Derivation of new Environmental Assessment Levels (EALs) to air consultation

Derivation of Ambient Air EALs for the Protection of Human Health within the Environmental Permitting Regulations (EPR)

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Executive summary

The Environment Agency uses environment assessment levels (EALs) to judge the acceptability of proposed emissions to air and their relative contribution to the environment. EALs represent a pollutant concentration in ambient air at which no significant risks to public health are expected.

Following the Health and Safety Executive's (HSE) review of their approach to occupational exposure, a large number of substances are no longer assigned an Occupational Exposure Limit (OEL), the principal source of EALs for air. Hence the need for the Environment Agency to develop new EALs for substances we continue to encounter in our regulatory activities. Originally, there were more than 400 substances assigned an EAL (Table 2), so to manage the change we have chosen to focus on substances we continue to see within our Pollution Inventory returns. Our objective now is to produce EALs incorporating the latest scientific data through a robust process.

This document provides an overview of the existing methods for deriving EALs. We also provide an outline of our proposed changes to this derivation process. This document is designed to help you understand our proposed changes and to comment on them.

Acknowledgements

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Department of Environment, Food & Rural Affairs (DEFRA)

Chemical Industries Association (CIA)

Health Protection Agency (HPA)

Contents

1 Purpose of the consultation

The purpose of this consultation is to seek comments on the Environment Agency's proposal to revise the hierarchy used to derive new Environmental Assessment Levels (EALs) for assessment of releases to air. However, it is important to note that this consultation is limited to the protection of human health, not the wider environment, and does not address changes to EALs for water or land.

Originally, there were more than 400 substances assigned an EAL (Table 2), so to manage the change we have chosen to focus on substances we continue to see within our Pollution Inventory returns. Our objective now is to produce EALs incorporating the latest scientific data through a robust process. Within this document we provide an overview of the existing methods for deriving EALs. We also provide an outline of our proposed changes to this derivation process.

We want to hear from process operators, trade associations and business to understand if our proposal works for industry, whilst providing the necessary protection for human health. We also want to hear from other regulators, the public, community groups and non-governmental organisations with an interest in environmental issues, so that we may form a view on whether you think our proposal provides the necessary protection for the environment and human health, whilst still working for industry.

To help you form a response we have compiled a series of questions interspersed within the text and summarised in section 9 of this report. The majority of questions are of a technical nature, but we also want to hear from you if you have any comments on this document and the way we have managed the public consultation.

2 What are we consulting on?

Emissions to air from industry are regulated by the Environment Agency through the provisions of the Environmental Permitting Regulations (formerly the Pollution Prevention and Control Regulations). The Environment Agency compares predicted ambient pollutant concentrations with environmental assessment levels (EALs) when assessing the acceptability of proposed emissions and best environmental options. Many of the EALs currently included within our horizontal guidance note H1 were derived from Occupational Exposure Standards (OESs) and Maximum Exposure Levels (MELs) previously published by HSE. H1 aims to make the acceptable ambient concentration of emissions clear to industry and other stakeholders, and to assist permit applicants when judging the acceptability of alternate process options.

The current approach uses a hierarchy to prioritise the source of EAL values. These include sources such as the UK's Expert Panel on Air Quality Standards (EPAQS), EU directives or the World Health Organisation. However, EPAQS has recently been disbanded and so in the future the Environment Agency will be looking to other government bodies of similar scientific standing for advice (eg. COMEAP and its subgroups). Occasionally substances are identified in impact assessments submitted to the Environment Agency for which we do not have EALs. So to enable the Environment Agency to carry out its permitting activities some new EALs may have to be derived from other sources.

One new source of relevant information is the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulations 2006. REACH has introduced a programme of phased registration, starting December 2010. In REACH, EU manufacturers and importers are required to register substances subject to defined criteria of capacity and toxicity. The registration requires the generation of risk management data on manufactured or imported substances above a given threshold. A safety assessment is produced and provided within a dossier to the European Chemicals Agency and to competent authorities within the Member State. Hence Environment Agency will have access to another source of evaluations of tolerable levels of exposure relating to a large number of chemicals. We propose using this information to generate substance EALs to supplement the existing register.

This consultation seeks feedback on an amended hierarchy for the sources of EALs for those substances that may be released to air. Please note this consultation is only concerned with the protection of human health, not the wider environment, and does not address changes to EALs for water or land.

In developing our proposed approach we have had preliminary discussions with a number of stakeholders. In light of this the Environment Agency has developed an in-house hazard characterisation method to assist with the derivation of EALs. This consultation includes the proposed in-house method (Section 7).

This document also discusses how these changes to EALs might be implemented, once values are available, and seeks views on our proposals from interested parties.

3 What does this consultation mean to you?

We think that this consultation will be of particular interest to:

Operators, trade associations and business: this is your opportunity to comment on the approach proposed for the derivation of EALs, such that it works for industry whilst providing the necessary protection for human health.

It is likely that the revised REACH derived EALs will be more stringent than those currently in use. As a consequence, an operator may be required to undertake more detailed assessment and, for some operators, to propose additional control measures. Hence it may be appropriate to review the significance criteria within H1 and operation of the H1 screening tool to ensure the necessary balance of risk is achieved. This review cannot be made before new EALs are available.

3.1 Cost of implementation

Our proposal is that new EALs will be applied to new applications and at the time of each sector permit review. A detailed estimate of any costs cannot be made until 2011 when REACH based EALs should become available. As a consequence some EALs may be tighter resulting in the need for detailed assessment of releases. This is likely to require some operators to engage consultants with the associated additional cost. Any additional controls necessary as a result of implementing new EALs would be the subject of an individual site specific BAT assessment.

Once a methodology for the derivation of new EALs has been agreed, we will use it to derive new EALs. When compiled these values will be reviewed ahead of a further round of public consultation on the values and their potential implications.

3.2 Consultation

Other regulators, the public, community groups and non-governmental organisations with an interest in environmental issues this is your opportunity to comment on the approach proposed for the derivation of EALs, such that it provides the necessary protection for the environment and human health, whilst still working for industry.

4 Background to the proposed method

4.1 Changes to occupational exposure levels

In 2003 the HSE consulted on proposed changes that would introduce new Workplace Exposure Limits (WELs) to replace the OELs and also remove those OELs that were deemed no longer reliable (HSE, 2003). Following the consultation, the final decision was to remove 102 OELs “where there is some concern about whether human health is protected at the value” (Topping, 2004).

As a result of these changes a number of the Environment Agency’s EALs are no longer supported by a comparable WEL. This left the Environment Agency with a need to develop another method for the derivation of EALs. Originally within H1 there were more than 400 substances with an EAL, and to derive new EALs for such a large range of substances would require substantial effort. To manage this development we have removed those substances we encountered less frequently, if at all, in our regulatory activities and concentrated our efforts on those substances reported to the Pollution Inventory. With respect to the Pollution Inventory substances for air emissions, over 60 have no corresponding WEL that could be used to derive an EAL. These are listed in Annex 1.

It is important to note that when developing the new WELs, the HSEs Advisory Committee on Toxic Substances (ACTS) identified the highest level of occupational exposure at which no health effect would be predicted to occur. It was then determined if this level was being achieved in the work place. If not then ACTS determined if it was reasonably practicable for industry to achieve this level before setting the WEL (HSE, 2001). In other words a WEL may take into account the practicability of achieving a particular level.

For example, in comparing EALs derived using the method detailed in H1, from HSEs current WELs and those provided as guidelines values by EPAQS or WHO,(see Table 1) it can be seen that for all but two of the 25 EALs (ozone and chlorine) the concentration of the latter value is lower. The difference is negligible for halogens and hydrogen halides, but greater for some of the organics like styrene. Overall the average is a 36 times lower concentration for the formally derived health based standard. The implication is that deriving EALs from WELs may not be providing the necessary protection to human health.

Table 1: Comparison between EALs (short & long term) derived from EH40 WELs using the method detailed in H1 and those provided as guidelines values by EPAQS or WHO.

Substance	Long or short term EAL	WEL ug/m3	EAL (WEL) ug/m3	EAL (EU, UK, EPAQS or WHO) ug/m3	Ratio of EAL WEL ÷ EAL other
Arsenic	LT	100	0.2	0.003	67
Beryllium	LT	2	0.004	0.0002	20
Bromine	ST	1,300	130	70	2
1,3 Butadiene	LT	22,000	44	2.25	20
Cadmium	LT	25	0.05	0.005	10
Carbon disulphide	LT	32	320	64	5
Carbon monoxide	ST	232,000	23,200	10,000	2
Chlorine	ST	1,500	150	290	0.5
Chromium VI	LT	50	0.1	0.0002	500
1,2-Dichloroethane	ST	63,000	1,260	700	2
Dichloromethane	ST	1,060,000	106,000	3,000	35
Formaldehyde	ST	2,500	250	100	3
Hydrogen bromide	ST	10,000	1,000	700	1
Hydrogen chloride	ST	8,000	800	750	1
Hydrogen fluoride	ST	2,500	250	160	2
Hydrogen sulphide	ST	14,000	1,400	150	9
Nickel	LT	100	0.2	0.02	10
Manganese	LT	500	5	0.15	33
Ozone	ST	400	40	84	0.5
Particulate matter (PM10)	LT	10,000	100	40	2.5
Styrene	ST	1,080,000	108,000	800	135
Tetrachloroethylene	LT	354,000	3,540	250	14
Tetrachloroethylene	ST	689,000	68,900	8,000	9
Toluene	ST	384,000	38,400	8,000	5
Trichloroethylene	ST	820,000	16,400	1,000	16

All short term EALs are corrected to 1 hour and long term to a year.

4.2 Options for EAL development

For substances for which there are no appropriate authoritative evaluations available, we have explored a number of options prior to this consultation. These are discussed briefly below. Additional sources of information are indicated where available.

The development of rigorously evaluated and peer-reviewed EALs for a limited number of priority air pollutants by the Expert Panel on Air Quality Standards (EPAQS). This method of derivation is significantly more robust than using OELs, but consequently was only able to deliver at a rate of one or two substances a year over the period of 2002 to 2009.

Use of a US method (Calabrese and Kenyon, 1991) that derives health based Ambient Air Level Goals (AALGs). This method was endorsed (EPAQS, 2003) to allow for a faster derivation of interim EALs for ambient air where there were no existing standards or guidelines. This method is based on US data and so required that input data be improved with more up-to-date UK and European data. On calculation of EALs for UK pollutants from the AALGs, it was found that many were orders of magnitude lower than existing EALs and were therefore not realistically achievable. Examples are provided in Annex 3.

Use of data reported under the EU REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) regulation. This new regulation requires industry, which has a high chemical usage or manufacture, to undertake a Chemical Safety Assessment (CSA) and submit a Chemical Safety Report (CSR). This should provide a human health hazard assessment in the form of Derived No Effect Levels (DNELs) for non-carcinogens or non-genotoxic carcinogens and Derived Minimal Effect Levels (DMELs) for genotoxic carcinogens.

Use of a new Environment Agency in-house hazard characterisation method to derive Tolerable Concentrations in Air (TCAs). This is a method developed by the Environment Agency to assist with the derivation of EALs. The derived TCAs will be used to calculate the EAL. The method will be based largely on a review of existing authoritative expert opinion and evaluations, such as those by national and international expert bodies.

The use of Indicative Occupational Exposure Limit Values (IOELVs) developed by the Scientific Committee on Occupational Exposure Limits (SCOEL) as the basis for derivation of the EAL. IOELVs are health based Occupational Exposure Limits derived by reference to thresholds below which exposure to the substance in question is not expected to lead to adverse effects. However, we have found that sourcing the underlying research has proved difficult and are also concerned that these values may not be based upon the most up-to-date evidence. This route does not therefore allow us to verify that the IOELVs fulfil one of our key aims of ensuring that the new EALs make appropriate use of existing and up-to-date toxicological information.

Health Criteria Values for inhalation have been derived by the Environment Agency for some substances as part of the CLEA (Contaminated Land Exposure Assessment) programme (Environment Agency, 2009) and could be considered for use in the derivation of EALs. The proposal is to adopt those CLEA HCVs that are based on threshold effects as Tolerable Concentrations in air. We would adopt those values for non-threshold effects only when the approach used is consistent with the approaches recommended in the Environment Agency hazard characterisation method. When the approach used is not consistent, the data underlying the HCV will be used.

These options have been discussed within the Environment Agency and with key stakeholders. The outcome of these discussions is the proposed method discussed in this document.

Aerial emissions from regulated facilities are unlikely to be the only source of the public's exposure to a chemical. In order to ensure that total exposures remain below the threshold for toxicity (for effects with a threshold), it will be necessary to take the likely extent of other exposures into account when deriving an EAL. The proposed approach to this (use of a relative source contribution, RSC) is outlined in section 7.4 and Annexes 2 and 5.

4.3 Summary

The majority of EALs for air were originally derived from the HSE's OELs. The HSE has replaced OELs with WELs. As part of this change the HSE reviewed the basis for WELs and as a consequence, some substances no longer have numeric standards. In addition others are acknowledged as lacking a robust derivation.

There is also concern that in deriving occupational values, HSE may take account of the practicability of achieving specific limits as well as health impacts. It is important that EALs are scientifically based and are not influenced by these other factors.

There have been discussions on a range of options for updating the source data and calculation of EALs leading up to this consultation. This document presents our proposed approach for the derivation of future EALs.

The following sections present the changes that we wish to consult on. These are split into the following topics:

- Proposed changes to the hierarchy of sources for EALs;
- Proposed changes to the number of substances maintained for permitting and EAL derivation;
- Proposed Environment Agency hazard characterisation method for deriving TCAs;
- Proposed use of Derived No Effect Levels (DNELs) and Derived Minimal Effect Levels (DMELs) as output from the REACH process.

5 Proposed change to the hierarchy of sources of EALs

The EALs currently included in Annex f of H1 are derived from various information sources according to the hierarchy shown in Figure 1. As discussed above we no longer consider that EALs derived from the HSE's WELs are appropriate with respect to carrying out health assessments using our H1 guidance. We propose to remove the HSE WELs from the hierarchy of information sources and replace them with:

Tolerable Concentrations in Air (TCA) derived in-house with advice from the Health Protection Agency and based largely on a review of existing authoritative expert opinion and evaluations, such as those by:

- national and international expert bodies
- Health Criteria Values for inhalation derived by the Environment Agency following "Human health toxicological assessment of contaminants in soil"
- Derived No-Effect-Levels (DNEL) or Derived Minimal Effect Levels (DMEL) calculated within the Chemical Safety Reports prepared under REACH
- Ambient Air Level Goals (AALGs) derived using the Calabrese and Kenyon method.

Figure 1 shows the hierarchy we propose to adopt.

Figure 1: Current and proposed information source hierarchy.

Current information source hierarchy	UK Expert Panel on Air Quality Standards (EPAQS)
	EC Air Quality Directives - limit values and guidelines
	WHO Air Quality Guidelines for Europe
	Other International Organisations (eg UN Economic Commission for Europe)
	Other National Organisations (eg US IRIS data base)
	Health and Safety occupational exposure limits.
	Expert judgement

Proposed information source hierarchy	UK Expert Air Quality Standards (EPAQS) standards and guidelines 1
	WHO Air Quality Guidelines for Europe
	TCAs derived according to the proposed Environment Agency hazard characterisation method to derive Tolerable Concentrations in Air (TCA)
	Environment Agency Health Criteria Values for inhalation 2
	DN(M)ELs derived using risk assessment guidance to support REACH
	TCAs derived using the Calabrese & Kenyon approach to deriving Ambient Air Level Goals

1. Existing EPAQS standards and guidelines will be adopted. As a consequence of the disbanding of the UK Expert Panel on Air Quality Standards (EPAQS) we would propose to consult other government committees with expertise in evaluating the effects of chemicals in air on health.

2. Inhalation HCVs will be adopted as TCAs, or used as the basis for the derivation of TCAs, as appropriate – as outlined in section 4.2, above.

In many cases EU Limit Values for air pollutant concentrations and associated UK Air Quality Objectives have been derived using a cost benefit analysis and subject to political negotiation. As such they may not be entirely health-based and therefore have been excluded from the hierarchy. However, within H1, Environment Agency takes account of EU Limit Values as a separate part of the assessment process. In carrying out the H1 assessment, we use the EPAQS standards as the EAL, not the Air Quality Objectives which often are presented as a percentile value. For example for sulphur dioxide, within H1 the EAL short term is 266ug/m3, we do not take account of the 35 exceedances of the 15-minute value incorporated within the AQO.

We intend to continue using the high quality guideline values derived by EPAQS and the WHO. For some priority substances for which EPAQS and WHO guidelines are not available, we will implement an Environment Agency hazard characterisation method to derive what we have termed Tolerable Concentrations in Air (TCA). This method follows conventional hazard characterisation principles and we propose to derive the TCAs in consultation with the Health Protection Agency (HPA). Section 7 describes the in-house hazard characterisation method we propose to use to derive the TCAs.

We propose to derive TCAs only for the highest priority substances. For the remaining substances, we propose to use the Derived No Effect Levels (DNELs) or Derived Minimal Effect Levels (DMELs) developed by industry as part of the REACH process. Where appropriate (i.e. where substances are released to the environment via the air) REACH specifies that industry must derive DNELs/DMELs for the general population, to include “humans via the environment”. We propose to review the Chemical Safety Reports prepared under REACH before adopting them as the basis for EALs to ensure that the information provided is adequate.

Where none of the above are available for the derivation of EALs, we will use, as a default position, EALs based on the Calabrese & Kenyon method which derives health-based

Ambient Air Level Goals (AALGs). These will be updated and based on UK rather than US data. As noted earlier, this method was endorsed by the government's Expert Panel on Air Quality Standards as a suitable way to quickly provide a large number of interim science based EALs.

The C&K method is considered in more detail in Annex 2, the proposed method for the derivation of TCAs is discussed in detail in Section 7, and the REACH process is discussed in Section 8.

Question 1: Do you agree with the proposed hierarchy for the derivation of new Environmental Assessment Levels provided in Section 5? If no, please tell us how you would improve it.

6 Changes to the number of substances

Due to the change in the number of substances assigned a WEL by the HSE, Environment Agency had to change its approach to the derivation of EALs. The number of pollutants affected by this change was large and to derive new EALs from other sources would have required significant resource. In addition, a large number of EALs that featured in earlier versions of H1 were not used. So we decided to focus our efforts on those substances we encountered through our regulatory activities, principally by reference to returns made via the Pollution Inventory. However, not all substances on the Pollution Inventory have an EAL, so further work is needed to find the appropriate values.

We have not derived EALs for dioxins / furans and PCBs (polychlorinated biphenyls) as their primary route to human exposure is through the food chain. However, we still assess the impact on the environment of the release of these substances. For example, with energy from waste plants where releases are assessed through food-chain modelling. Annex 4 presents a list of current pollution inventory substances and indicates if they are assigned an EAL.

Question 2: Annex 4 contains a list of substances in the Environment Agency's Pollution Inventory for which no Environmental Assessment Level is currently available. Are there any other substances for which you feel an Environmental Assessment Level should be derived? If yes, please list below those substances for which you feel an EAL should be derived and why.

7 Proposed Environment Agency hazard characterisation method

This section summarises the hazard characterisation and is supported by further detail in Annex 5.

Aside from the high quality guideline values derived by EPAQS and the WHO, the Environment Agency proposes to derive TCAs for a number of high priority substances, based largely on a review of existing authoritative expert opinion and evaluations. Preference is likely to be given to recommendations consistent with the approach preferred by the Environment Agency (Hazard Characterisation Method). Where no appropriate recommendations are available, a TCA will be derived using the preferred approaches based on epidemiological or toxicological data.

Evaluations reviewed will include, but are by no mean restricted to, those by UK expert advisory committees (such as Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) and COMEAP), EU expert committees, the EU Chemicals Bureau (ECB), CLEA, the World Health Organization (WHO), the International Programme on Chemical Safety (IPCS), the US Environmental Protection Agency Integrated Risk Information System (US EPA IRIS), the US Agency for Toxic Substances and Disease Registry (ATSDR), the Dutch National Institute for Public Health and the Environment (RIVM), the Interdepartmental Group on the Health Risks of Chemicals (IGHRC). The primary literature on which these evaluations are based will, in general, not be consulted.

Question 3: Are there any further authoritative evaluations that should be considered besides those listed in Section 7? If yes, please provide details.

Current understanding suggests that there is a threshold for most toxicological effects of chemicals (i.e. below the threshold dose, no adverse effects will occur). However, for some effects – notably cancer caused by a direct interaction of the chemical with the genetic material of the cell – there may not be a threshold for effect. For such substances, there is a risk of an adverse effect at even very low levels of exposure, although the likelihood of an effect decreases with decreasing exposure. Like most other organisations, we propose to take different approaches to characterising the hazard from these two types of effect and they are discussed separately below.

Five examples of TCAs have been derived using the proposed hazard characterisation method, and the acrylonitrile document is provided as additional material to this consultation document. The remaining substances are: N, N-dimethylformamide (DMF); antimony; vinyl chloride; and trichloroethylene.

7.1 Chemicals where the critical effect has a threshold

7.1.1 The proposed method

Annex 5 shows schematically the method we propose to use to derive the TCAs for those chemicals for which there is an observed critical effect threshold. In effect this method provides two options, the choice of which is dependent on available data. The first step for all derivations will be a review of the existing authoritative expert opinions and

evaluations. The findings of this initial investigation will dictate which of the two options below is most suitable to adopt:

1. Use of inhalation studies
The initial reviews will establish whether inhalation studies have identified a No Observed Adverse Effect Level (NOAEL). If no suitable NOAEL is available then a Lowest Observed Adverse Effect Level (LOAEL) or BMDL10 value will be used as an estimate of the critical effect threshold where sufficient reliable data is available.

2. Use of oral or dermal studies for route-to-route extrapolation
If no suitable inhalation studies have been undertaken and so no inhalation threshold is available, then most expert evaluations base the assessment of the threshold on data obtained from other routes of exposure, such as ingestion or dermal contact. This process is known as route-to-route extrapolation (IGHRC, 2006).

Once a suitable value has been identified this will be used to derive a tolerable concentration in air appropriate for the general population using uncertainty factors to take into account factors such as inter - and intra-species variability, adequacy of database, use of LOAEL, short duration of critical study, severity of effect etc. The TCA is calculated by dividing the threshold value (NOAEL, LOAEL or BMDL10) by the uncertainty factor.

Question 4a: Section 7.1 provides information on our proposed method for the derivation of Environmental Assessment Levels for chemicals with a toxicological effect threshold. Do you think our proposal is most appropriate? If no, please tell us why.

Question 4b: Section 7.1 provides information on our proposed method for the derivation of Environmental Assessment Levels for chemicals with a toxicological effect threshold. Do you think our proposals are scientifically valid? If no, please tell us why.

7.2 Chemicals where the critical effect does not have a threshold

Current understanding suggests that there is no threshold for some effects, notably those that involve interaction with genetic material. Such interactions can pose a risk of heritable diseases and, more often, cancer. The method applied to derive the TCAs for those chemicals where there is no observed critical effect threshold is demonstrated in Annex 5.

Human data

UK expert advisory committees have indicated their concerns over the use of mathematical models for cancer risk assessment when extrapolating from the relatively high dose levels used in laboratory animal studies to those relevant to human exposure via the environment (COC, 2004). Quantitative estimates based on epidemiological data are less uncertain and we will derive EALs using this type of approach when the human data is available.

Guidance on assessing health risks under the new EU Chemicals legislation (REACH) has recently been published (EChA, 2008a). This notes that there is no EU legislation or policy guidance setting the 'tolerable' risk level for carcinogens in society. Nonetheless, the REACH technical guidance suggests that, within the context of REACH, a cancer risk level of 1 in 1,000,000 (10-6) could be seen as an indicative tolerable risk level when

setting DMELs for the general population. These suggestions are based on a review of cancer risk levels used in different countries and contexts.

Where suitable human data are available and a Quantitative Risk Assessment has been undertaken, we would use a linear extrapolation, unless there was evidence that an alternative approach would be more appropriate. The dose (µg/m3) calculated as posing a lifetime excess cancer risk of 1 in 1,000,000 (10-6) would be selected as the TCA. This seems an appropriate basis for a screening value to be used in an environmental permitting regime whose aim is to prevent pollution.

Where human data have not undergone or are not suitable for quantitative modelling, it may be possible to propose a TCA based on identification of the dose associated with no discernible increase in cancer and the use of expert judgement to extrapolate this to the wider population.

Laboratory Animal Data

In some cases, the most appropriate data on which to base an assessment of a genotoxic carcinogen are generated by a cancer bioassay in laboratory animals. Where these laboratory animal data are suitable this would be a starting point for the derivation of a tolerable atmospheric concentration for a general human population. The application of an uncertainty factor of 10,000 to an inhalation BMDL10 to produce a TCA ensures that the margin of exposure, the ratio of the carcinogenic dose in the laboratory animal to the permitted human exposure, is sufficiently large that any cancer risk associated with the TCA would be, in the opinion of expert groups, of "low concern from a public health point of view"[1] or "unlikely to be a concern"[2]. Applying a large uncertainty factor to the BMDL10 is one of the methods recommended in the REACH guidance to derive DMELs (EChA, 2008a), and is also suggested as appropriate for the derivation of exposures representing minimal cancer risk in the context of land contamination (Defra, 2008; Environment Agency, 2009).

Question 5a: Section 7.2 provides information on our proposed method for the derivation of Environmental Assessment Levels for genotoxic carcinogens. Do you think our proposals are most appropriate? If no, please tell us what other methods you would propose and why.

Question 5b: Section 7.2 provides information on our proposed method for the derivation of Environmental Assessment Levels for genotoxic carcinogens. Do you think our proposals are scientifically valid? If no, please tell us why.

Question 6: In section 7.2, where the assessment is based on human data, is an exposure calculated as posing a lifetime excess cancer risk of 10-6 an appropriate basis for an Environmental Assessment Level for genotoxic carcinogens? If no, please tell us what alternative level of risk you think is appropriate and why.

Question 7: In section 7.2, where a 'BMDL10 and large assessment factor' approach is used to derive Environmental Assessment Levels for genotoxic carcinogens, is 10,000 the most appropriate factor to use? If no, please tell us what other factor you would recommend and why.

[1] European Food Safety Authority (EFSA) Opinion of the Scientific Committee on a request from EFSA related to A Harmonised Approach for Risk Assessment of Substances Which are both Genotoxic and Carcinogenic. Adopted 18 October 2005

[2] Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) Minutes of meeting 12 July 2007. Item 7: Further consideration of the MoE approach for communicating the risks of exposure to genotoxic carcinogens (CC/07/08)

7.3 Application of averaging times to TCAs

In order to compare measured or predicted concentrations of contaminants in air with the EALs, the concentrations need to be averaged over an appropriate time period. H1 (Vr 2.2 2010) Annex F includes long-term (annual and monthly) and short-term (1 hour) EALs for air for some substances. In contrast, most air quality guidelines recommend averaging times dependent on whether the critical exposure is chronic or acute. This may be as little as 15 minutes (eg for asthmagens) or as long as a year (eg carcinogens).

In the derivation of EALs, we intend to propose, as far as possible, an averaging time which takes account of the nature (acute or chronic) of critical exposure. In most cases, we anticipate that this would be either an annual average (where the endpoint is non-threshold, genotoxic carcinogenicity), or a 24-hour time-weighted average (for effects with a threshold). The 24-hour averaging period for threshold effects is suggested in line with the convention to base oral assessments of such effects on a tolerable **daily** intake. Where the TCA is based on epidemiological studies, the averaging time may be based on that used in the study. Where effect may be related to exposure concentration rather than systemic doses it may be more appropriate to set substance-specific shorter averaging times. For example, where substances are local irritants, or where peak, rather than daily, exposures are indicated as the relevant exposure metric.

We propose to update the H1 software tool in due course to allow assessments to be made for a range of averaging times.. The Environment Agency will provide guidance for Permit Applicants in the interim.

Question 8: In section 7.3 we propose that the default averaging times for genotoxic carcinogenesis and most threshold effects should be annual, 24 hour time weighted or reflect a time period defined within a relevant epidemiological study. Do you agree that these timings are appropriate? If no, please tell us what defaults you would suggest that might be appropriate to other endpoints.

7.4 Application of Relative Source Contribution to TCAs to derive EALs

Public exposure from chemicals within the environment can arise from a number of sources including from air, from water and from dietary intake. In some cases, exposure from all these different pathways can combine to contribute to the same toxicological effect on health. This particularly needs to be considered when the effect is systemic, rather than at the point of contact, and where it is important to keep combined exposures below a threshold for effect. Thus, when considering what exposure from air is tolerable, it may be also be necessary to take account of exposure from other sources, ie to take into consideration the relative contribution of air to total exposure. Calabrese and Kenyon called this consideration the relative source contribution (RSC).

Where the critical effects occur at the point of contact (eg irritation of the lung) exposures via other routes are not relevant to the assessment of a tolerable concentration in air, and an RSC need not be applied. Similarly, in line with convention, exposures from other sources will not be considered in assessing genotoxic carcinogenicity and other non-threshold effects.

Calabrese and Kenyon suggested use of a default value of 50% RSC for exposure from chemicals in air where critical effects are systemic and have a threshold, unless there is evidence to support an alternate value. It is proposed to adopt this approach to derive an

EAL from a tolerable concentration of pollutant in air developed using the Environment Agency's proposed Hazard Characterisation Method.

Question 9: In section 7.4 we propose to include information on the Relative Source Contribution in the Hazard Characterisation Method for chemicals where the critical effect has a threshold. Do you support this? If no, please tell us why.

Question 10: In section 7.4 we propose not to include a Relative Source Contribution in the Hazard Characterisation Method for chemicals where the critical effect is not systemic (eg sensory irritants) or does not have a threshold (eg genotoxic carcinogens). Do you support this? If no, please tell us why.

Question 11: In section 7.4, where there is little data on public exposure by other routes, do you support the proposed Relative Source Contribution default of 50%? If no, please tell us what other defaults you would suggest and why.

8 The REACH process

The European Union has recently adopted a new system to control the risks that chemicals may pose to human health and the environment. The REACH Regulation (Registration, Evaluation, Authorisation and restriction of Chemicals) came into force on 1 June 2007 and is being progressively introduced. It forms the EU's framework legislation for the management, control and use of chemicals, replacing much of the existing legislation.

In summary, REACH requires manufacturers, importers, distributors and professional users who market or use chemicals to ensure those chemicals are registered with the new European Chemicals Agency in Helsinki (EChA), which will oversee the operation of REACH throughout the EU. Before a chemical can be registered, the applicant must provide information about the physic-chemical properties, hazards and risks associated with that chemical. Those chemicals which pose a serious hazard may be restricted or may be used only following the grant of a specific 'authorisation'.

Utilising EALs derived using a method based on REACH in EPR permitting has a number of advantages:

- Audited REACH derived EALs will be more robust than OEL EALs and C&K EALs
- EALs based on REACH will ensure consistency between the use and marketing of chemicals and industrial regulatory regimes
- Industry is responsible for the derivation of relevant values under REACH and see this process as an opportunity to gain further value from their investment in REACH. It is consistent with the 'polluter pays' principle
- REACH time scales mean that EALs for carcinogens and high volume chemicals should be available for permit reviews by 2011
- as REACH has been implemented across Europe, REACH derived EALs should be consistent across Europe.

The basic components of the REACH registration process and the phasing arrangements for the registration of substances that are currently manufactured are described in EChA (2008b). The great majority of the substances that we require EALs for are all either high production volume (HPVs) chemicals or highly hazardous substances (CMRs - Carcinogens, Mutagens, Reprotoxins) and should have been registered in the first phase of REACH i.e. before the 30 November 2010.

The EChA encourages users and manufactures of specific chemicals to form Substance Information Exchange Forums (SIEFs) to pool data, carry out the Chemical Safety Assessments (CSA) and make the REACH registration. Part of the CSA process includes assessing the intrinsic hazards of substances including determining the hazard classification and further characterising hazards, including where possible derivation of no-effect-levels (Derived No-Effect-Levels or Derived Minimal Effect Levels for human health, Predicted No-Effect-Concentrations for environment). This includes generation of new information if needed. Exposure assessments for all events are carried out, controls identified and the risks are characterised. This assessment is recorded in the substance Chemical Safety Report (CSR) that is submitted on registration.

The CSR will include the characterisations of dose/concentration–response for human health for relevant toxicological effects to the general public that we are proposing to use as EALs. These will be as Derived No-Effect Levels (DNELs) for threshold effect substances or Derived Minimal Effect Levels (DMELs) for non-threshold effect mutagen/carcinogen substances. It is these DNEL and DMEL values that we propose to adopt as EALs. As with the derivation of TCA, in deriving EALs from DN(M)ELs it would be necessary to apply a RSC. It should be noted that we are not proposing to use the REACH risk assessments or exposure scenarios that may be submitted with a substance CSR as we feel this is adequately addressed by our H1 guidance.

Chapter R.8 – Dose (Concentration)-Response Regarding Human Health of the Guidance on Information Requirements and Chemical Safety Assessments (EChA, 2008a) details the method for deriving DNELs and DMELs. It must be noted that at the time of writing, the section R.8.5.1 "Deriving a DMEL for a non-threshold carcinogen, with adequate human cancer data" was still under development.

Chapter R.8, Appendix R.8-13[3] considers the derivation of a DNEL when a EU indicative occupational exposure limit (IOELV) has been adopted. However, as IOELVs apply to occupational exposures, rather than the public, whose exposures and susceptibilities will differ from those exposed occupationally, we would not expect to see IOELVs adopted directly as EALs. In the interests of transparency, the Environment Agency is concerned at the lack of available background data used in the early derivation of IOELVs. And there are some 100 of these, 21 of which are for substances which require a new EAL. We would welcome any data provided to us through this consultation that demonstrates the basis for the derivation of individual IOELVs for substances for which IOELVs are required.

A registrant under REACH is allowed to use an IOELV as a DNEL for the same exposure route and duration, only if they have obtained no new scientific information whilst fulfilling their obligations under REACH. If new scientific information does not support the use of the IOELV then a relevant DNEL should be derived. Nonetheless, it may be appropriate to base the derivation of the DNEL on the same toxicological end point selected by the Scientific Committee on Occupational Exposure Limits (SCOEL) in the derivation of the IOELV. However, this would need to be assessed on a case-by-case basis.

The majority of substances in which we are interested were due to come into the 1st tranche of the REACH requirements by 30th November 2010. Once received, our quality checking of the derivation of EALs from the REACH process will include a brief review of the dossier presented by the user to the EChA, consideration of proposed DNELs/DMELs, followed by identification of those over which we have concerns and then consultation with the HPA before the values are published. Should any data presented to the EChA prove to be unavailable to the Environment Agency, then that assessment may not be available to us and our proposed in-house method may have to be used.

It is proposed that consideration of exposures from other sources be incorporated when deriving and EAL based on a DN(M)EL (see section 7.4 for details).

[3] Available via:
http://guidance.EChA.europa.eu/docs/guidance_document/information_requirements_en.htm#r8

Question 12a: In section 8 we propose to use REACH DNELs/DMELs derived for the 'humans via the environment' exposure route. Do you think that our proposal is justified as a source of Environmental Assessment Levels? If no, please tell us why.

Question 12b: In section 8 we propose to use REACH DNELs/DMELs derived for the "humans via the environment" exposure route. Do you think that our proposal is legitimate as a source of Environmental Assessment Levels? If no, please tell us why.

Question 13a: Section 8 looks at the potential use of IOELVs to derive environmental exposure. Do you think our proposals are valid? If no, please tell us why.

Question 13b: Section 8 looks at the potential use of IOELVs to derive environmental exposure. Do you think our proposals are scientifically robust? If no, please tell us why.

Question 14: In section 8 we propose a way of handling DNELs/DMELs supplied to the EChA ahead of publishing the values. Do you support our approach? If no, please tell us what other approach you would propose and why.

Question 15: In section 8 we propose our in-house method for the derivation of new EALs where data is not available to us via the REACH process. Do you support this method? If no, please tell us what alternative method you would propose and why.

9 Consultation questions

This consultation is your opportunity to comment on proposed changes to the derivation of EALs. Including changes to the hierarchy used to prioritise the source of EAL values and an updated Environment Agency method for the derivation of more robust EALs. We would particularly welcome your feedback on the questions below:

Question 1: Do you agree with the proposed hierarchy for the derivation of new Environmental Assessment Levels provided in Section 5? If no, please tell us how you would improve it.

Question 2: Annex 4 contains a list of substances in the Environment Agency's Pollution Inventory for which no Environmental Assessment Level is currently available. Are there any other substances for which you feel an Environmental Assessment Level should be derived? If yes, please list below those substances for which you feel an EAL should be derived and why.

Question 3: Are there any further authoritative evaluations that should be considered besides those listed in Section 7? If yes, please provide details.

Question 4a: Section 7.1 provides information on our proposed method for the derivation of Environmental Assessment Levels for chemicals with a toxicological effect threshold. Do you think our proposal is most appropriate? If no, please tell us why.

Question 4b: Section 7.1 provides information on our proposed method for the derivation of Environmental Assessment Levels for chemicals with a toxicological effect threshold. Section 7.1 provides information on our proposed method for the derivation of EALs for chemicals with a toxicological effect threshold. Section 7.1 provides information on our proposed method for the derivation of EALs for chemicals with a toxicological effect threshold. Do you think our proposals are scientifically valid? If no, please tell us why.

Question 5a: Section 7.2 provides information on our proposed method for the derivation of Environmental Assessment Levels for genotoxic carcinogens. Do you think our proposals are most appropriate? If no, please tell us what other methods you would propose and why.

Question 5b: Section 7.2 provides information on our proposed method for the derivation of Environmental Assessment Levels for genotoxic carcinogens. Do you think our proposals are scientifically valid? If no, please tell us why.

Question 6: In section 7.2, where the assessment is based on human data, is an exposure calculated as posing a lifetime excess cancer risk of 10-6 an appropriate basis for an Environmental Assessment Level for genotoxic carcinogens? If no, please tell us what alternative level of risk you think is appropriate and why.

Question 7: In section 7.2, where a 'BMDL10 and large assessment factor' approach is used to derive Environmental Assessment Levels for genotoxic carcinogens, is 10,000 the most appropriate factor to use? If no, please tell us what other factor you would recommend and why.

Question 8: In section 7.3 we propose that the default averaging times for genotoxic carcinogenesis and most threshold effects should be annual, 24 hour time weighted or reflect a time period defined within a relevant epidemiological study. Do you agree that

these timings are appropriate? If no, please tell us what defaults you would suggest that might be appropriate to other endpoints.

Question 9: In section 7.4 we propose to include information on the Relative Source Contribution in the Hazard Characterisation Method for chemicals where the critical effect is systemic and has a threshold. Do you support this? If no, please tell us why.

Question 10: In section 7.4 we propose not to include a Relative Source Contribution in the Hazard Characterisation Method for chemicals where the critical effect is not systemic (eg sensory irritants) or does not have a threshold (eg genotoxic carcinogens). Do you support this? If no, please tell us why.

Question 11: In section 7.4, where there is little data on public exposure by other routes, do you support the proposed Relative Source Contribution default of 50%? If no, please tell us what other defaults you would suggest and why.

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Question 13a: Section 8 looks at the potential use of IOELVs to derive environmental exposure. Do you think our proposals are valid? If no, please tell us why.

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Question 15: In section 8 we propose our in-house method for the derivation of new EALs where data is not available to us via the REACH process. Do you support this method? If no, please tell us what alternative method you would propose and why.

Question 16: Please tell us if you have any other views or comments to make on this document that have not been covered by previous questions.

Question 17: Please tell us if you have any views or comments on the way we have conducted this consultation.

Question 18: How did you find out about this consultation?

10 Responding to this consultation

Key dates

This consultation runs for 14 weeks from 19th December 2011 to 1st April 2012.

How to respond

We would prefer you to respond online at https://consult.environment-agency.gov.uk/portal/. This will enable you to manage your comments more effectively, whilst helping us to gather and summarise responses quickly and accurately. It will also drive down the costs of the consultation for the taxpayer. However, we will also accept hardcopy responses but please send us your comments on a separate document – do not use tracked changes. And please ensure that your response can be read by Microsoft Office or Adobe Acrobat.

You can view the consultation documents and consultation questions online. However, for a printed version of the document and/or hardcopy of the response form please contact our National Customer Contact Centre on 03708 506 506 (Mon-Fri, 8am - 6pm). Written response forms should be returned to:

Lorraine K Harrison
National Operations Group
Environment Agency
Phoenix House
Global Avenue
Leeds LS11 8PG

Email: lorraine.harrison@environment-agency.gov.uk

What will the responses be used for

After the consultation has closed we will compile a report on the consultation feedback and publish it on our website. This will include all the consultation responses. Please tell us on your response if you want us to treat it as confidential. We will publish responses made on behalf of organisations with the organisation's name. We will not publish names of individuals who respond.

How we will use your information

Throughout the consultation we will look to make all comments (excluding personal information) publicly available on our website. This includes comments received online, by email, post and by fax, unless you have specifically requested that we keep your response confidential. We will not publish names of individuals who respond. But we will publish the name of the organisation for those responses made on behalf of organisations.

* Calls to 03 numbers cost no more than a national rate call to an 01 or 02 number and must count towards any inclusive minutes in the same way as 01 and 02 calls. These

rules apply to calls from any type of line including mobile, BT, other fixed line or payphone.

If you respond online or provide us with an email address, we will acknowledge your response. And after the consultation has closed we will publish a summary of the responses on our website. We will contact you to let you know when this is available.

In accordance with the Freedom of Information Act 2000, we may be required to publish your response to this consultation, but will not include any personal information. If you have requested your response to be kept confidential, we may still be required to provide a summary of it.

Code of Practice on Consultation

We are running this consultation in accordance with the criteria set out in the government's Code of Practice on Consultation.

If you have any queries or complaints about the way this consultation has been carried out, please contact:

Emma Hammonds, Consultation Co-ordinator
Environment Agency,
Horizon House
Deanery Road
Bristol BS1 5AH

Email: emma.hammonds@environment-agency.gov.uk

Please do not send consultation responses to this address.

The seven consultation criteria

1 When to consult
Formal consultation should take place at a stage when there is scope to influence the policy outcome.

2 Duration of consultation exercises
Consultations should normally last for at least 12 weeks, taking into account longer timescales where feasible and sensible.

3 Clarity of scope and impact
Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

4 Accessibility of consultation exercises
Consultation exercises should be accessible to, and clearly targeted at, those people the exercise is intended to reach.

5 The burden of consultation
Keeping the burden of consultation to a minimum is essential if consultations are to be effective and for consultees' to buy-in to the process.

6 Responsiveness of consultation exercises

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

7 Capacity to consult

Staff running consultations should seek guidance on how to run an effective consultation exercise and share what they have learned from the experience.

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List of abbreviations

AALG	Ambient Air Quality Goal
COC	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment
COMEAP	Committee of Medical Experts on the Effects of Air Pollution
COSHH	Control of Substances Hazardous to Health
DEFRA	Department for the Environment, Food and Rural Affairs
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EPAQS	Expert Panel on Air Quality Standards
EU	European Union
HSE	Health and Safety Executive
IARC	International Agency for Research into Cancer
IPCS	International Program for Chemical Safety
IOELV	Indicative Occupational Exposure Limit Value
IRIS	Integrated Risk Information System
IVL	Indicative Limit Value
LOAEL	Lowest observed adverse effect level
MoE	Margin of Exposure
NOAEL	No observed adverse effect level
NOEL	No observed (adverse) effects level
NIOSH (US)	National Institute for Occupational Safety and Health
OEL	Occupational Exposure Limit
OES	Occupational Exposure Standard
OSHA (US)	Occupational Safety and Health Administration
TCA	Tolerable Concentration in Air
TDI	Tolerable daily intake
US EPA	US Environmental Protection Agency
WHO	World Health Organisation

Glossary

BMD (Benchmark dose): The BMD concept involves fitting a mathematical model to dose-response data. The BMD is defined as the dose causing a predetermined change in response.

BMD10: The Benchmark dose associated with a 10% response (for tumours upon lifetime exposure after correction for spontaneous incidence, for other effects in a specified study).

BMDL10: The lower 95% confidence interval of a Benchmark dose representing a 10% response (eg tumour response upon lifetime exposure), i.e. the lower 95% confidence interval of a BMD10.

Derived Minimal Effect Level (DMEL): For non-threshold effects, the underlying assumption is that a no-effect-level cannot be established and a DMEL therefore expresses an exposure level corresponding to a low, possibly theoretical, risk, which should be seen as a tolerable risk.

Derived No Effect Level (DNEL): For threshold effects a DNEL expresses an exposure level above which humans should not be exposed.

EChA: European Chemicals Agency: Administrative body for the REACH Regulations.

Environment Assessment Level (EAL): Environmental benchmarks for comparing the significance within and across media of proposed releases of pollutants.

Genotoxic: Genotoxic chemicals are those which are capable of causing damage to DNA. Such damage can potentially lead to the formation of a malignant tumour, but DNA damage does not lead inevitably to the creation of cancerous cells.

Indicative Occupational Exposure Limit Value (IOELV): Human exposure limits to hazardous substances specified by the Council of the European Union based on expert research and advice. They are not binding on member states but must be taken into consideration in setting national occupational exposure limits.

Lowest observed adverse effect level: Lowest concentration or amount of a substance, found by experiment or observation, which causes an adverse alteration of morphology, functional capacity, growth, development, or life span of a target organism distinguishable from normal (control) organisms of the same species and strain under defined conditions of exposure.

Margin of Exposure: The ratio of the no-observed adverse-effect-level to the estimated exposure dose.

No observed adverse effect level (NOAEL): Greatest concentration or amount of a substance, found by experiment or observation, which causes no detectable adverse alteration of morphology, functional capacity, growth, development, or life span of the target organism under defined conditions of exposure.

No-observed-effect-level (NOEL): Greatest concentration or amount of a substance, found by experiment or observation, that causes no alterations of morphology, functional capacity, growth, development, or life span of target organisms

distinguishable from those observed in normal (control) organisms of the same species and strain under the same defined conditions of exposure.

Occupational exposure Limit (OEL): A (generally legally-enforceable) limit on the amount or concentration of a chemical to which workers may be exposed.

Point of departure: The dose or concentration selected from a toxicity or epidemiology study as the basis for derivation of a health criteria value or a margin of exposure. Examples include the NOAEL, LOAEL, BMDL10.

Quantitative Risk Assessment: An assessment leading to a numerical estimate of risk.

Route-to-route extrapolation: The prediction of the total amount of a substance administered by one route of exposure (eg oral) that would produce the same toxic endpoint or response to that obtained for a given amount of that substance administered by another route (eg inhalation).

Systemic Effect: A systemic effect of a chemical is one that is either of a generalised nature or that occurs at a site distance from the site of entry of the chemical.

T25: The chronic dose rate that will give 25% of the animals' tumours at a specific tissue site after correction for spontaneous incidence, within the standard life time of that species.

Tolerable Concentration in Air (TCA): The values derived by the new Environment Agency Environment Agency hazard characterisation method for the calculation of EALs.

Table 2 Future EALs for EPR substances

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Acetaldehyde	Acetaldehyde	HSE	HSE	Acetaldehyde	75-07-0	Acetaldehyde	75-07-0				REACH
Acetic acid	Acetic acid	HSE	HSE			Acetic acid	64-19-7				REACH
Acetic anhydride	Acetic anhydride	HSE	HSE			Acetic anhydride	108-24-7				REACH
Acetone	Acetone	HSE	HSE			Acetone	67-64-1				REACH
Acetonitrile	Acetonitrile	HSE	HSE			Acetonitrile	75-05-8				REACH
o-Acetylsalicylic acid											Deleted
Acrylaldehyde				Acrolein	107-02-8	Acrylaldehyde	107-02-8				REACH
Acrylamide	Acrylamide	HSE	HSE	Acrylamide	79-06-1	Acrylamide	79-06-1				REACH
Acrylic acid	Acrylic acid	HSE	HSE			Acrylic acid	79-10-7				REACH
Acrylonitrile	Acrylonitrile	HSE	HSE	Acrylonitrile	107-13-1	Acrylonitrile	107-13-1			Yes	New EA
Aldrin (ISO)				Aldrin	309-00-2						C&K
Allyl alcohol	Allyl alcohol	HSE	HSE	Allyl alcohol [	107-18-6	Allyl alcohol	107-18-6				REACH
Allyl-2,3-epoxypropyl ether											Deleted
Aluminium alkyl compounds											Deleted
2-Aminoethanol						2-aminoethanol	141-43-5				Deleted
Ammonia	Ammonia	HSE	HSE	Ammonia	7664-41-7	Ammonia, anhydrous	7664-41-7				REACH

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Ammonium sulphamidate											Deleted
Aniline	Aniline	HSE	HSE	Aniline	62-53-3	Aniline	62-53-3				REACH
Anisidines, o- and p- isomers											Deleted
Antimony and compounds (as Sb) except antimony trisulphide and antimony trioxide	Antimony and compounds (as Sb) except antimony trisulphide and antimony trioxide	HSE	HSE	Antimony and compounds - as Sb	7440-36-0	Antimony	7440-36-0			Yes	New EA
Arsenic and compounds (as As)	Arsenic (total inorganic arsenic in the PM10 fraction)	EPAQS		Arsenic and compounds - as As	7440-38-2			Yes	Yes		EPAQS
Arsine	Arsine	HSE	HSE								C&K
Azinphos-methyl (ISO)											Deleted
Azodicarbonamide											Deleted
Barium compounds, soluble (as Ba)											Deleted
Benomyl (ISO)											Deleted
Benzene				Benzene	71-43-2	Benzene	71-43-2	Yes	Yes		EPAQS
Benzenethiol						Benzenethiol	108-98-5				Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Benzene-1,2,4-tricarboxylic acid, 1,2-anhydride											Deleted
Benzo-a-pyrene	Benzo-a-pyrene	EPAQS	HSE	Benzo(a)pyrene	50-32-8			Yes			EPAQS
p-Benzoquinone											Deleted
Benzyl butyl phthalate				Benzyl butyl phthalate (BBP)	85-68-7	Benzyl butyl phthalate	85-68-7				REACH
Benzylchloride	Benzylchloride	HSE	HSE	Benzyl chloride	100-44-7						C&K
Beryllium and compounds (as Be)	Beryllium (total in the PM10 fraction)	EPAQS		Beryllium and compounds - as Be	7440-41-7	Beryllium	7440-41-7	Yes			EPAQS
Biphenyl						Biphenyl	92-52-4				Deleted
Bis(chloromethyl) ether											Deleted
Bis(2,3-epoxypropyl)ether											Deleted
Bis(2-ethylhexyl)phthalate											Deleted
Bornan-2-one											Deleted
Boron tribromide											Deleted
Boron trifluoride	Boron trifluoride	HSE	HSE			Boron trifluoride	7637-07-2				REACH

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Bromacil (ISO)											Deleted
Bromine	Bromine	HSE	EPAQS			Bromine	7726-95-6	Yes			EPAQS
Bromine pentafluoride											Deleted
Bromochloromethane											Deleted
Bromoethane											Deleted
Bromoform											Deleted
Bromomethane	Bromomethane	HSE	HSE	Methyl bromide	74-83-9						C&K
Bromotrifluoromethane											Deleted
Buta-1,3-diene				Butadiene	106-99-0	Buta-1,3-diene	106-99-0	Yes			EPAQS
Butane	Butane	HSE	HSE			Butane	106-97-8				REACH
Butan-1-ol						Butan-1-ol	71-36-3				Deleted
Butan-2-ol						Butan-2-ol	78-92-2				Deleted
Butan-2-one	Butan-2-one (Methyl ethyl ketone MEK)	HSE									C&K
2-Butoxyethanol						2-butoxyethanol	111-76-2				Deleted
Butyl acetate											Deleted
sec-Butyl acetate											Deleted
tert-Butyl acetate						Tert-butyl acetate	540-88-5				Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Butyl acrylate						Butyl acrylate	141-32-2				Deleted
n-Butylamine											Deleted
n-Butyl chloroformate											Deleted
n-Butyl glycidyl ether											Deleted
Butyl lactate											Deleted
2-sec-Butylphenol						2-sec-butylphenol	89-72-5				Deleted
Cadmium and its compounds (as Cd)	Cadmium	WHO		Cadmium and compounds – as Cd	7440-43-9	Cadmium	7440-43-9		Yes		WHO
Caesium hydroxide											Deleted
Calcium cyanamide						Calcium cyanamide	156-62-7				Deleted
Calcium hydroxide											Deleted
Calcium oxide						Calcium oxide	1305-78-8				Deleted
Captafol (ISO)											Deleted
Captan (ISO)											Deleted
Carbofuran (ISO)											Deleted
Carbon black						Carbon black	1333-86-4				Deleted
Carbon disulphide	Carbon disulphide	WHO	HSE	Carbon disulphide	75-15-0	Carbon disulphide	75-15-0				WHO

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Carbon tetrachloride	Carbon tetrachloride	HSE	HSE	Carbon tetrachloride	56-23-5	Carbon tetrachloride	56-23-5				REACH
Chlorine dioxide						Chlorine dioxide	10049-04-4				Deleted
Chlorine trifluoride											Deleted
Chloroacetaldehyde											Deleted
2-Chloroacetophenone											Deleted
Chlorobenzene						Chlorobenzene	108-90-7				Deleted
2-Chlorobuta-1,3-diene						2-chlorobuta-1,3-diene	126-99-8				Deleted
Chlorodifluoromethane						Chlorodifluoromethane	75-45-6				Deleted
1-Chloro-2,3-epoxypropane						1-chloro-2,3-epoxypropane	106-89-8				Deleted
Chloroethane						Chloroethane	75-00-3				Deleted
2-Chloroethanol						2-chloroethanol	107-07-3				Deleted
Chloroform	Chloroform	HSE	HSE	Chloroform	67-66-3	Chloroform	67-66-3				REACH
Chloromethane	Chloromethane	HSE	HSE	Methyl chloride	74-87-3	Chloromethane	74-87-3				REACH
1-Chloro-4-nitrobenzene						1-chloro-4-nitrobenzene	100-00-5				Deleted
Chloropentafluoroethane											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Chlorosulphonic acid											Deleted
2-Chlorotoluene						2-chlorotoluene	95-49-8				Deleted
2-Chloro-6-(trichloromethyl)pyridine											Deleted
Chlorpyrifos (ISO)											Deleted
Chromium, chromium (II) compounds and chromium (III) compounds (as Cr)	Chromium, chromium (II) compounds and chromium (III) compounds (as Cr)	HSE	HSE	Chromium and compounds - as Cr	7440-47-3	Chromium	7440-47-3				REACH
Chromium (VI) compounds (as Cr)	Chromium, (vi) oxidation state in the PM10 fraction	EPAQS		Chromium VI and compounds – as Cr	18540-29-9	Chromium trioxide	1333-82-0	Yes			EPAQS
Cobalt and cmds (as Co)						Cobalt	7440-48-4				Deleted
Copper fume						Copper	7440-50-8				Deleted
Copper dusts and mists (as CU)	Copper dusts and mists (as CU)	HSE	HSE	Copper and compounds - as Cu	7440-50-8	Copper	7440-50-8				REACH
Cresols, all isomers											Deleted
Cryofluorane											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
(INN)											
Cumene						Cumene	98-82-8				Deleted
Cyanamide						Cyanamide	420-04-2				Deleted
Cyanides, except HCN, cyanogen and cyanogen chloride, (as CN)											Deleted
Cyanogen chloride											Deleted
Cyclohexane						Cyclohexane	110-82-7				Deleted
Cyclohexanol						Cyclohexanol	108-93-0				Deleted
Cyclohexanone						Cyclohexanone	108-94-1				Deleted
Cyclohexene						Cyclohexene	110-83-8				Deleted
Cyclohexylamine						Cyclohexylamine	108-91-8				Deleted
Cyhexatin (ISO)											Deleted
2,4-D (ISO)											Deleted
Dialkyl 79 phthalate											Deleted
Diallyl phthalate						Diallyl phthalate	131-17-9				Deleted
1,2-Diaminoethane											Deleted
Diammonium peroxodisulphate (measured as											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
[S2O8])											
Diazinon (ISO)											Deleted
Dibenzoyl peroxide						Dibenzoyl peroxide	94-36-0				Deleted
Dibismuth tritelluride											Deleted
Dibismuth tritelluride, selenium doped											Deleted
Diborane											Deleted
Diboron trioxide						Diboron trioxide	1303-86-2				Deleted
Dibromodifluoromethane											Deleted
1,2-Dibromoethane	1,2-Dibromoethane	HSE	HSE			1,2-dibromoethane	106-93-4				REACH
Dibutyl hydrogen phosphate											Deleted
Dibutyl phthalate	Dibutyl phthalate	HSE		Dibutyl phthalate	84-74-2	Dibutyl phthalate	84-74-2				REACH
6,6'-Di-tert-butyl-4,4'-thiodi-m-cresol						6,6'-di-tert-butyl-4,4'-thiodi-m-cresol	96-69-5				Deleted
6,6-Di-tert-butyl-4,4-thiodi-m-cresol											Deleted
Dichloroacetylene											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
1,2-Dichlorobenzene						1,2-dichlorobenzene	95-50-1				Deleted
1,4-Dichlorobenzene	1,4-Dichlorobenzene	HSE	HSE	p-Dichlorobenzene	106-46-7	1,4-dichlorobenzene	106-46-7				REACH
Dichlorodifluoromethane											Deleted
1,3-Dichloro-5,5-dimethyl-hydantoin											Deleted
1,1-Dichloroethane											Deleted
1,2-Dichloroethane	1,2-Dichloroethane (ethylene dichloride)	HSE		Ethylene dichloride	107-06-2	1,2-dichloroethane	107-06-2				REACH
1,2-Dichloroethylene, cis:trans isomers 60:40											Deleted
Dichlorofluoromethane											Deleted
Dichloromethane	Dichloromethane (DCM, Methylene chloride)	HSE		Dichloromethane	75-09-2	Dichloromethane	75-09-2				REACH

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
2,2'-Dichloro-4,4'-methylene dianiline											Deleted
Dichlorvos (ISO)											Deleted
Dicyclohexyl phthalate											Deleted
Dicyclopentadiene											Deleted
Dieldrin (ISO)				Dieldrin	60-57-1						C&K
Diethylamine						Diethylamine	109-89-7				Deleted
2-Diethylaminoethanol						2-diethylaminoethanol	100-37-8				Deleted
Diethyl ether	Diethyl ether	HSE	HSE	Diethyl ether	60-29-7	Diethyl ether	60-29-7				REACH
Diethyl phthalate						Diethyl phthalate	84-66-2				Deleted
Diisobutyl phthalate	Diisobutyl phthalate	HSE	HSE			Diisobutyl phthalate	84-69-5				REACH
Diisodecyl phthalate											Deleted
Diisononyl phthalate											Deleted
Diisooctyl phthalate				Di(2-Ethylhexyl)phthalate	117-81-7	Bis(2-ethylhexyl) phthalate	117-81-7				REACH

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Diisopropylamine						Diisopropylamine	108-18-9				Deleted
Diisopropyl ether	Diisopropyl ether	HSE	HSE	Diisopropyl ether	108-20-3	Diisopropyl ether	108-20-3				REACH
Dimethoxymethane						Dimethoxymethane	109-87-5				Deleted
NN-Dimethylacetamide											Deleted
Dimethylamine						Dimethylamine	124-40-3				Deleted
NN-Dimethylaniline											Deleted
1,3-Dimethylbutyl acetate											Deleted
NN-Dimethylethylamine											Deleted
Dimethylformamide	Dimethylformamide	HSE	HSE	Dimethylformamide	68-12-2	N,N-dimethylformamide	68-12-2			Yes	New EA
2,6-Dimethylheptan-4-one						2,6-dimethylheptan-4-one	108-83-8				Deleted
Dimethyl phthalate						Dimethyl phthalate	131-11-3				Deleted
Dimethyl sulphate	Dimethyl sulphate	HSE	HSE	Dimethyl sulphate	77-78-1	Dimethyl sulphate	77-78-1				REACH

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Dinitrobenzene, all isomers											Deleted
Dinonyl phthalate											Deleted
1,4-Dioxane	1,4-Dioxane	HSE	HSE	1,4-Dioxane	123-91-1	1,4-dioxane	123-91-1				REACH
Dioxathion (ISO)											Deleted
Diphenylamine						Diphenylamine	122-39-4				Deleted
Diphenyl ether vapour											Deleted
Diphosphorus pentasulphide						Diphosphorus pentasulphide	1314-80-3				Deleted
Diphosphorus pentoxide											Deleted
Dipotassium peroxodisulphate (measured as [S2O8])											Deleted
Diquat dibromide (ISO)											Deleted
Disodium disulphite						Disodium disulphite	7681-57-4				Deleted
Disodium peroxodisulphate (measured as [S2O8])											Deleted
Disodium tetraborate anhydrous											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Disodium tetraborate decahydrate											Deleted
Disodium tetraborate pentahydrate											Deleted
Disulfoton (ISO)											Deleted
Disulphur dichloride						Disulphur dichloride	10025-67-9				Deleted
Disulphur decafluoride											Deleted
Diuron (ISO)											Deleted
Divinadium pentaxode (as V)											Deleted
Divinylbenzene											Deleted
Endosulfan (ISO)											Deleted
Endrin (ISO)				Endrin	72-20-8						C&K
2,3-Epoxypropyl isopropyl ether											Deleted
Ethane-1,2-diol particulate											Deleted
Ethane-1,2-diol vapour											Deleted
Ethanethiol						Ethanethiol	75-08-1				Deleted
Ethanol						Ethanol	64-17-5				Deleted
2-Ethoxyethanol						2-	110-80-5				Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
						ethoxyethanol					
2-Ethoxyethyl acetate											Deleted
Ethyl acetate						Ethyl acetate	141-78-6				Deleted
Ethyl acrylate	Ethyl acrylate	HSE	HSE	Ethyl acrylate	140-88-5	Ethyl acrylate	140-88-5				REACH
Ethylamine						Ethylamine	75-04-7				Deleted
Ethylbenzene	Ethylbenzene	HSE	HSE	Ethyl benzene	100-41-4	Ethylbenzene	100-41-4		Yes		HCV
Ethyl chloroformate						Ethyl chloroformate	541-41-3				Deleted
Ethyl cyanoacrylate											Deleted
Ethylene dinitrate						Ethylene dinitrate	628-96-6				Deleted
Ethylene oxide	Ethylene oxide	HSE	HSE	Ethylene oxide	75-21-8	Ethylene oxide	75-21-8				REACH
Ethyl formate											Deleted
2-Ethylhexyl chloroformate						2-ethylhexyl chloroformate	24468-13-1				Deleted
4-Ethylmorpholine											Deleted
Fenchlorphos (ISO)											Deleted
Ferbam (ISO)											Deleted
Ferrocene											Deleted
Fluoride (as F)											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Fluorine											Deleted
Formaldehyde	Formaldehyde	HSE	WHO	Formaldehyde	50-00-0	Formaldehyde	50-00-0				WHO
Formamide						Formamide	75-12-7				Deleted
Formic acid						Formic acid	64-18-6				Deleted
2-Furaldehyde						2-furaldehyde	98-01-1				Deleted
Furfuryl alcohol						Furfuryl alcohol	98-00-0				Deleted
Germane											Deleted
Glutaraldehyde											Deleted
Glycerol mist											Deleted
Glycerol trinitrate						Glycerol trinitrate	55-63-0				Deleted
Hafnium											Deleted
Heptan-2-one											Deleted
Heptan-3-one											Deleted
Hexachloroethane vapour											Deleted
Hexachloroethane total inhalable dust											Deleted
Hexachloroethane respirable dust											Deleted
Hexahydro-1,3,5-trinitro-1,3,5-triazine											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
n-Hexane	n-Hexane	HSE	HSE	Hexane	110-54-3	N-hexane	110-54-3				REACH
1,6-Hexanolactam dust											Deleted
1,6-Hexanolactam vapour											Deleted
Hexan-2-one											Deleted
Hydrazine	Hydrazine	HSE	HSE			Hydrazine	302-01-2				REACH
Hydrogen bromide	hydrogen bromide	HSE	EPAQS			Hydrogen bromide	10035-10-6	Yes			EPAQS
Hydrogen chloride	Hydrogen chloride	HSE	EPAQS	Hydrogen chloride	7647-01-0	Hydrogen chloride	7647-01-0	Yes			EPAQS
Hydrogen cyanide	Hydrogen cyanide	HSE	HSE	Hydrogen cyanide	74-90-8	Hydrogen cyanide	74-90-8				REACH
Hydrogen fluoride (as F)	Hydrogen fluoride	EPAQS		Fluorine and inorganic compounds - as HF	7782-41-4	Hydrogen fluoride	7664-39-3	Yes			EPAQS
Hydrogen peroxide						Hydrogen peroxide	7722-84-1				Deleted
Hydrogen selenide (as Se)											Deleted
Hydrogen sulphide	Hydrogen sulphide	HSE	WHO			Hydrogen sulphide	7783-06-4				WHO
Hydroquinone						Hydroquinone	123-31-9				Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
4-Hydroxy-4-methyl-pentan-2-one											Deleted
2-Hydroxypropyl acrylate											Deleted
2,2'-Iminodiethanol						2,2'-iminodiethanol	111-42-2				Deleted
2,2'-Iminodi(ethylamine)						2,2'-iminodi(ethylamine)	111-40-0				Deleted
Indene											Deleted
Indium and compounds (as In)											Deleted
Iodine						Iodine	7553-56-2				Deleted
Iodoform											Deleted
Iron salts (as Fe)											Deleted
Isobutyl acetate						Isobutyl acetate	110-19-0				Deleted
Isocyanates (as NCO)											Deleted
Isooctyl alcohol (mixed isomers)											Deleted
Isopentyl acetate						Isopentyl acetate	123-92-2				Deleted
Isopropyl acetate						Isopropyl acetate	108-21-4				Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Isopropyl chloroformate											Deleted
Ketene											Deleted
Lindane (hexachlorocyclohexane)				Lindane	58-89-9						C&K
Lithium hydride											Deleted
Lithium hydroxide						Lithium hydroxide	1310-65-2				Deleted
Malathion (ISO)											Deleted
Manganese and compounds (as Mn)	Manganese and compounds (as Mn)	WHO	HSE	Manganese and compounds - as Mn	7439-96-5	Manganese	7439-96-5				WHO
Mequinol (INN)											Deleted
Mercaptoacetic acid						Mercaptoacetic acid	68-11-1				Deleted
Mercury alkyls (as Hg)									Yes		HCV
Mercury and compounds, except mercury alkyls, (as Hg)	Mercury and compounds, except mercury alkyls, (as Hg)	HSE	HSE	Mercury and compounds – as Hg	7439-97-6	Mercury	7439-97-6		Yes		HCV
Methacrylic acid						Methacrylic acid	79-41-4				Deleted
Methacrylonitrile						Methacrylonitrile	126-98-7				Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Methanethiol						Methanethiol	74-93-1				Deleted
Methanol	Methanol	HSE	HSE	Methanol	67-56-1	Methanol	67-56-1				REACH
Methomyl (ISO)											Deleted
Methoxychlor (ISO)											Deleted
2-Methoxyethanol						2-methoxyethanol	109-86-4				Deleted
2-Methoxyethyl acetate											Deleted
1-Methoxypropan-2-ol						1-methoxypropan-2-ol	107-98-2				Deleted
Methyl acetate						Methyl acetate	79-20-9				Deleted
Methyl acrylate						Methyl acrylate	96-33-3				Deleted
Methylamine						Methylamine	74-89-5				Deleted
N-Methylaniline						N-methylaniline	100-61-8				Deleted
3-Methylbutan-1-ol						3-methylbutan-1-ol	123-51-3				Deleted
1-Methylbutyl acetate											Deleted
methyl-tert-butyl-ether											Deleted
Methylcyclohexanol											Deleted
2-											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Methylcyclohexanone											
2-Methyl-4,6-dinitrophenol											Deleted
4,4'-Methylenedianiline				4,4'-Methylene dianiline	101-77-9	4,4'-methylenedianiline	101-77-9				REACH
Methyl ethyl ketone peroxides											Deleted
Methyl formate						Methyl formate	107-31-3				Deleted
5-Methylheptan-3-one											Deleted
5-Methylhexan-2-one						5-methylhexan-2-one	110-12-3				Deleted
Methyl methacrylate						Methyl methacrylate	80-62-6				Deleted
2-Methylpentane-2,4-diol						2-methylpentane-2,4-diol	107-41-5				Deleted
4-Methylpentan-2-ol						4-methylpentan-2-ol	108-11-2				Deleted
4-Methylpentan-2-one						4-methylpentan-2-one	108-10-1				Deleted
4-Methylpent-3-en-2-one						4-methylpent-3-en-2-one	141-79-7				Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
2-Methylpropan-1-ol						2-methylpropan-1-ol	78-83-1				Deleted
2-Methylpropan-2-ol						2-methylpropan-2-ol	75-65-0				Deleted
1-Methyl-2-pyrrolidone						1-methyl-2-pyrrolidone	872-50-4				Deleted
Methylstyrenes, all isomers except α-methylstyrene											Deleted
N-Methyl-N, 2,4,6-tetranitroaniline											Deleted
Mevinphos (ISO)											Deleted
Molybdenum compounds (as Mo) soluble compounds											Deleted
Molybdenum compounds (as Mo) insoluble											Deleted
Monochloroacetic acid											Deleted
Morpholine						Morpholine	110-91-8				Deleted
Naled (ISO)											Deleted
Naphthalene	Naphthalene	HSE	HSE	Naphthalene	91-20-3	Naphthalene	91-20-3				REACH

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Nickel and inorganic compounds (as Ni)	Nickel (total nickel compounds in the PM10 fraction)	EPAQS		Nickel and compounds – as Ni	7440-02-0	Nickel	7440-02-0	Yes	Yes		EPAQS
Nickel, organic compounds (as Ni)											Deleted
Nicotine											Deleted
Nitric acid	Nitric acid	HSE	HSE			Nitric acid	7697-37-2				REACH
4-Nitroaniline											Deleted
Nitrobenzene						Nitrobenzene	98-95-3				Deleted
Nitroethane											Deleted
Nitrogen dioxide				Nitrogen oxides - NO and NO2 as NO2	-			Yes			EPAQS
Nitrogen monoxide	Nitrogen monoxide	HSE	HSE								C&K
Nitrogen trifluoride											Deleted
Nitromethane											Deleted
1-Nitropropane						1-nitropropane	108-03-2				Deleted
2-Nitropropane						2-nitropropane	79-46-9				Deleted
Nitrotoluene, all isomers											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Octachloronaphthalene											Deleted
Orthophosphoric acid	Orthophosphoric acid	HSE	HSE			Orthophosphoric acid	766-38-2				REACH
Osmium tetraoxide (as Os)											Deleted
Oxalic acid						Oxalic acid	144-62-7				Deleted
Oxalonitrile											Deleted
2,2'-Oxydiethanol						2,2'-oxydiethanol	111-46-6				Deleted
Ozone											Deleted
Parathion (ISO)											Deleted
Parathion-methyl (ISO)											Deleted
Particulates				Particulate matter - PM10	-			Yes			EPAQS
Pentacarbonyliron (as Fe)											Deleted
Pentachlorophenol				Pentachlorophenol	87-86-5						C&K
Pentan-2-one	Pentan-2-one	HSE	HSE								C&K
Pentan-3-one	Pentan-3-one	HSE	HSE			Pentan-3-one	96-22-0				REACH
Pentyl acetate											Deleted
Perchloryl fluoride											Deleted
Phenol	Phenol	HSE	HSE	Phenol	108-95-2	Phenol	108-95-2		Yes		HCV

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
p-Phenylenediamine						P-phenylenediamine	106-50-3				Deleted
Phenyl-2,3-epoxypropyl ether											Deleted
2-Phenylpropene						2-phenylpropene	98-83-9				Deleted
Phorate (ISO)											Deleted
Phosgene	Phosgene	HSE	HSE	Phosgene	75-44-5						C&K
Phosphine	Phosphine	HSE	HSE			Phosphine	7803-51-2				REACH
Phosphorus, yellow											Deleted
Phosphorus pentachloride						Phosphorus pentachloride	10026-13-8				Deleted
Phosphorus trichloride						Phosphorus trichloride	7719-12-2				Deleted
Phosphoryl trichloride						Phosphoryl trichloride	10025-87-3				Deleted
Phthalic anhydride						Phthalic anhydride	85-44-9				Deleted
Picloram (ISO)											Deleted
Picric acid											Deleted
Piperazine dihydrochloride											Deleted
Piperidine											Deleted
Platinum metal											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Polychlorinated biphenyls	Polychlorinated biphenyls (PCBs)	HSE		Polychlorinated biphenyls (PCBs)	1336-36-3						Food chain
Potassium hydroxide						Potassium hydroxide	1310-58-3				Deleted
Propane-1,2-diol vapour & particulates											Deleted
Propan-1-ol	Propan-1-ol	HSE	HSE			Propan-1-ol	71-23-8				REACH
Propan-2-ol	Propan-2-ol	HSE	HSE			Propan-2-ol	67-63-0				REACH
Propionic acid						Propionic acid	79-09-4				Deleted
Propoxur (ISO)											Deleted
n-Propyl acetate											Deleted
Propylene dinitrate											Deleted
Propylene oxide	Propylene oxide	HSE	HSE	Propylene oxide	75-56-9	Methyloxirane	75-56-9				REACH
Prop-2-yn-1-ol						Prop-2-yn-1-ol	107-19-7				Deleted
Pyrethrins (ISO)											Deleted
Pyridine						Pyridine	110-86-1				Deleted
2-Pyridylamine											Deleted
Rhodium (as Rh) metal fume and dust											Deleted
Rhodium (as Rh)											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
soluble salts											
Rotenone (ISO)											Deleted
Selenium and compounds, except hydrogen selenide (as Se)	Selenium and compounds, except hydrogen selenide (as Se)	HSE	HSE	Selenium and compounds – as Se	7782-49-2				Yes		HCV
Silane						Silane	7803-62-5				Deleted
Silver compounds (as Ag)											Deleted
Sodium azide (as NaN3)											Deleted
Sodium 2-(2,4-dichlorophenoxy) ethyl sulphate											Deleted
Sodium fluoroacetate											Deleted
Sodium hydrogensulphite											Deleted
Sodium hydroxide	Sodium hydroxide	HSE	HSE			Sodium hydroxide	1310-73-2				REACH
Stibine											Deleted
Strychnine											Deleted
Styrene	Styrene	WHO	WHO	Styrene	100-42-5	Styrene	100-42-5				WHO

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
Sulfotep (ISO)											Deleted
Sulphur dioxide				Sulphur oxides - SO2 and SO3 as SO2	-	Sulphur dioxide	7446-09-5	Yes			EPAQS
Sulphur hexafluoride	Sulphur hexafluoride	HSE	HSE	Sulphur hexafluoride	2551-62-4	Sulphur hexafluoride	2551-62-4				REACH
Sulphuric acid	Sulphuric acid	HSE	HSE			Sulphuric acid	7664-93-9				REACH
Sulphur tetrafluoride											Deleted
Sulphuryl difluoride											Deleted
2,4,5-T (ISO)											Deleted
TEPP (ISO)											Deleted
Tantalum											Deleted
Tellurium and compounds, except hydrogen telluride, (as Te)											Deleted
Terphenyls, all isomers											Deleted
1,1,2,2-Tetrabromoethane											Deleted
Tetracarbonylnickel (as Ni)											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
1,1,1,2-Tetrachloro-2,2-difluoroethane											Deleted
1,1,2,2-Tetrachloro-1,2-difluoroethane											Deleted
Tetrachloroethylene	Tetrachloroethylene (PER)	HSE		Tetrachloroethylene	127-18-4	Tetrachloroethylene	127-18-4				REACH
Tetrachloronaphthalenes, all isomers											Deleted
Tetraethyl orthosilicate						Tetraethyl orthosilicate	78-10-4				Deleted
Tetrahydrofuran	Tetrahydrofuran	HSE	HSE			Tetrahydrofuran	109-99-9				REACH
Tetramethyl orthosilicate											Deleted
Tetramethyl succinonitrile											Deleted
Tetrasodium pyrophosphate						Tetrasodium pyrophosphate	7722-88-5				Deleted
Thallium, soluble compounds (as Tl)											Deleted
Thionyl chloride											Deleted
Thiram (ISO)											Deleted
Tin compounds,						Tin	7440-31-5				Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
inorganic, except SnH4, (as Sn)											
Tin compounds, organic, except cyhexatin (ISO), (as Sn)											Deleted
Titanium dioxide total inhalable dust						Titanium dioxide	13463-67-7				Deleted
Titanium dioxide respirable dust						Titanium dioxide	13463-67-7				Deleted
Toluene	Toluene	HSE	WHO	Toluene	108-88-3	Toluene	108-88-3		P		WHO
p-Toluenesulphonyl chloride											Deleted
o-Toluidine						O-toluidine	95-53-4				Deleted
Tributyl phosphate, all isomers											Deleted
Tricarbonyl(eta-cyclopentadienyl) manganese (as Mn)											Deleted
Tricarbonyl(methylcyclopentadienyl) manganese (as Mn)											Deleted

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
1,2,4-Trichlorobenzene	1,2,4-Trichlorobenzene	HSE	HSE	Trichlorobenzene - all isomers	12002-48-1	1,2,4-trichlorobenzene	120-82-1				REACH
1,1,1-Trichlorobis(chlorophenyl)ethane											Deleted
1,1,1-Trichloroethane	1,1,1-Trichloroethane (Methyl chloroform)	HSE		Methyl chloroform	71-55-6	1,1,1-trichloroethane	71-55-6				REACH
Trichloroethylene	Trichloroethylene	HSE	WHO	Trichloroethylene	79-01-6	Trichloroethylene	79-01-6			Yes	WHO
Trichlorofluoromethane											Deleted
Trichloronitromethane											Deleted
1,2,3-Trichloropropane						1,2,3-trichloropropane	96-18-4				Deleted
1,1,2-Trichlorotrifluoroethane											Deleted
Triethylamine						Triethylamine	121-44-8				Deleted
Trimanganese tetraoxide						Trimanganese tetraoxide	1317-35-7				Deleted
Trimethylamine						Trimethylamine	75-50-3				Deleted
Trimethylbenzene	Trimethylbenze	HSE	HSE	Trimethylben	25551-						C&K

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
s, all isomers or mixtures	nes, all isomers or mixtures			zene - all isomers	13-7						
3,5,5-Trimethylcyclohex-2-enone						3,5,5-trimethylcyclohex-2-enone	78-59-1				Deleted
Trimethyl phosphite											Deleted
2,4,6-Trinitrotoluene											Deleted
Triphenyl phosphate						Triphenyl phosphate	115-86-6				Deleted
Tri-o-tolyl phosphate											Deleted
Tungsten and compounds (as W) soluble											Deleted
Tungsten and compounds (as W) insoluble											Deleted
Turpentine											Deleted
Uranium compounds, natural, soluble, (as U)											Deleted
Vanadium	Vanadium	HSE	WHO	Vanadium and	7440-62-2	Vanadium	7440-62-2				WHO

EPR substance	H1 substance	Basis for H1 EAL		Pollution Inventory substance		Substance registered under REACH (8 March 2011)		UK reports			Future
		Long	Short	Name	CAS	Name	CAS	EPAQS	CLEA HCV	EA TCA	
				compounds - as V							
Vinyl acetate	Vinyl acetate	HSE	HSE	Vinyl acetate	108-05-4	Vinyl acetate	108-05-4				REACH
Vinyl chloride	Vinyl chloride	HSE	HSE	Vinyl chloride	75-01-4	Chloroethylene	75-01-4			Yes	New EA
Vinylidene chloride											Deleted
Warfarin (ISO)											Deleted
Xylene, o-, m-, p- or mixed isomers	Xylene, o-, m-, p- or mixed isomers	HSE	HSE	Xylene – all isomers	1330-20-7	Xylene	1330-20-7		Yes		HCV
Xylidine, all isomers											Deleted
Yttrium											Deleted
Zinc chloride						Zinc chloride	7646-85-7				Deleted
Zinc oxide	Zinc oxide	HSE	HSE	Zinc and compounds - as Zn	7440-66-6	Zinc oxide	1314-13-2				REACH
Zirconium compounds (as Zr)						Zirconium	7440-67-7				Deleted

Annex 1 Pollution Inventory Substances with and without associated WEL's

PI substance with no WEL	**PI substance with a WEL**
Hydrobromofluorocarbons (HBFCs)	Acetaldehyde (Ethanal)
Acrolein	Acrylamide (2-Propenamide)
Aldrin	Acrylonitrile (2-Propenenitrile)
Anthracene	Allyl alcohol (2-Propen-1-ol)
Asbestos	Ammonia (NH3)
Benzo(a)pyrene	Aniline (Benzeneamine)
Benzo(b)fluoranthene	Antimony
Benzo (g,h,i)perylene	Arsenic
Benzo(k)fluoranthene	Benzene
Brominated diphenylethers- penta-, octa- & deca	Benzyl butyl phthalate (BBP)
Bromoethene	Benzyl chloride (Chloromethylbenzene)
Chlordane	Beryllium
Chlordecone	Boron (as Boron tribromide)
Chrysene	Butadiene (1,3-Butadiene)
Di(2-ethylhexyl)phthalate (DEHP)	Cadmium
Dichlorodiphenyltrichloroethane (DDT)	Carbon dioxide
Dieldrin	Carbon disulphide
Dioxins and furans (PCDDs/PCDFs) - as ITEQ	Carbon monoxide
Dioxins and furans (PCDDs/PCDFs) - WHO TEQ	Carbon tetrachloride (Tetrachloromethane)
Endrin	Chlorine & inorganic chlorine compounds as HCl
Ethyl toluene-all isomers	Chlorofluorocarbons (CFCs) (as dichlorofluoromethane)
Ethylene (Ethene)	Chloroform (Trichloromethane)

PI substance with no WEL	PI substance with a WEL
Ethylene dichloride (1,2-dichloroethane)	Chromium
Fluoranthene	Copper
Heptachlor	Dibutyl phthalate (DBP)
Hexabromobiphenyl	Dichloromethane (DCM) (Methylene chloride)
Hexabromocyclododecane	Diethyl ether
Hexachlorobenzene (HCB)	Diisopropyl ether
Hexachlorocyclohexane - all isomers (HCH))	Dimethyl sulphate
1-Hexane	Dimethylformamide
Indenol (1,2,3-cd)pyrene	Dioxane (1,4-dioxane)
Isoprene	Ethyl acrylate
Lead	Ethyl benzene
Lindane	Ethylene oxide (1,2 Epoxyethane)
Mercury	Fluorine and inorganic fluorine compounds as HF
Methane	Formaldehyde (Methanal)
2-Methyl-2-butene	Hexane
Mirex	Hydrochlorofluorocarbons (HCFCs) (chlorodifluoromethane)
Naphthalene	Hydrofluorocarbons (HFCs) (as 1,1,2,2-tetrafluoroethane)
Nitrogen oxides (NO and NO2) as NO2	Hydrogen chloride
Nitrogen oxides (only for LCPD reporting unit)	Hydrogen cyanide
Particulate matter - PM10	Hydrogen fluoride
Particulate matter - PM2.5	Maleic anhydride
Particulate matter – total	Manganese
Particulate matter (only for LCPD reporting unit)	Methanol
Pentachlorobenzene	Methyl bromide (Bromomethane)
Pentachlorophenol (PCP)	Methyl chloride (Chloromethane)
Pentane	Methyl chloroform (1,1,1-Trichloroethane)

PI substance with no WEL	PI substance with a WEL
Pentene -all isomers	4,4'-Methylene dianiline (MDA)
Perfluorocarbons (PFCs)	Nickel
Propylene (1-Propene)	Nitrous oxide
Sulphur dioxide (only for LCPD reporting unit)	p-Dichlorobenzene (1,4-Dichlorobenzene)
Sulphur oxides (SO2 and SO3) as SO2	Phenols - total as C
Tetrachloroethane (1,1,2,2-Tetrachloroethane)	Phosgene (Carbonic dichloride)
Tetrafluoroethylene	Polychlorinated biphenyls (PCBs)
Toluene diisocyanate – all isomers	Polychlorinated biphenyls (PCBs) - as WHO TEQ
Toxaphene	Propylene oxide
Vinyl acetate	Selenium
Zinc (oxide)	Styrene
	Sulphur hexafluoride
	Tetrachloroethylene (PER)
	Toluene
	Trichlorobenzene - all isomers
	Trichloroethylene
	Trimethylbenzene - all isomers
	Vanadium (as Vanadium pentoxide)
	Vinyl chloride
	Xylene - all isomers

Annex 2 Calabrese & Kenyon Method

The outline of the approach to deriving Ambient Air Level Goals (AALGs) proposed by Calabrese and Kenyon (1991) described here is taken from Gowers and Coleman (2004) and Searl and Maud (unpublished). This unpublished document has been provided for reference as part of this consultation.

The approach to deriving Ambient Air Level Goals (AALGs) proposed by Calabrese and Kenyon follows a decision tree procedure and is based on secondary literature sources. The type and quality of existing data and evaluations, as well as the most relevant toxicological endpoint, are taken into account in selecting the method to evaluate each substance considered. This approach, and the calculated AALGs, were intended to aid authorities in the US which were required to establish guidelines for ambient air quality. Thus, the proposed methods for deriving AALGs were designed to be consistent with the United States Environmental Protection Agency (US EPA) guideline procedures for risk assessment current at the time.

One of the key data sources they used to identify the health endpoints of concern and key references was the US National Institute for Occupational Safety and Health (NIOSH) Registry of the Toxic Effects of Chemical Substances (RTECS). They then derived further information from a range of secondary literature sources. The proposed method draws heavily on the US EPA's IRIS database as a validated and peer-reviewed source of evaluations. OELs, and their supporting datasets, are also integral to the decision-tree system.

In determining how to derive an AALG for a particular contaminant, the assessor should:

- Undertake a preliminary assessment to determine the toxicological endpoints of potential concern (carcinogenic, genotoxic, developmental, reproductive, systemic toxicity, eye/skin irritation);
- Determine the critical effect and the principal and supporting studies;
- Decide whether the substance should be assessed as a non-threshold carcinogen (using Quantitative Risk Assessment extrapolations) or as causing effects for which there are thresholds for toxicity;
- Assess the suitability of available OELs as the basis for the evaluation.

Carcinogens

The assessment procedure to evaluate a carcinogen is governed largely by its classification by the US EPA or the International Agency for Research on Cancer (IARC). Mathematical modelling is used to extrapolate from epidemiological or laboratory animal studies to estimate cancer risks from exposures to chemicals which have been classified as human carcinogens or probably carcinogenic to humans (Quantitative Risk Assessment, QRA). Thus, although Calabrese and Kenyon discuss the different procedures for assessing "threshold" and "non-threshold" effects, there is no explicit consideration of the mechanism of tumour induction in this decision step.

A lifetime excess cancer risk of 10-6 (1 in a million) is recommended as the basis of AALGs, although it is acknowledged that some jurisdictions may consider a higher (10-5) or lower (10-7) risk acceptable.

If a No Observed Adverse Effect Level (NOAEL) and Uncertainty Factor (UF) approach is adopted for the assessment of carcinogens in USEPA Group C or IARC Group 2B, it is recommended that the Uncertainty Factors (UFs) applied should incorporate (a) a 10-fold factor (rather than the otherwise recommended 5-fold factor) if a Lowest Observed Adverse Effect Level (LOAEL) is used rather than a NOAEL and (b) a factor to take into account the severity of effect and the weight of evidence.

NOAEL/UF Approach for Assessing Threshold Effects

At the time of publication of the AALGs (1991) the IRIS database did not include recommendations for Reference Concentrations (RfCs) (estimates of the air concentrations which would be likely to be without an appreciable risk of deleterious effects during a lifetime) for threshold, non-tumour inducing effects. Nonetheless, Calabrese and Kenyon make a very clear recommendation that an IRIS RfC should be used as the basis for the AALG whenever available.

If an RfC is not available, then the toxicological dataset should be used to identify the principal and supporting studies. The suitability of available OELs as the basis for an AALG derivation is also assessed. In deriving AALGs, Calabrese and Kenyon used only Recommended Exposure Limits (RELs) published by NIOSH and Threshold Limit Values (TLVs) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH), since these are primarily intended as health-based guidelines. Permissible Exposure Levels (PELs) promulgated by the Occupational Safety and Health Administration (OSHA) were not used. PELs are legally enforceable standards and, as such, their derivation must take into account wider considerations, such as detection limits and economic and technological feasibility, which should not be taken into account in deriving AALGs.

Nonetheless, Calabrese and Kenyon recognised that some of these non-health based aspects may also influence the recommendation of a REL or TLV. Thus, an OEL is not used as the basis of an AALG unless a careful assessment of the background studies has been undertaken and the following questions addressed:

Is the endpoint on which the OEL is based the critical endpoint for the general population?
Is there evidence that the OEL is a reasonable surrogate human NOAEL or LOAEL?

In view of the judgement required to make these assessments, Calabrese and Kenyon suggest that any AALGs based on OELs should be considered provisional. Unless an OEL is based directly on well-conducted human studies, data from a well-conducted laboratory animal inhalation study (of at least 90 days duration) are generally a better basis for the derivation of an AALG. However, even if the OEL doesn't unequivocally meet these two criteria, it is still preferable to base the AALG on the OEL rather than, for example, acute toxicological data or a short-term laboratory animal ingestion study.

Uncertainty Factors and Relative Source Contribution

In extrapolating from NOAELs (or LOAELs) in laboratory animal studies, a series of (multiplicative) uncertainty factors (UFs) are applied in order to ensure that possible

inter-species and inter-individual variability is taken into account and that the health criterion derived will be protective of sensitive members of the human population. Additional UFs can also take into account aspects such as the (in)adequacy of the available database and the severity of the potential adverse effects. Where an OEL is used as the basis of the AALG, adjustments to account for continuous, rather than occupational, exposure also have to be made.

In addition, the potential for exposure from other sources also needs to be taken into account. Calabrese and Kenyon proposed three options for the Relative Source Contribution (RSC) for air: 80%, 50% or 20%. A default of 50% is allocated unless there are data to suggest that this is inappropriate. As well as monitoring data and information on use patterns, physico-chemical data (indicating likely distribution in the environment) contribute to the selection of the appropriate RSC. Adjustment for RSC is not appropriate where the AALG is based on a concentration-dependent, non-cumulative endpoint such as irritation. Nor is it appropriate where there is strong evidence that an adverse effect is specific to inhalation. In this way, RSCs may be used to evaluate what might be a tolerable exposure from air in light of typical exposures via other routes.

Uncertainty factors recommended by Calabrese and Kenyon, and consideration of where an RSC adjustment should be applied, are outlined in Table A1.

Averaging Times

Calabrese and Kenyon note that averaging times should correspond to the expected duration of exposure that would be required for the manifestation of the toxic effect of concern. For AALGs, the following averaging times have been recommended:

- Annual – for AALGs based on carcinogenicity;
- 24-hour for AALGs based on other endpoints except;
- 8 hours (or other averaging time of OEL) for AALGs based on OELs.

However, they note that the actual time period selected for averaging is at the discretion of the authority and may be selected based on practical considerations of ambient air monitoring. However, such aspects have not been taken into account in deriving AALGs. Furthermore they themselves use two further averaging times; an ambient air concentration ceiling for certain effects and for the heavy metal, lead, they propose to use the US air quality standard averaging time of monthly mean concentrations.

Table 3 Uncertainty factors and relative source contribution

	Based on OELs	**Based on NOAEL/LOAEL**
Systemic, reproductive or developmental toxicity	UF 4.2 for continuous exposure 10 for inter-individual variation 5 if OEL approximates a LOAEL 1-10 as appropriate (eg database, severity of effect) RSC 20, 50 or 80%	UF 10 for inter-species variation 10 for inter-individual variation 5-10 if length of study not chronic 5 for use of a LOAEL 1-10 as appropriate (eg database, severity of effect) RSC 20, 50 or 80%
Sensory irritation	UF 10 for inter-individual variation 5 if OEL approximates a LOAEL 1-10 as appropriate (eg database, severity of effect) RSC Not applicable	UF 10 for inter-species variation 10 for inter-individual variation 5 for use of a LOAEL 1-10 as appropriate (eg database, severity of effect) RSC Not applicable
Carcinogen (where QRA is not used)	UF 4.2 for continuous exposure 10 for inter-individual variation 10 if OEL approximates a LOAEL 1-10 as appropriate (eg database, severity of effect) NB Factor for severity of effect is appropriate. RSC 20, 50 or 80%	UF 10 for inter-species variation 10 for inter-individual variation 5-10 if length of study not chronic 10 for use of a LOAEL 1-10 as appropriate (eg database, severity of effect) NB Factor for severity of effect is appropriate. RSC 20, 50 or 80%

Annex 3 Comparison between Calabrese & Kenyon EALs normalised to 1 hour averaging period with current H1 EALS derived from HSE EH40 OEL's

Substance	Short / Long Term	Current H1 EAL ug/m3	New C&K EAL ug/m3	Factor of difference
Acetic acid	ST	3700	2450	X 2
Acetone	ST	362000	860	x 420
Acetonitrile (ethane nitrile)	ST	10200	50.8	x 200
Ammonia (NH3)	ST	2500	170	x 15
Antimony	ST	150	0.014	x 10,700
Carbon tetrachloride (Tetrachloromethane)	ST	3900	8.5	x 460
Chloroform (Trichloromethane)	ST	2970	29.7	x 100
Chromium II, III & 0	ST	150	2.9	x 50
Copper dust, mist & fumes	ST	200	28.6	X 7
Dibutyl phthalate (DBP)	ST	1000	13.6	x 74
Dioxane (1,4-dioxane)	ST	36600	119	x 310
Ethyl acrylate	ST	6200	110	x 56
Ethyl benzene	ST	55200	237	x 230
Hexane	ST	21600	170	x 130
Hydrogen cyanide	ST	220	4.1	x 54
Maleic anhydride	ST	NA	2.8	New
Methanol	ST	33300	220	x 150
Methyl bromide (Bromomethane)	ST	5900	27	x 150
Methyl chloride (Chloromethane)	ST	21000	31	x 680
Methyl ethyl ketone MEK butan-2-one	ST	89900	4240	x 21
Naphthalene	ST	8000	5.1	x 1,500
Nitric acid	ST	1000	5	x 200
Phenols - total as C	ST	3900	11.9	x 330
Phosphoric acid (orthophosphoric acid)	ST	200	17	x 12
Propylene (1-Propene)	ST	NA	9300	New
Sodium hydroxide (caustic soda)	ST	200	40	x 5
Sulphuric acid mist or vapour	ST	300	2.9	x 100
Xylene – all isomers	ST	66200	85	x 780
Zinc (oxide)	ST	1000	6.9	x 150

Annex 4 Pollution Inventory Substances with their EALs

Reportable Substance: common name [alternative name]	CAS no.	EAL available
Inorganics		
Ammonia	7664-41-7	Yes
Asbestos	1332-21-4	No
Carbon dioxide	124-38-9	No
Carbon dioxide from qualifying renewable fuel sources	124-38-9	No
Carbon disulphide	75-15-0	Yes
Carbon monoxide	630-08-0	Yes
Hydrogen chloride	7647-01-0	Yes
Hydrogen cyanide	74-90-8	Yes
Nitrous oxide	10024-97-2	No
Phosgene	75-44-5	Yes
Sulphur hexafluoride	2551-62-4	Yes
Organics		
Acetaldehyde [Ethanal]	75-07-0	Yes
Acrolein	107-02-8	No
Acrylamide [2-Propenamide]	79-06-1	Yes
Acrylonitrile [2-Propenenitrile]	107-13-1	Yes
Aldrin	309-00-2	No
Allyl alcohol [2-Propen-1-ol]	107-18-6	Yes
Aniline [Benzeneamine]	62-53-3	Yes
Anthracene	120-12-7	No
Benzene	71-43-2	Yes
Benzo(a)pyrene	50-32-8	Yes
Benzo(b)fluoranthene	205-99-2	No
Benzo(g,h,i)perylene	191-24-2	No
Benzo(k)fluoranthene	207-08-9	No
Benzyl butyl phthalate (BBP)	85-68-7	No
Benzyl chloride	100-44-7	Yes
Butadiene [1,3-Butadiene]	106-99-0	Yes
Butene - all isomers	-	No
Carbon tetrachloride [Tetrachloromethane]	56-23-5	Yes
Chlordane	57-74-9	No
Chlordecone	143-50-0	No
Chloroform [Trichloromethane]	67-66-3	Yes
Chrysene	218-01-9	No
Dibutyl phthalate (DBP)	84-74-2	Yes
p-Dichlorobenzene [1,4-Dichlorobenzene]	106-46-7	Yes
Dichlorodiphenyltrichloroethane (DDT)	50-29-3	No
Dichloromethane [Methylene chloride]	75-09-2	Yes
Dieldrin	60-57-1	No
Di(2-Ethylhexyl)phthalate (DEHP)	117-81-7	No
Diethyl ether	60-29-7	Yes
Diisopropyl ether	108-20-3	Yes
Dimethyl sulphate	77-78-1	Yes
Dimethylformamide	68-12-2	Yes

Reportable Substance: common name [alternative name]	CAS no.	EAL available
1,4-Dioxane	123-91-1	Yes
Endrin	72-20-8	No
Ethyl acrylate	140-88-5	Yes
Ethyl benzene	100-41-4	Yes
Ethylene [Ethene]	74-85-1	No
Ethylene dichloride [1,2-Dichloroethane]	107-06-2	Yes
Ethylene oxide [1,2-Epoxyethane]	75-21-8	Yes
Ethyl toluene - all isomers	25550-14-5	No
Fluoranthene	206-44-0	No
Formaldehyde [Methanal]	50-00-0	Yes
Heptachlor	76-44-8	No
Hexabromobiphenyl	36355-1-8	No
Hexabromocyclododecane	25637-99-4	No
Hexachlorobenzene	118-74-1	No
1,2,3,4,5,6-Hexachlorocyclohexane (HCH)	608-73-1	No
Hexane	110-54-3	Yes
1-Hexene	592-41-6	No
Indeno(1,2,3-cd)pyrene	193-39-5	No
Isoprene	78-79-5	No
Lindane	58-89-9	No
Maleic anhydride	108-31-6	No
Methane	74-82-8	No
Methanol	67-56-1	Yes
Methyl bromide [Bromomethane]	74-83-9	Yes
2-Methyl-2-butene	513-35-9	No
Methyl chloride [Chloromethane]	74-87-3	No
Methyl chloroform [1,1,1-Trichloroethane]	71-55-6	Yes
4,4’-Methylene dianiline	101-77-9	No
Mirex	2385-85-5	No
Naphthalene	91-20-3	Yes
Pentachlorobenzene	608-93-5	No
Pentachlorophenol	87-86-5	No
Pentane	109-66-0	No
Pentene – all isomers	25377-72-4	No
Phenol	108-95-2	Yes
Propylene	115-07-1	No
Propylene oxide	75-56-9	Yes
Styrene	100-42-5	Yes
Tetrachloroethane [1,1,2,2-Tetrachloroethane]	79-34-5	No
Tetrachloroethylene	127-18-4	Yes
Tetrafluoroethylene	116-14-3	No
Toluene	108-88-3	Yes
Toluene diisocyanate - all isomers	-	No
Toxaphene	8001-35-2	No
Trichlorobenzene - all isomers	12002-48-1	Yes
Trichloroethylene	79-01-6	Yes
Trimethylbenzene - all isomers	25551-13-7	Yes
Vinyl acetate	108-05-4	Yes
Vinyl chloride	75-01-4	Yes
Xylene – all isomers	1330-20-7	Yes

Reportable Substance: common name [alternative name]	CAS no.	EAL available
Metals and compounds expressed as mass of the metal only		
Antimony and compounds - as Sb	7440-36-0	Yes
Arsenic and compounds - as As	7440-38-2	Yes
Beryllium and compounds - as Be	7440-41-7	Yes
Boron and compounds - as B	7440-42-8	No
Cadmium and compounds – as Cd	7440-43-9	Yes
Chromium and compounds - as Cr	7440-47-3	Yes
Chromium VI and compunds – as Cr	18540-29-9	Yes
Copper and compounds - as Cu	7440-50-8	Yes
Lead and compounds - as Pb	7439-92-1	Yes
Manganese and compounds - as Mn	7439-96-5	Yes
Mercury and compounds – as Hg	7439-97-6	Yes
Nickel and compounds – as Ni	7440-02-0	Yes
Selenium and compounds – as Se	7782-49-2	Yes
Vanadium and compounds - as V	7440-62-2	Yes
Zinc and compounds - as Zn	7440-66-6	Yes
Other substance groups reported as total mass unless otherwise stated		
Brominated diphenylethers – penta-, octa- and deca-BDE	-	No
Chlorine and inorganic compounds - as HCl	7782-50-5	Yes
Chlorofluorocarbons (CFCs)	-	No
Dioxins and furans (PCDDs/PCDFs) - as WHO- and I-TEQ	-	No
Fluorine and inorganic compounds - as HF	7782-41-4	Yes
Halons	-	No
Hydrobromofluorocarbons (HBFCs)	-	No
Hydrochlorofluorocarbons (HCFCs)	-	No
Hydrofluorocarbons (HFCs)	-	No
Nitrogen oxides - NO and NO2 as NO2	-	Yes
Non-methane volatile organic compounds (NMVOCs)	-	No
Particulate matter - PM2.5	-	Yes
Particulate matter - PM10	-	Yes
Particulate matter – total	-	No
Perfluorocarbons (PFCs)	-	No
Polychlorinated biphenyls (PCBs)	1336-36-3	Yes
Polychlorinated biphenyls (PCBs) - as WHO TEQ	1336-36-3	Yes
Sulphur oxides - SO2 and SO3 as SO2	-	Yes
Other individual organic compounds – required only if releases total more than 5 tonnes of any individual organic compound not covered in Part 2.	-	N/A
Other individual halogens – required only if releases total more than 1 tonne of any individual halogens not covered in Part 2.	-	N/A
Other individual acid forming gases – required only if releases total more than 1 tonne of any individual acid	-	N/A

Reportable Substance: common name [alternative name]	CAS no.	EAL available
forming gases not covered in Part 2.		

Large Combustion Plant Directive – required only from sites affected by the LCPD.

Nitrogen oxides	-	Yes
Particulate matter	-	Yes
Sulphur dioxide	-	Yes

Annex 5 Environment Agency hazard characterisation method

Our overall approach is similar to the approach we have used in deriving Health Criteria Values for exposure to contaminated land. Our report "Human health toxicological assessment of contaminants in soil" (Environment Agency, 2009), describes the toxicological basis and approaches to deriving Health Criteria Values (HCVs) that serve as benchmarks for protecting human health from exposure to contaminated land. However, it should be noted that EALs are used in a different context (the prevention of current and future pollution), from the use of HCVs in prioritising historical contamination, and differences in the detail reflect this.

We envisage that the derivation of Tolerable Concentrations in Air (TCA) using this method would, in most cases, rely on assessing existing evaluations and reviews, adopting the TCA which most closely reflects the Environment Agency's preferred method. Where such evaluations are not available, it may be necessary to derive a TCA from first principles. We propose to publish the details of the derivation of each of the TCAs.

We will place the highest priority on developing TCAs for substances taking into account several factors including:

- The number of permitted installations emitting the substance;
- The quantity of the substance emitted;
- The existence of high quality standards from EPAQS or WHO;
- The availability of Environment Agency Health Criteria Values for inhalation via the CLEA programme;
- The availability of existing authoritative expert opinion and evaluations;
- The existence of adequate standard DNELs/DMELs obtained under REACH.

Although for many toxicological effects there is a threshold below which no adverse effects will occur, for some effects there may be no discernable threshold (eg carcinogens). For such substances, there is a risk of an adverse effect at even very low levels of exposure, although the likelihood of an effect decreases with decreasing exposure. The Environment Agency will take different approaches to characterising the hazard from these two types of effect.

Chemicals where the critical effect has a threshold

Figure A1 shows schematically the proposed method to use to derive the TCAs for those chemicals for which there is an observed critical effect threshold.

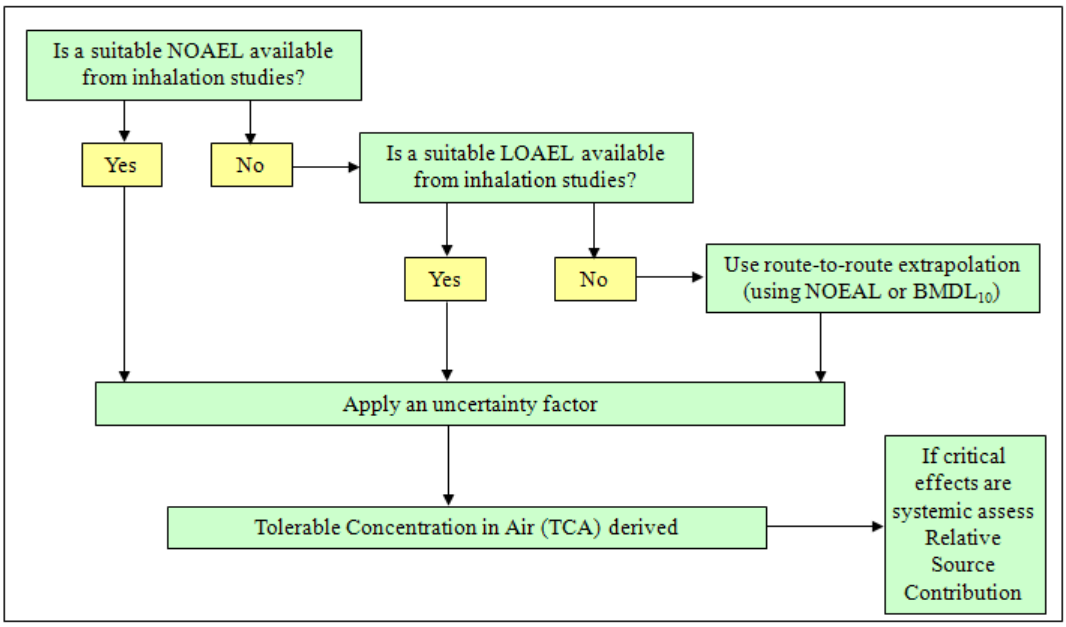

Figure A1: Derivation of Tolerable Concentrations in Air for chemicals with a critical effect threshold.

Many of the expert evaluations of human impacts rely extensively on data from laboratory animal experiments. Where no human data are available, the NOAEC (or LOAEC or BMCL10) obtained from these experiments are adjusted using uncertainty factors to take into account factors such as inter- and intra-species variability, adequacy of database, use of LOAEL, short duration of critical study, severity of effect etc. The Tolerable Concentration in Air is calculated by dividing the threshold value (NOAEC, LOAEC or BMCL10) by the uncertainty factor.

Where the critical effects are systemic (i.e. they are of a generalised nature or occur at a site distance from the site of entry of the chemical) it can be important to account for exposures via other routes and from other sources (eg in the diet or drinking water) to ensure that total exposure remains below the threshold dose. The Environment Agency proposes to assess this Relative Source Contribution (RSC) where data on background exposure via other routes (RSC) are available. RSCs may be used to evaluate what might be a tolerable exposure from air in the light of typical exposure via other routes. In some cases, we will adjust the TCA to take account of the RSC.

Chemicals where the critical effect has no threshold

The method applied to derive the TCAs for those chemicals where there is no observed critical effect threshold (eg genotoxic carcinogens) is demonstrated in Figure A2 below.

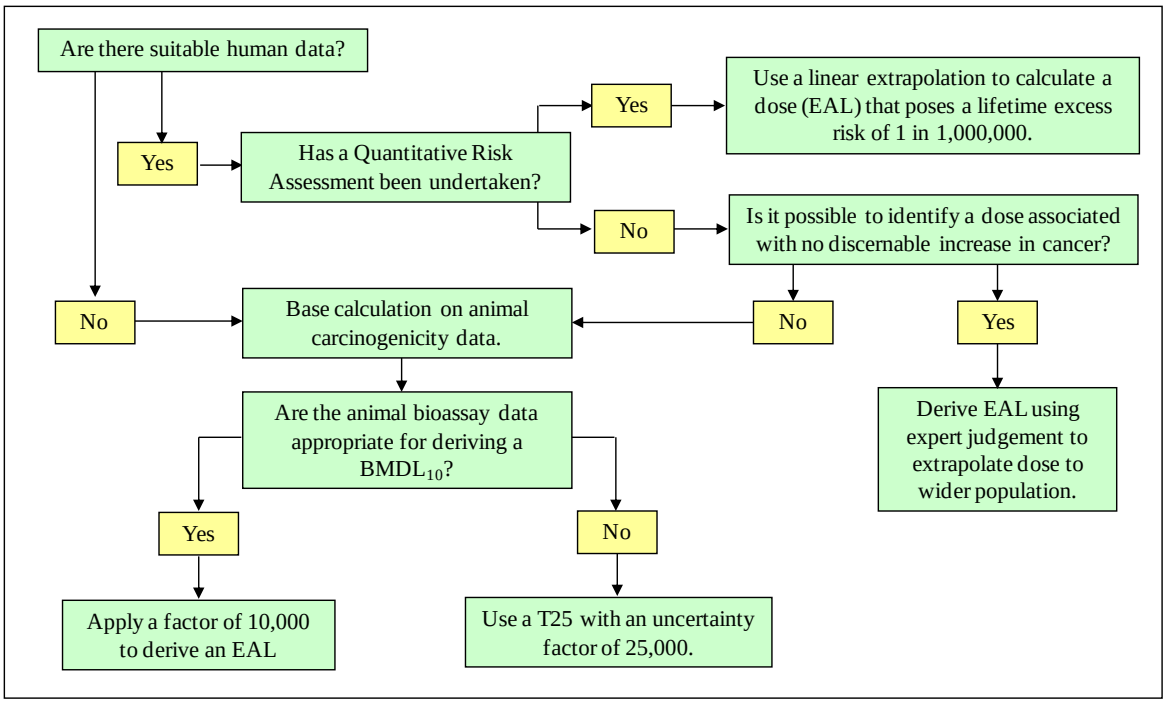

Figure A2: Derivation of Tolerable Concentrations in Air for carcinogens.

The Environment Agency do not propose to apply RSC adjustments in the derivation of EALs for genotoxic carcinogens. This is because risk management for these substances is not based on aiming to maintain total exposures at a level below a toxic threshold. Guidelines for carcinogens are normally based on exposures believed to pose a negligible risk and evaluations are of additional/excess risk posed by a particular source.

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