence. For example, because of an observed association some preventive action is taken. Does it in fact prevent? Is the frequency of the associated events affected? Here the strongest support for the causation hypothesis may be revealed."*

(9) ***Analogy:*** *"In some circumstances it would be fair to judge by analogy"*. As stated above, there may be some prospects for comparison of exposures (e.g. to irritants or allergens in persons with asthma or infections etc) of persons moving in and out of the area.

Overall, Hill said: "*What* (these principles) *can do, with greater or less strength, is to help us to make up our minds on the fundamental question--is there any other way of explaining the set of facts before us, is there any other answer equally, or more, likely than cause and effect?"*

Bradford Hill stated that when "e*vidence was clear-cut, no formal tests could really contribute to anything of value to the argument. So why use them? …there are innumerable situations in which they are totally unnecessary--because the difference is obvious, because it is negligible, or because, whether it be formally significant or not, it is too small to be of any practical importance."*

Bradford Hill criticized the overuse of meaningless calculations – what he called "*The magic formulae*". (He was himself a mathematician and statistician). He said: "*too often I suspect we waste a deal of time, we grasp the shadow and lose the substance, we weaken our capacity to interpret data and to take reasonable decisions… Like fire, the* (mathematical) *test is an excellent servant and a bad master…All scientific work is incomplete--whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time."*

Appendix 4: Use of the term *de minimis* to characterize risk in the Health Risk Assessment

The Latin term *de minimis* is used in the HRA to give a quantitative level of risk. However it is not explained fully. The HRA provides this explanation:

incremental carcinogenic risk (ICR) was calculated to provide an indication of the incremental probability that an individual will develop cancer over a lifetime as a direct result of exposure to potential carcinogens

The incremental carcinogenic risk that is considered acceptable varies amongst jurisdictions, typically ranging from one in a million ($1x10^{-6}$) to one in ten thousand ($1x10^{-4}$). The most stringent criterion of one in a million represents the USEPA's de minimis, or essentially negligible incremental risk level, and has therefore been adopted for this screening assessment as a conservative (i.e. health protective) indicator of acceptable carcinogenic risk.

The HRA refers to risk levels being *de minimis* or "*negligible*". *De minimis* is a Latin phrase used by some authorities, primarily the United States Government (Environmental Protection Agency). It specifically does not mean that the risk arising from the exposure is zero.

The Australian approach has been to take an incremental risk value of one in a million ($1x10^{-6}$) to one in one hundred thousand ($1x10^{-5}$) as the risk above which acceptability becomes contentious. This may be applied to the risk of fatal accident, or the risk of additional cases of cancer occurring.

These concepts of acceptability are somewhat arbitrary benchmarks, but to date no better way of making decisions regarding acceptability has been put forward. The concept of acceptability refers to political acceptability, or what the community will accept, and clearly this will be influenced by the benefits which the activity might also bring to the community, alongside any potential for risk. These issues are discussed in the enHealth 2001 and enHealth 2002 documents.

Human cancer risks at the levels quoted as *de minimis* or "*negligible*" cannot be measured in reality in real communities; they are abstract mathematical models. Risks in ranges 10 to 100 times (one to two orders of magnitude) higher than the *de minimis* levels are part of everyday life, and can be measured in epidemiological studies, e.g. risks of human cancer cases arising from drinking alcohol, smoking, certain dietary habits, taking certain drugs, undergoing X-rays, and adopting other lifestyle choices.

In summary, where a risk has been assessed as being at a *de minimis* level, then the position taken by authorities and regulators is that exposures creating such risk need not be restricted or regulated or mitigated with a view to reducing that level of undetectable risk.

The concept originally arose from complications and contradictions arising in the United States in relation to regulating Pesticides and Food residues; and was later applied to issues of air pollution. Governments recognized that regulation for zero risk was impracticable and developed the concept of defining a "*risk level*" which would be politically acceptable and achievable.

Other phrases have been used to describe the *de minimis* concepts:

- *a reasonable certainty of no harm (US FDA 1996)*
- *EPA has treated risk in the range of 1 in 1 million (meaning that, at most, an individual would have a one in one million chance of developing cancer if exposed over a lifetime) as a reference point and required that substantial benefits be demonstrated for any risk which exceeds that level (EPA report).*

A recent report provides a further explanation of *de minimis* criteria as follows:

(de minimis) criteria are intended to provide upper bounds on risks that are trivial (negligible). Thus, action to reduce risks at these levels or below, generally would not be warranted, regardless of cost-benefit or any other considerations. Furthermore, reduction of risks is not necessarily required whenever risks exceed the upper bounds on de minimis levels. Rather, the proper interpretation in this case is that the feasibility of risk reduction generally must be considered, but action to reduce risk would be required only if it is practicable (i.e., if the risks are above levels judged as low as reasonably achievable). From Criteria for Establishing *De Minimis* Levels of Radionuclides and Hazardous Chemicals in the Environment, Health Sciences Research Division, U.S. Department of Energy, Office of Environmental Management.

The US FEDERAL REGISTER notice published by EPA in 1991 (56 FR 7750, 2757):

There are inherent uncertainties in quantitative risk assessment because, among other things, of the necessity of relying on data from animal studies to predict human risk.

As a result, the same starting data in risk assessments can yield predictions that vary over several orders of magnitude, depending on the assumptions that go into the model. As FDA Deputy Director Robert Scheuplein warned in 1987, in a paper called *Risk Assessment and Food Safety: A Scientist's and Regulator's View*, agencies like EPA:

risk losing the integrity of the science and objectivity they need from it by continuing to suggest risk assessments are better than they are and that cancer risk can be so clearly self-evidently dismissed as DE MINIMIS [so small they don't matter] solely on a scientific basis. We have not seen a scientific breakthrough which now permits the precise assessment of low-level cancer risks.

In another recent paper, a further explanation is provided (*Assessment of Potential Risk Levels Associated with U.S. Environmental Protection Agency Reference Values*, authors from Center for Children's Environmental Health Research, School of Public Health, University of California, Berkeley, California, USA; U.S. Environmental Protection Agency, Washington, DC, USA):

legal maxim; "de minimis non curat lex" (the law does not deal with trifles). This need NOT be the same as a threshold dose. For example even if we know there is a true threshold dose, one may wish to set a "de minimis" level a little lower to allow for a margin in implementation. On the other hand if a linear dose response relationship is assumed, and a "practical" threshold is taken as the level where the effect cannot be proven (a risk of about 1 - 15%) one may need to assign a "de minimis" level that corresponds to a dose that it would be too expensive to reduce.