

## EXPERT PANEL ON AIR QUALITY STANDARDS

### STATEMENT ON THE USE OF AN INTERIM METHODOLOGY FOR SETTING GUIDELINE VALUES FOR ENVIRONMENTAL ASSESSMENT LEVELS

#### Purpose of this paper

1. At its meeting on 23 May 2003, the Panel was asked to advise the Agency on the suitability of using a methodology developed by Calabrese and Kenyon<sup>1</sup> to derive interim guideline values for Environmental Assessment Levels (EALs) for ambient concentrations of substances. This paper summarises the Panel's conclusions and provides advice to the Agency.

#### Background

2. The Panel's current work programme includes advising the Environment Agency (the Agency) on the derivation of additional environmental criteria for use in the determination of authorisations under the Pollution Prevention and Control (PPC) and Integrated Pollution Control (IPC) regimes.
3. The PPC regime requires the Agency to consider impacts on both human health and the natural environment. However, bearing in mind the terms of reference for the Panel and members' expertise, the work programme focuses on setting values for the protection of human health.
4. In determining applications for authorisation under PPC and IPC the Agency makes use of environmental standards or other benchmarks in order to judge the relative impact of a release.
5. There are many substances however for which standards are not available. Overall, there are only recognised ambient human health air standards set by EPAQS or WHO for approximately 31 substances, compared with the approximately 260 substances, which are reported as being released to air on the Agency's Pollution Inventory. The USEPA have set National Air Quality Standards for 7 substances of which only one (PM<sub>2.5</sub>) is in addition to the 31 substances mentioned above.
6. The PPC Regulations require the regulator to ensure that '*no significant pollution is caused*' and to apply Best Available Techniques (BAT).

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<sup>1</sup> Calabrese EJ and Kenyon EM (1991). Air Toxics and Risk Assessment. Lewis Publishers, Inc. Michigan

7. To gain a permit, operators will have to show that their proposals represent BAT to prevent and minimise pollution from the installation. To assess the environmental impact of either an installation alone or identify BAT from a range of options, the EA is updating its assessment methodology known as H1: *Guidance on Environmental Assessment and Appraisal of BAT*.
8. To fulfil its regulatory role the EA has developed environmental criteria, known as Environmental Assessment Levels (EALs), for use within the H1 methodology. EALs are non-statutory guideline values and represent, for threshold substances, a no-effect level or a low level of effect for non-threshold substances.
9. The regulations implementing the PPC regime came into force in 2000 and industrial processes are progressively being brought within the regime up to 2007. It is therefore important that air quality guidelines for substances to be assessed are made available as rapidly as possible.

## **Setting EALs**

10. Paper EPAQS 03/10 discussed at the meeting on 23 May 2003 described the current approach the Agency uses to set EALs and its limitations. Currently the majority of EALs for air have been derived by extrapolation from UK Occupational Exposure Limits (OELs). The extrapolation procedure applies uncertainty factors that allow for the differences between occupational exposure to chemicals and the exposure of the general population to the pollutant in ambient air.
11. Whilst this approach makes use of the relatively large body of information on the effects of chemicals as a result of occupational exposure there are a number of problems with uncritically extrapolating from these values to effects in ambient air.
  - a. Some occupational exposure limits may take account of technological considerations, such as the practicality of monitoring or control;
  - b. The toxicological endpoint considered for the occupational work force may not be the same as that of most relevance to the wider public.
  - c. The applied uncertainty factor may be suitable for some substances but not others.
12. In order to overcome some of these problems the Agency has proposed a revised methodology in relation to EALs for air and the protection of human health. This methodology similarly uses a hierarchical approach but seeks to make better use of substance specific information. The revised approach is outlined below:

- a. Use EPAQS standards or WHO guidelines where available.
  - b. Develop a work programme for EPAQS that will derive air quality guidelines<sup>2</sup> for a number of priority substances identified by the Agency.
  - c. Use existing WHO or IPCS evaluations and exposure assessments to derive air quality assessment levels.
  - d. Derive tolerable daily intakes or reference concentrations from toxicity data through the application of uncertainty factors.
  - e. Use an existing evaluation such as that of Calabrese and Kenyon to provide a rapid initial assessment, for a large number of substances. These values should progressively be replaced by EALs based on EPAQS air quality guidelines (see 12b above) – or EALs derived from other toxicological evaluations - for individual pollutants as they become available.
13. Stages (a) – (d) are likely to provide more robust EALs compared to the existing approach outlined in paragraph 10. Given the need for adequate consideration of the data and consultation it is unlikely that the first set of air quality guidelines will be published by EPAQS much before September 2004. Even then there will be many substances for which guideline values are not available.
14. Consequently the Agency has requested the Panel to advise on the suitability of the Calabrese and Kenyon methodology as an interim approach for setting EALs until EPAQS guidelines - or EALs derived from other toxicological evaluations - become available.

### **Review of the Calabrese and Kenyon methodology**

15. To help inform the Panel's consideration, independent consultants AEA Technology and WRC-NSF carried out a review of the Calabrese and Kenyon methodology. The Panel discussed the review (paper EPAQS 03/10<sup>3</sup>) at the meeting on 23 May 2003.
16. Calabrese and Kenyon propose a methodology for the derivation of ambient air quality guidelines based on the assessment of secondary literature sources and American occupational exposure standards. Calabrese and Kenyon have assessed and provided guidance on limit

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<sup>2</sup> the term air quality guideline relates to evaluations used by the Agency as a basis for setting EALs for concentrations of substances in ambient air for which the Agency is responsible for regulating.

<sup>3</sup> paper EPAQS 03/10 will be published simultaneously with this statement

values (termed “ambient air level goals”, AALGs) for a large number of substances.

17. The Calabrese and Kenyon approach follows a decision-tree methodology. The methodology draws on the US EPA’s Integrated Risk Information System (IRIS) database as a validated and peer reviewed source of evaluations. Occupational Exposure Limits (OELs) published by the National Institute for Occupational Safety and Health (NIOSH) and the American Conference of Governmental Industrial Hygienists (ACGIH) were also included in the decision-tree system.
18. The approach requires that an initial assessment of the relevant toxicological end point should be made; the critical effect should be identified and the principal and supporting studies used to develop No Adverse Effect Levels or Lowest Adverse Effect Levels. Then, taking into account the toxicological effect, appropriate uncertainty factors and relative allowable contributions from air, an ambient air level goal (AALG) is derived.
19. The review highlighted a number of key issues, advantages and disadvantages of the Calabrese and Kenyon methodology compared to the current UK approach to setting EALs using 10 potential contaminants as illustrative examples: (see paper 03/10 for details):
  - a. **Age of AALGs** – the Calabrese and Kenyon assessment was published in 1991 and has not been updated since. AALGs for a large proportion of substances might be different from those published if they were derived using currently available data and evaluations.
  - b. **Use of US OELs** - the Calabrese and Kenyon approach makes use of the American OELs in some cases. However, use of current US or UK OELs in the Calabrese and Kenyon decision tree, in place of the 1991 US OELs, does not appear to significantly impact on the majority of the 10 illustrative AALGs examined.
  - c. **Carcinogens** - the evaluation of carcinogens differs from current UK practice. There is less emphasis on distinguishing genotoxic from non-genotoxic carcinogens and Quantitative Risk Assessment (QRA) is applied to estimate cancer risk to humans. A lifetime risk of  $10^{-6}$  is recommended as the basis of the AALGs.
  - d. **Safety factors** – Calabrese and Kenyon consider each substance individually according to a defined procedure and uncertainty factors applied (where appropriate) to take into account the characteristics of the study being considered, quality of the data, type of toxic effects and the relative source contribution. This contrasts with the current UK approach to

EALs where a simple safety factor is applied to extrapolate directly from UK OELs.

- e. **Averaging period** - the averaging periods for the majority of EALs are currently arbitrarily set at annual average or 1 hour periods. Averaging periods suggested by Calabrese and Kenyon are more closely related to the toxicological effect of concern, and therefore represent an improvement on the existing methodology.
  - f. **Targeted control** - on occasion, the AALGs more exactly specify the substance under consideration than is the case for current EALs. This enables more targeted control of the substances of concern.
  - g. **Conservative** - in most of the 10 illustrative cases, the published AALGs are more conservative (i.e. lower) than the current long-term EALs.
20. Following discussion of paper 03/10, the Panel came to the following conclusions:
- a. the Panel agreed that there were disadvantages to the current approach of deriving environmental assessment levels (EALs) from dividing occupational exposure limits by a standard factor (outlined in para 11 above);
  - b. the Panel considered that the Calabrese and Kenyon approach offered some advantages over the current system, moreover EAL's derived using this methodology would appear to be more conservative than those derived using the current Agency methodology;
  - c. the Panel considered that the 1991 AALGs would need to be updated but that this could be done reasonably quickly using the Calabrese and Kenyon decision tree;
  - d. the Panel noted the difficulties with quantitative risk assessment of genotoxic carcinogens that often involved extrapolation over several orders of magnitude. Different answers could be obtained with the use of different mathematical models or by adopting different values for the level of risk acceptable by society. The Panel considered that these uncertainties were not sufficiently reflected in the use of a single figure for an AALG. As a pragmatic approach, the Panel proposed expressing the

'AALG' as a range of concentrations equivalent to different lifetime excess risks<sup>4</sup>.

- e. For simplicity it was suggested that scaling from the IRIS risk estimate could derive this range. This takes into account the likely range of outcomes associated with different models and variations in the tolerable level of risk proposed by different organisations. In determining an application for authorisation of a process under PPC and IPC, this approach allows genotoxic carcinogens to be screened into bands, a) those where there would be wide agreement that the specific risk of a process was low, b) those where there would be wide agreement that the specific risk of a process was high and c) those where more a detailed assessment might need to be made before a judgement could be reached. Those compounds where the concentrations released were found to be in the b) or c) category could be subsequently prioritised for full assessment by EPAQS.

## Conclusion

21. In conclusion, the Panel has agreed the following:

- a. The Panel recognises that the Agency wishes to derive Environmental Assessment Levels (EALs) for a large number of substances to support its regulatory activities. The Panel further recognises that the method based on Occupational Exposure Limits that the Agency currently uses to derive EALs for substances for which there are no existing standards or guidelines has a number of disadvantages.
- b. The Panel has assessed the suitability of a number of methodologies to derive interim guideline values for EALs for ambient concentrations of substances. The Panel has concluded that the best approach is offered by an existing methodology developed by Calabrese and Kenyon. The Panel's assessment of this method is based on the information provided in EPAQS paper 03/10 (Annex 1).
- c. The Panel endorses the Calabrese and Kenyon methodology, using updated evaluations as appropriate, as an interim approach for the Agency to derive guideline values for setting EALs for concentrations of substances in ambient air for which the Agency is responsible for regulating. Guideline values derived in this way should be used only until such time as a fuller evaluation can be undertaken. The Panel emphasises that this methodology is satisfactory only as an interim approach for any individual substance.

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<sup>4</sup> the additional risk associated with lifetime exposure to a certain concentration of a carcinogen in the air (see Chapter 2 of WHO Air Quality Guidelines – Second Edition. WHO Regional Office for Europe, Copenhagen, Denmark, 2000)

- d. The Panel recommends that non-carcinogens, carcinogens and genotoxic carcinogens should be considered separately and that a range of values might be given for carcinogens based on estimates of different levels of risks.
- e. Applying this methodology would not invalidate any current ambient air standard (e.g. standards in the Air Quality Strategy). EALs derived using the Calabrese and Kenyon methodology should progressively be replaced by EALs based on EPAQS evaluations - or EALs derived from other specific toxicological evaluations - as they become available.

**FOR EXPERT PANEL ON AIR QUALITY STANDARDS**

**PAPER BY: THE ENVIRONMENT AGENCY**

**SUBJECT: SETTING INTERIM ENVIRONMENTAL ASSESSMENT LEVELS BASED  
ON AMBIENT AIR LEVEL GOALS PROPOSED BY CALABRESE AND  
KENYON.**

**RECOMMENDATIONS**

The Panel is invited to;

1. Consider the attached review of the Calabrese and Kenyon methodology and guidelines;
2. Prepare a statement on the suitability of the Calabrese and Kenyon approach and guidelines for use as interim EALs in the UK.

**1.0 PURPOSE**

- 1.1 To consider the suitability of applying ambient air level goals (AALGs) proposed by Calabrese and Kenyon<sup>5</sup> as Environmental Assessment Levels compared with the existing approach based on Occupational Exposure Limits.

**2.0 INTRODUCTION**

- 2.1 The Environment Agency is responsible for authorising releases to air and other environmental media from industrial processes regulated under the Integrated Pollution Control (IPC) and Pollution Prevention and Control (PPC) regimes. In determining applications for authorisation under these regimes the Agency makes use of environmental standards or other benchmarks in order to judge the relative impact of a release.
- 2.2 However, there are many substances for which standards are not available. Overall, there are only recognised ambient human health air standards for approximately 31 substances, compared with the approximately 260 substances, which are reported as being released to air on the Agency's Pollution Inventory.

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<sup>5</sup> Edward J. Calabrese and Elaina M. Kenyon, Air Toxics and Risk Assessment, Lewis Publishers, 1991

2.3 The regulations implementing the PPC regime came into force in 2000 and industrial processes are progressively being brought within the regime up to 2007. It is therefore important that air quality guidelines for substances to be assessed are made available as rapidly as possible.

### 3.0 DERIVATION OF EXISTING ENVIRONMENTAL ASSESSMENT LEVELS

3.1 In order to fulfil its regulatory role under the IPC and PPC regimes the Agency has sought to develop environmental criteria, known as Environmental Assessment Levels (EALs) for use within the Agency's H1 guidance on Environmental Assessment and appraisal of Best Available Techniques (BAT) under IPC/PPC.

3.2 Currently EALs are derived from a hierarchy of information sources as shown in Table 1. However, the majority of EALs for air have been derived by extrapolation from UK Occupational Exposure Limits (OELs). The extrapolation procedure applies uncertainty factors, shown in Table 2, which allow for the differences between occupational exposure to chemicals and the exposure of the general population to the pollutant in ambient air.

**Table 1 Hierarchy of information sources for the derivation of current EALs for air**

#### Information source

Expert Panel on Air Quality Standards (EPAQS)  
 EC Air Quality Directives - limit values and guidelines  
 World Health Organisation Air Quality Guidelines for Europe (1987, 1995)  
 Other International Organisations (e.g. United Nations Economic Commission for Europe)  
 Other National Organisations (e.g. US IRIS data base)  
 Health and Safety occupational exposure limits.  
 Expert judgement

**Table 2 Uncertainty factors used for deriving long and short term EALs from occupational exposure limits**

	Long term EAL (as an annual average)	Short term EAL (as a 1 hour average)
<b>OES 8 hour time weighted average</b>	$\frac{\text{OES}}{100}$	
<b>MEL 8 hour time weighted average</b>	$\frac{\text{MEL}}{500}$	
<b>OES STEL 15 minute average</b>		$\frac{\text{OES STEL}}{10}$
<b>MEL STEL 15 minute average</b>		$\frac{\text{MEL STEL}}{50}$

From: Environment Agency, 2002

3.3 Whilst this approach makes use of the relatively large body of information on the effects of chemicals as a result of occupational exposure there are a number of problems with uncritically extrapolating from these values to effects in ambient air.

- i) Some occupational exposure limits may take account of technological considerations, such as the practicality of monitoring or control;
- ii) The toxicological endpoint considered for the occupational work force may not be the same as that for the wider public.
- iii) The applied uncertainty factor may be suitable for some substances but not others.

3.4 In order to overcome some of these problems a revised methodology has been proposed which similarly makes use of a hierarchical approach but seeks to make better use of substance specific information. The revised approach is outlined below;

- i) Use EPAQS standards or WHO guidelines where available.
- ii) Develop a work programme for EPAQS, which will derive air quality guidelines for a number of priority substances identified by the Environment Agency.
- iii) Use existing WHO or IPCS evaluations and exposure assessments to derive air quality assessment levels.
- iv) Derive tolerable daily intakes or reference concentrations from toxicity data through the application of uncertainty factors.
- v) Use an existing evaluation such as that of Calabrese and Kenyon to provide a rapid initial assessment, for a large number of substances. These values would then be progressively replaced as EPAQS guidelines or assessment levels derived from toxicity assessments became available.

3.5 Stages (i) – (iv) are likely to provide more robust EALs compared to the existing approach outlined in paragraph 3.3. However, these stages cannot be applied quickly and a method such as that suggested in paragraph (v) is required to provide interim values.

3.6 The attached review, prepared by AEA Technology and WRc-NSF, summarises the methodology published by Calabrese and Kenyon (i.e. stage (v) of the above hierarchy) and highlights some of the advantages and disadvantages of adopting this methodology to set interim EALs in the UK.

3.7 In addition to the Calabrese and Kenyon review an alternative evaluation, “Environmental Quality Standards in the Netherlands<sup>6</sup>” was considered by the Project Board as a possible source of readily available air standards/guidelines. However, it was apparent that the list of substances for which air guidelines were listed was quite short and principally covered pollutants for which either the WHO or EU have also derived standards. Furthermore, it was not clear from the information given in the report whether the basis for the derived guidelines was human health or a combination of human health and eco-toxicological concern. As a result, the Project Board decided that this reference was not a suitable source of readily available guidelines.

## 4 CALABRESE AND KENYON REVIEW

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<sup>6</sup> Environmental Quality Standards in the Netherlands: A review of environmental quality standards and their policy framework in the Netherlands. (1999) Ministry of Housing, Spatial Planning and the Environment. Kluwer, Alphen aan den Rijn.

- 4.1 The Calabrese and Kenyon approach follows a decision-tree methodology. The proposed methodology draws on the US EPA's Integrated Risk Information System (IRIS) database as a validated and peer reviewed source of evaluations. Occupational Exposure Levels (OELs) published by the National Institute for Occupational Safety and Health (NIOSH) and the American Conference of Governmental Industrial Hygienists (ACGIH) were also included in the decision-tree system.
- 4.2 The approach requires that an initial assessment of the relevant toxicological end point should be made; the critical effect should be identified and the principal and supporting studies used to develop No Adverse Effect Levels or Lowest Adverse Effect Levels. Then, taking into account the toxicological effect, appropriate uncertainty factors and relative allowable contributions from air, an ambient air level goal (AALG) is derived.
- 4.3 For substances reported as being released to air by the Agency's Pollution Inventory, the review compares the Calabrese and Kenyon AALGs with the existing long and short term EALs. AALGs are given for approximately 75 of the substances listed on the Pollution Inventory as being released to air.
- 4.4 A further ten representative AALGs (benzene, 1,3-butadiene, butan-2-one, cadmium, chlorine, hydrogen chloride, mercury, styrene, tetrachloroethene and toluene) were reviewed in more detail, in order to inform the judgement on the suitability of the AALGs, as interim EALs. Comparison was made between the ten AALGs and current EALs, EPAQS standards, WHO air quality guidelines and recalculated AALGs using more recent evaluations. Further comparisons were made between current and previous OELs and between UK and US OELs, with an evaluation as to their effect on the AALG derivation. Finally the use of relative source contributions, the choice of toxicological endpoints and the averaging times used are discussed.

## **5 KEY ISSUES**

- 5.1 The Calabrese and Kenyon assessment was published in 1991 and has not been updated since. At the time, the IRIS database, which forms the basis of the assessment, did not include Reference Concentrations (RfCs) (estimates of the air concentrations which would be likely to be without appreciable risk of deleterious effects during a lifetime, for threshold non-neoplastic effects).
- 5.2 AALGs for a large proportion of substances might be different from those published if they were derived using currently available data and evaluations. In many cases, a revised AALG would be based on recent US EPA evaluations published on the IRIS database. This suggests that current IRIS evaluations (RfCs and cancer risk estimates) might provide a more suitable starting point for values to be adopted as EALs than the published AALGs.
- 5.3 The Calabrese and Kenyon approach makes use of the American OELs in a limit number of cases. However, use of current US or UK OELs in the Calabrese and Kenyon decision tree, in place of the 1991 US OELs, does not appear to significantly impact on the majority of the AALGs examined.

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- 5.4 The evaluation of carcinogens applies quantitative Risk Assessment (QRA) to estimate cancer risk to humans. A lifetime risk of  $10^{-6}$  is recommended as the basis of the AALGs. This approach differs from UK practice in;
- the use of low-dose extrapolation to quantify cancer risk
  - basing the decision as to which extrapolation method to use for carcinogens on weight of evidence for carcinogenicity rather than weight of evidence regarding the mechanisms of carcinogenicity.
- 5.5 Calabrese and Kenyon provide explicit treatment of different toxicological endpoints, for example, sensory irritants, carcinogens and substances showing threshold effects. Each substance is considered individually according to a defined procedure and uncertainty factors applied (where appropriate) to take into account the characteristics of the study being considered, quality of the data and the relative source contribution. This contrasts with the current approach to EALs where a simple safety factor is applied to extrapolate directly from UK Occupational Exposure Limits.
- 5.6 The averaging periods suggested by Calabrese and Kenyon are more closely related to the toxicological effect of concern. Averaging periods for EALs are currently arbitrarily set at annual average or 1 hour periods
- 5.7 On occasion, the AALGs more exactly specify the substance under consideration than is the case for current EALs. This enables more targeted control of the substances of concern.
- 5.8 In most cases, the published AALGs are more conservative (i.e. lower) than the current long-term EALs.

## **6 CONCLUSIONS AND RECOMMENDATIONS**

- 6.1 The Calabrese and Kenyon methodology appears to offer a number of advantages in setting interim EALs compared to the current approach, particularly in taking account of substance specific characteristics.
- 6.2 However the principle draw-backs to the approach appear to be;
- i) Differences between the US EPA-endorsed risk assessment techniques underlying the AALG methodology and usual regulatory practice in the UK
  - ii) Scientific developments since the AALGs were derived.
- 6.3 The Panel is invited to comment on the suitability of the Calabrese and Kenyon approach for setting interim EALs for use in determining applications for authorisation under either the IPC or PPC regimes.

**CP**  
**14/05/2003**