



Using our 2012 methodology to derive new Environmental Assessment Levels for emissions to air

Revision of 10 existing EALs and derivation of two new EALs

Date: October 2020

We are the Environment Agency. We protect and improve the environment.

We help people and wildlife adapt to climate change and reduce its impacts, including flooding, drought, sea level rise and coastal erosion.

We improve the quality of our water, land and air by tackling pollution. We work with businesses to help them comply with environmental regulations. A healthy and diverse environment enhances people's lives and contributes to economic growth.

We can't do this alone. We work as part of the Defra group (Department for Environment, Food & Rural Affairs), with the rest of government, local councils, businesses, civil society groups and local communities to create a better place for people and wildlife.

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Executive summary

Environmental Assessment Levels (EALs) are used by the Environment Agency to judge the acceptability of proposed emissions to air from industrial sites, and their relative contribution to the environment. EALs represent a pollutant concentration in ambient air at which no significant risks to human health are expected. In 2012 we ran a consultation to identify a new hierarchy for the derivation of EALs. You can view the consultation document and its responses <u>here.</u>

As part of that consultation, we made a commitment to undertake further engagement prior to adopting any new substance specific EALs.

Working with Public Health England, we are proposing to change EALs for 10 existing substances and introduce two new substances EALs using the revised methodology. The supporting document (a chemical dossier) can be found in Appendix I.

We also propose to withdraw the published EAL for arsenic and use the 4th Daughter Directive¹ Target Value as the regulatory benchmark.

The purpose of this round of consultation is to follow up on the previous consultation, implement the revised methodology, and consult on proposed new EALs for 12 substances. Subject to our consultation response, we will use the proposed values in our regulatory activities.

1. About this consultation

The Environment Agency uses Environment Assessment Levels (EALs) to judge the acceptability of proposed emissions to air from industrial processes, and their relative contribution to the environment. EALs represent a pollutant concentration in ambient air at which no significant risks to human health are expected.

In 2012 we ran a consultation to identify a new hierarchy for the derivation of EALs and published our response in 2015 (<u>www.gov.uk/government/consultations/derivation-of-new-environmental-assessment-levels-to-air</u>). We made a commitment that prior to introducing any new EALs, a further round of public consultation would be held to ask for comments on proposed substance-specific levels, which we would then consider before their adoption.

There are currently 88 substances with EALs published on GOV.UK (<u>www.gov.uk/guidance/air-emissions-risk-assessment-for-your-environmental-permit</u>). Using the revised methodology and working with Public Health England (PHE), we have derived new EALs for 9 existing substances and two new substances. We also propose to withdraw the published EAL for Arsenic, relying instead on the environmental standards set out in the 4th Daughter Directive.

The purpose of this consultation is to implement the revised methodology, consult on the changes to the EALs for 10 substances, and on the new EALs for 2 substances associated with carbon capture and storage.

2. Background

2.1 What are Environmental Assessment Levels and why do we need them?

European and National Environmental Standards exist only for a limited number of substances emitted to air. Therefore, regulators-derived benchmarks for other substances are published, known as "Environmental Assessment Levels" (EALs).

EALs for emissions to air represent a pollutant concentration in ambient air at which no significant risks to human health are expected.

Although EALs do not carry any statutory basis, they are a benchmark for harm against which any exceedance should be viewed as unacceptable. They are needed to ensure that we have the right level of protection in place for emissions from the sites which we regulate, in order to protect human health.

2.2 How are Environmental Assessment Levels used in environmental risk assessments?

Our methodology for assessing the impact of emissions to air from the sites we regulate is outlined in our guidance "Air emissions risk assessment for your environmental permit", published at www.gov.uk/guidance/air-emissions-risk-assessment for your environmental permit".

Based on the nature of the release and the type of sensitive receptors nearby, operators need to compare the impact of their emissions to air against the relevant environmental standards:

- Ambient Air Directive Limit Values
- Ambient Air Directive and 4th Daughter Directive Target Values
- UK Air Quality Strategy Objectives
- Environmental Assessment Levels
- Predicted Environmental Concentration targets for protected conservation areas.

2.3 Which substance-specific Environmental Assessment Levels are changing and why?

The current EALs are based on a percentage of the Health and Safety Executive's (HSE) Occupational Exposure Limits (OEL). Following a HSE review of its approach to occupational exposure, a large number of substances are no longer assigned an OEL. Hence the need for the Environment Agency to develop new EALs for substances we continue to encounter in our regulatory activities.

Using Pollution Inventory data from 2016, we have identified the substances with existing EALs which were reported above the substance reporting threshold. We have used this information to focus on these key substances.

In addition, to address the use of solvents in the new Carbon Capture and Storage technology, in consultation with PHE we have derived EALs for two new substances. Mono-ethanolamine (MEA) is a solvent used in post-combustion carbon capture plants and Nitrosodimethylamine (NDMA) is a by-product of the use of MEA.

The new EALs in Section 3 are the first to be developed using the new methodology and are presented for public consultation.

2.4 How have we derived these new EALs?

We have derived the new EALs using the methodology outlined in our 2012 consultation. The approach for each substance is described in <u>Appendix 1</u>, which presents a short chemical dossier for each substance.

It should be noted that in the original consultation we opted to use an Excess Lifetime Cancer Risk of 1 in 1 million. However, following a further review of this methodology, and having regard for the derivation of statutory air quality limits, we have opted to apply the 1 in 100,000 Excess Lifetime Cancer Risk in the derivation of these new EALs.

It is accepted that in the case of chemicals where the critical health effect exhibits no threshold (such as genotoxic carcinogens), there is a risk to health at any level of exposure. The principle of 'as low as reasonably practicable' (ALARP) is applied to risk management for these industrial chemicals.

We apply the excess lifetime cancer risk (ELCR) approach to the derivation of EALs where there is sufficient human data on dose-response from either environmental or occupational epidemiology. What constitutes an appropriate minimal level of ELCR for these carcinogens in order to protect the general public depends on a range of chemical-specific factors (both technical and practical) and is partly a socio-economic decision. The ELCR is usually in the range 1 in 100,000 to 1 in 1,000,000. We are proposing the application of the 1 in 100,000 ELCR as consistent with the current land contamination approach, and appropriate for the chemicals under consideration. For example, the grounds for using an ELCR of 1 in 100,000 for tetrachloroethylene and vinyl chloride relates to current estimates of ambient concentrations in air.

Q1. What are your thoughts about our change in thinking on the Excess Lifetime Cancer Risk in deriving the EALs?

3. The proposed changes

The table below lists the substances for which new EALs are proposed. It outlines the pollutant, its current EALs and proposed new EALs, for both short term and long term using our revised methodology. Long term means annual mean unless stated otherwise.

Pollutant	Current Short Term (1hr) EAL	Current Long Term EAL	Proposed new Short Term EAL	Proposed new Long Term EAL
Arsenic		0.003 µg/m3		0.006 µg/m3
				Target Value*
Benzene	195 µg/m3	5 µg/m3	30 µg/m3**	No change
Chloroform	2,970 µg/m3	99 µg/m3	Withdraw ST EAL	100 µg/m3**
Chromium VI		0.00025 µg/m3	No change	No change
Ethylene dichloride	700 µg/m3	42 µg/m3	Withdraw ST EAL	3 µg/m3
Methyl chloroform	222,000 µg/m3	11,100 µg/m3	Withdraw ST EAL	5,000 µg/m3**
Mono-ethanolamine	No current EAL	No current EAL	400 µg/m3	100 µg/m3**
Naphthalene	8,000 µg/m3	530 µg/m3	Withdraw ST EAL	3 µg/m3**
NDMA ***	No current EAL	No current EAL	None proposed	0.2 ng/m3
Tetrachloroethylene	8,000 µg/m3	3,450 µg/m3	Withdraw ST EAL	40 µg/m3**
Trichloroethylene	1,000 µg/m3	1,100 µg/m3	Withdraw ST EAL	2 µg/m3
Vinyl chloride	1,851 µg/m3	159 µg/m3	1300 µg/m3**	10 µg/m3

Table 1. Proposed EALs based on new methodology

* 4th Daughter Directive (2004/107/EC) Target Value is a level fixed with the aim of avoiding, preventing or reducing harmful effects on human health and/or the environment as a whole, to be attained where possible over a given period

** 24 hour mean value

*** N-nitrosodimethylamine

Q2. Which of the current substance EALs that we are proposing to change do you routinely use to assess the impact of your proposed emissions in support of permit applications?

3. We are planning to use the new methodology to revise existing EALs for other substances in the future. To help us prioritise our work please list any other substance EALs from the GOV.UK list that are relevant to your permit applications.

4. Carbon Capture Storage and new EALs

Two new EALs are included within this consultation relating to Carbon Capture & Storage (CCS). One of these is N-nitrosodimethylamine (NDMA), which is one of a closely related group of compounds called nitrosamines. NDMA is one of the most potent nitrosamines, but it is not the only nitrosamine emitted in a typical mixture. Other compounds such as N-nitrosodiethanolamine (NDELA) and N-nitrosomorpholine (NMOR) may also be released in lesser or greater quantities than NDMA. In order to determine whether further work on EALs for nitrosamines is required, we need further empirical data from industry on:

- total nitrosamine concentrations in emissions from CCS installations (specifying how this is measured and the compounds included in the total) based on plant design and solvent type
- concentrations of individual nitrosamines in emissions including NDMA.

As a first step, we are proposing to compare the total nitrosamine concentration from plant emissions with the EAL for NDMA. In order to understand the implications for this, we need information to define what compounds should be in a total nitrosamine measurement and whether this varies from plant to plant. We need to know whether NDMA is always present in plant emissions and the contribution it makes to the total concentration. We need to understand the proportion of emissions that may be represented by other compounds such as NDELA and NMOR, which potentially have a lower carcinogenic potency than NDMA.

To help operators collect this emissions information, we are providing in Appendix 2 a list of guidelines and methods for stack emissions monitoring and testing for CCS facilities (amine scrubbing).

Q4. Please provide any information regarding the speciation, concentration or content of stack emissions from CCS plants, or other information that you think may help us in further development work on EALs for nitrosamines.

5. Financial implications

We appreciate that the proposed changes in the value of EALs may result in you incurring either one-off or recurring costs. Evidence of either or both should be presented if possible. We want to understand the financial impacts of the proposed changes on individual businesses, industries and sectors.

Q5. Please provide an estimate of the financial costs of the proposed EAL changes on your or your sectors operations, supported by cost data, to include a choice of alternative substance if relevant.

6. Timing implications

Once the new EALs are published on GOV.UK, we are proposing to implement their introduction:

- either when a new permit application or substantial permit variation is made, or
- following sector reviews.

We would like your thoughts on the proposed timing for the implementation of the new EALs.

Q6. What are your thoughts on our proposed timing for the implementation of the new EALs?

7. Future EAL development

Finally, we foresee the need for development of new EALs in the future, as new substances are brought into use and into the market. We would like industry to consider taking more of a role in future EAL development, through the application of the methodology we have developed.

Q7. Please tell us of any substances, for which we do not currently have an EAL on the gov.uk website, for which you would like to see an EAL developed.

Q8. What role do you think industry should play in proposing new values?

8. Other comments

We really value your feedback on our proposals.

Q9. Please tell us if you have any further comments on any of the information presented in our consultation and provide as much information as possible to support your answer.

9. Responding to this consultation

9.1 How to respond

The consultation runs from 2 November 2020 to 7 February 2021 and you can view both the consultation document and questions online at https://consult.environment-agency.gov.uk/environment-and-business/new-air-environmental-assessment-levels. You can submit your response using our online tool which provides an easy and efficient way to respond. It will also help us to gather and summarise responses quickly and accurately as well as reducing the cost of the consultation.

If you would prefer to submit your response by email please send your completed response form with the subject header of **New EALs Consultation Response** to <u>EAL.consultation@environment-agency.gov.uk</u> by 7 February 2021.

We encourage you to contact us through the online portal or by email. However, if you would prefer to submit your response by letter please send your completed response form by 7 February 2021 to this address:

Environment Agency Environment & Business Regulated Industry Monitoring & Assessment Team Horizon House Deanery Road Bristol BS1 5AH

To request a hard copy of the consultation document or the response form, please contact us on 03708 506 506 (Monday to Friday, 8am to 6pm).

Please respond to the consultation no later than 7 February 2021. After this time we will consider your feedback to form our final proposal to submit to government for approval.

9.2 Publishing our consultation response

We will publish our full response on both GOV.UK and Citizen Space within 12 weeks of this consultation closing and before we implement any changes. It will include a summary of the comments and queries we received. It will not include individual comments. We will outline our recommendations which take these into account. We will circulate a link to our response to all consultees and other interested parties who have asked to be kept informed. We will not respond individually to consultees.

9.3 How we will use your information

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.

9.4 Consultation principles

We are running this consultation in accordance with the guidance set out in the government's Consultation Principles which can be found at https://www.gov.uk/government/publications/consultation-principles-guidance.

If you have any questions or complaints about the way this consultation has been carried out, please contact <u>consultation.enquiries@environment-agency.gov.uk</u>.

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

9.5 Privacy notice

The Environment Agency would like to keep you informed about the outcomes of the consultation. If you would like to receive an email acknowledging your response and be notified that the summary of responses has been published please provide your email address with your response.

By providing us with your email address you consent for us to email you about the consultation. We will keep your details until we have notified you of the response document publication.

We will not share your details with any other third party without your explicit consent unless required to by law.

You can withdraw your consent to receive these emails at any time by contacting us at: EAL.consultation@environment-agency.gov.uk.

9.6 Your email address

The Environment Agency is the data controller for the personal data you provide. For further information on how we deal with your personal data please see our Personal Information Charter on GOV.UK or contact our Data Protection team.

Address: Data Protection team, Environment Agency, Horizon House, Deanery Road, Bristol, BS1 5AH

Email: dataprotection@environment-agency.gov.uk

Appendix 1 Dossier of substances included within our 2020 EAL Consultation

Introduction

This document provides a short technical background to the decisions that underpin the derivation of the new Environmental Assessment Levels (EALs) in the Environment Agency's consultation.

The document briefly summarises the toxicity to human health, primarily via inhalation, of priority substances in air following short-term and long-term exposure. Substances have been prioritised for EAL review based on their appearance in the Pollution Inventory for 2016 (the last published dataset). Ten substances listed here have an existing EAL, which will be withdrawn following this consultation and replaced with the recommended guideline. In addition, EALs are introduced for two new substances.

Toxicity summaries are provided for each of the twelve substances presented in the consultation. Key individual references for each substance are provided at the end of each summary. A list of abbreviations and definitions is provided at the end of the document.

Practical Compliance Constraints on a Short Term EAL

Depending on the toxicity of a substance, both a short- and long-term EAL may be appropriate, reflecting adverse effects to health over different exposure periods. Notwithstanding the possible differences in the toxicology (dose-response and endpoints) between potential short-term and long-term health effects, there is a practical limit on the value of a short-term EAL if the long-term EAL or statutory value is not to be exceeded. The limit depends on whether the long-term EAL is based on either a threshold or a non-threshold health effect.

Threshold Effects

The long-term EAL is usually based on a 24-hour time weighted mean concentration. The highest short-term air concentration that will not exceed the long-term EAL can be estimated by multiplying the long-term value by 24 for a short-term hourly upper limit. There is no short-term daily upper limit.

Non-thresholded Effects

The long-term EAL is usually based on the annual mean (either 90% of 1-hour values or all 24-hour values averaged over a year). The highest short-term air concentration that will not exceed the long-term EAL or statutory value can be estimated by multiplying the long-term value by either 365 or 8,760 (24 * 365) for a short-term daily or hourly upper limit, respectively.

Any proposed short-term EAL should be less than the appropriate daily or hourly upper limit to be useful without any practical constraint imposed by the need to ensure compliance with the long-term EAL or statutory value. If a recommended short-term EAL is equal to or exceeds the upper limit then it is assumed that compliance with the long-term EAL will be protective of short-term exposures and health effects.

1. Arsenic and its compounds (CAS Number 7440-38-2 and others)

Arsenic is a naturally occurring metalloid, which is commonly present in air as mixtures of arsenite (As III) and arsenate (As V) compounds (EPAQS 2009). Because of the high vapour pressure of some compounds such as arsenic (III) trichloride, it can be present as vapour and particulate matter in the environment.

Arsenic is classified as a human carcinogen and the most important effect for inhaled inorganic arsenic appears to be the induction of lung cancer. There is insufficient evidence to conclude whether it is genotoxic via the inhalation route or whether the relationship between dose and risk is linear at low levels of exposure (EPAQS 2009).

Regulatory Guidelines

Ambient Air Directive Target Value	6 ng/m ³ as an annual mean of total content in PM_{10}
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Recommended Environmental Assessment Level in Air

Long-term EAL	Not recommended (use Target Value)
Short-term EAL	None (constrained by compliance with the regulatory guideline)

Supporting Information

Since there is a statutory Target Value for inorganic arsenic under the Ambient Air Directive, no longterm EAL has been recommended. Short-term exposures to higher concentrations of inorganic arsenic (mostly As III) have reported respiratory irritation and death. A short-term EAL of 1.1 mg/m³ as an hourly mean can be calculated from the 1-hour Acute Exposure Guideline Level (AEGL-2) value after correction from arsenic (III) trioxide to arsenic (NAC/AEGL 2009).² Although this shortterm EAL is in agreement with the indicative safe range suggested by EPAQS (2009) for non-

² A correction of 0.379 was applied to account for the relative mass difference between arsenic (74.92 g/mol) and arsenic (III) trioxide (197.84 g/mol).

carcinogenic effects, it is still greater than an hourly upper limit of 0.053 mg/m³ (the practical compliance constraint calculated from the Target Value).

References

EPAQS, 2009. Metals and Metalloids. Expert Panel on Air Quality Standards. ISBN 978-0-85521-185-1.

NAC/AEGL, 2009. Interim Acute Exposure Guideline Levels (AEGLs) for Arsenic Trioxide (CASRN 1327-53-3).

2. Benzene (CAS Number 71-43-2)

Benzene is a petroleum hydrocarbon used in many workplace applications (EPAQS 1994). It is ubiquitous in ambient air through volatilisation and combustion processes and is naturally broken down by chemical reactions in the atmosphere.

Benzene is a well-known genotoxic carcinogen with chronic exposure associated with the development of certain leukaemias (ATSDR 2007, EPAQS 1994, WHO 2000 and 2010). Short-term exposures to higher levels of benzene have been associated with a range of health effects including immunotoxicity; haematotoxicity; respiratory, cardiovascular, neurological and renal toxicity; skin and eye irritation; and in some cases death (ATSDR 2007).

Regulatory Guidelines

Ambient Air Directive Limit Value0.005 mg/m³ as an annual mean
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Recommended Environmental Assessment Level in Air

Long-term EAL	Not recommended (use Limit Value)
Short-term EAL	30 µg/m³ as a 24-hour mean

Supporting Information

Since there is a statutory Limit Value for benzene under the Ambient Air Directive, no long-term EAL has been recommended. A short-term EAL of 0.03 mg/m³ as a 24-hour mean concentration is recommended to protect the general public, which is based on the acute Minimal Risk Level (MRL) proposed by ATSDR (2007) for immunological effects.

References

ATSDR, 2007. Toxicological Profile for Benzene, TP3.

EPAQS, 1994. Expert Panel on Air Quality Standards for benzene. ISBN 0-11-752859-5.

WHO, 2000. Air Quality Guidelines for Europe, Second Edition.

WHO, 2010. Guidelines for Indoor Air Quality: Selected Pollutants.

3. Chloroform (CAS Number 67-66-3)

Chloroform, also known as trichloromethane, is a clear, colourless and volatile liquid at room temperature with a pleasant etheric odour (IPCS 2004). Its main uses are in the production of halocarbons and pesticides, as a solvent and degreasing agent, in fire extinguishers, and in the rubber industry. Chloroform is also unintentionally formed during chlorination processes such as paper bleaching and water treatment.

Adverse effects from exposure to chloroform have been reviewed by several authoritative bodies (ATSDR 1997, IPCS 2004, NAC/AEGL 2012). Acute exposures to high concentrations of chloroform can cause central nervous system (CNS) depression, sub-narcotic effects, ocular and respiratory irritation, nausea, vomiting and dizziness. The main targets of systemic short-term and chronic toxicity are the CNS, liver and the kidneys. Available epidemiological data is equivocal on its potential carcinogenicity in humans, although it is a carcinogen of the liver and kidney in animals. Tumours seen in animal studies are induced only at doses causing chronic cytotoxicity and most authoritative bodies consider chloroform is not genotoxic.

Regulatory Guidelines

None

Recommended Environmental Assessment Level in Air

Long-term EAL	100 μg/m³ as a 24-hour mean
Short-term EAL	None (constrained by compliance with the long-term EAL)

Supporting Information

Long-term chronic Health-Based Guidance Values (HBGVs) have been proposed by ATSDR (1997), IPCS (2004), and the industry REACH Dossier, based on either liver or kidney toxicity. Although they are derived from different pivotal studies, there is close agreement between them (from 0.099 – 0.18 mg/m³). A long-term EAL of 0.1 mg/m³ as a 24-hour mean is recommended to protect the general public, which is based on the chronic MRL proposed by ATSDR (1997), who concluded that liver toxicity was the most sensitive effect.

Short-term exposures to higher concentrations of chloroform results in a range of reported effects including liver toxicity, foetotoxicity, and death over exposure durations from hours to days (ATSDR 1997, NAC/AEGL 2012). A proposed short-term EAL of 0.5 mg/m³ as a 24-hour mean, which is based on the acute MRL proposed by ATSDR (1997), would exceed the long-term EAL.

References

ATSDR, 1997. Toxicological Profile for Chloroform, TP 6.

IPCS, 2004. Chloroform, Concise International Chemical Assessment Document (CICAD) 58. Geneva: International Programme on Chemical Safety.

NAC/AEGL, 2012. Acute Exposure Guideline Levels for Selected Airborne Chemicals. Volume 12. ISBN 978-0-309-25501-1.

4. Chromium VI and its compounds (CAS Number 7440-47-3)

Chromium is a metallic element, which is hard, dense and resistant to chemical attack (EPAQS 2009). Hexavalent chromium (Cr VI) is used for chrome plating, manufacture of dyes and pigments, leather tanning, wood preservation, drilling muds, rust corrosion inhibitors, textiles and toners.

Cr VI is a potent carcinogen with evidence from occupational studies on associations between exposure and increased risk of lung cancer (ATSDR 2012, EPAQS 2009, WHO 2000). Inhalation of Cr VI causes local nasal and lung irritation and altered pulmonary function, and systemic haematological effects (microcytic, hypochromic anaemia) and also reproductive toxicity (effects on male reproductive organs). Chromium sensitization, the major immunological effect of Cr VI, typically presents as allergic contact dermatitis resulting from dermal exposures in sensitized individuals, although respiratory effects of sensitization (asthma) may also occur. Accidental or intentional ingestion of extremely high doses of Cr VI compounds by humans has resulted in severe respiratory, cardiovascular, gastrointestinal, haematological, hepatic, renal, and neurological effects as part of the sequela leading to death.

Regulatory Guidelines

None

Recommended Environmental Assessment Level in Air

Long-term EAL	0.00025 μ g/m ³ as Cr VI (annual mean in PM ₁₀ fraction)
Short-term EAL	None (constrained by compliance with the long-term EAL)

Supporting Information

Long-term HBGVs have been proposed based on increased incidence of lung cancer in occupational studies. Air concentrations associated with an excess lifetime cancer risk (ELCR) at 1 in 100,000 have range from 0.00025 μ g/m³ to 0.0008 μ g/m³. The recommended long-term EAL is 0.00025 μ g/m³ as Cr VI (the annual mean from the PM₁₀ fraction), which is based on the unit risk calculated by WHO (2000).

Short-term exposure to higher concentrations of Cr VI results in potential sensitisation with respiratory irritation reported in workers exposed to 2 μ g/m³ (ATSDR 2012). This is comparable with an hourly upper limit of 2.2 μ g/m³ and much higher than a daily upper limit of 0.09 μ g/m³ (the practical compliance constraints calculated from the long-term EAL). Therefore a short-term EAL is not recommended.

References

ATSDR, 2012. Toxicological Profile for Chromium. TP 7.

EPAQS, 2009. Metals and Metalloids. Expert Panel on Air Quality Standards.

US EPA, 1998. Chemical Assessment Summary for Chromium VI, CASRN 18540-29-9.

WHO, 2000. Air Quality Guidelines for Europe, Second Edition.

5. Ethylene dichloride (CAS Number 107-06-2)

Ethylene dichloride or 1,2-dichloroethane is a high volume industrial chemical, which is primarily used in the manufacture of vinyl chloride, mostly for polyvinyl chloride (PVC) production, and in the production of other organic solvents (SCOEL 2016).

Exposure to ethylene dichloride causes CNS depression and also respiratory and ocular irritation at high concentrations (ATSDR 2001, SCOEL 2016, and WHO 2000). It is also known to cause systemic toxicity to the liver and the kidneys. Exposures at relatively low concentrations in animal studies have resulted in pulmonary oedemas. It is genotoxic *in vitro*, but results are less conclusive *in vivo*. Increased incidence of tumours in rodents has been observed in the liver, lung and mammary glands following long-term inhalation exposure (Nagano et al. 2006).

Regulatory Guidelines

None

Recommended Environmental Assessment Level in Air

Long-term EAL	3 μg/m³ as an annual mean
Short-term EAL	None (insufficient evidence)

Supporting Information

The recommended long-term EAL of 0.003 mg/m^3 as an annual mean is derived from the Benchmark Concentration (BMC₁₀) of 30.8 mg/m³ (analysis of data from Nagano et al. 2006) provided by the industry REACH dossier divided by an appropriate margin of safety of 10,000. While SCOEL (2016) and the industry REACH dossier both addressed the prior lack of evidence on a dose-response relationship between inhalation and increased tumour incidence, only the latter also corrected for continuous exposure.

There was insufficient evidence on which to derive a short-term EAL. The current 8-hour workplace exposure limit (WEL) of 21 mg/m³ (HSE 2020) is close to the hourly upper limit of 27 mg/m³ and greatly exceeds a daily upper limit of 1.1 mg/m³ (the practical compliance constraint calculated from the long-term EAL).

References

ATSDR, 2001. Toxicological Profile for 1,2-Dichloroethane. TP 38.

HSE, 2020. Workplace exposure limits. EH40/2005 (Fourth Edition). London: TSO.

NAGANO K., UMEDA Y., SENOH H., GOTOH K., ARITO H., YAMAMOTO S., MATSUSHIMA T., 2006. Carcinogenicity and chronic toxicity in rats and mice exposed by inhalation to 1,2dichloroethane for two years. J. OCCUP. HEALTH, 48, 424 – 436.

SCOEL, 2016. Dichloroethane (Ethylene dichloride). Recommendation from the Scientific Committee on Occupational Exposure Limits. SCOEL/REC/302.

WHO, 2000. Air Quality Guidelines for Europe, Second Edition.

6. Methyl Chloroform (CAS Number 71-55-6)

Methyl chloroform or 1,1,1-trichloroethane is a colourless volatile liquid at room temperature with an ethereal chloroform-like odour (ATSDR 2006). Mainly used in production of hydrochlorofluorocarbons, it was also widely used in vapour degreasing and cold cleaning of metal parts, adhesives, coatings and inks, textiles, and in electronics. However, it has been rapidly phased out under the Montreal Protocol because of its ozone-depletion properties and is registered under REACH for only intermediate uses.

Adverse effects from exposure to methyl chloroform have been reviewed by several authoritative bodies (ATSDR 2006, IPCS 1992, and US EPA 2007). The most sensitive target for acute and short-term toxicity is the CNS. Evidence for chronic exposures is limited.

Regulatory Guidelines

None

Recommended Environmental Assessment Level in Air

Long-term EAL	5,000 μg/m³ as a 24-hour mean
Short-term EAL	None (constrained by compliance with the long-term EAL)

Supporting Information

There is a lack of evidence on the long-term effects from chronic exposure to methyl chloroform. The long-term EAL of 5 mg/m³ as a 24-hour mean is based on the Reference Concentration (RfC) proposed by US EPA (2007), who considered acute (neurotoxicity), as well as sub-chronic and chronic effects (liver toxicity) in deciding on the most health protective HBGV.

Short-term exposure to higher concentrations of methyl chloroform results in symptoms of CNS depression and subtle neurological effects (ATSDR 2006). A proposed short-term EAL of 10.8 mg/m³ as a 24-hour mean, which is based on the acute MRL proposed by ATSDR (2006), would exceed the long-term EAL.

References

ATSDR, 2006. Toxicological Profile for 1,1,1-Trichloroethane, TP 70.

IPCS, 1992. 1,1,1-Trichloroethane, Environmental Health Criteria Monograph 136. International Programme on Chemical Safety: World Health Organization.

US EPA, 2007. Chemical Assessment Summary for 1,1,1-Trichloroethane CASRN 71-55-6.

7. Monoethanolamine (CAS Number 141-43-5)

Monoethanolamine (MEA), 2-aminoethanol, or ethanolamine is a colourless, viscous liquid with an ammoniacal odour (HSE 2016), whose vapour is denser than air. It is widely used in industry in the production of detergents and soaps, dyestuffs, rubber vulcanisation, and as a scrubber for acidic gases in enclosed atmospheres such as submarines. MEA is used in a range of consumer products including cosmetics and personal care products, washing and cleaning products, coating products, biocides, inks and toners, and adhesives and sealants.

Regulatory Guidelines

None

Recommended Environmental Assessment Level in Air

Long-term EAL	100 μg/m³ as a 24-hour mean
Short-term EAL	400 μg/m³ as a 1-hour mean

There are few authoritative reviews on the adverse effects from exposure to MEA (CNESST 2019, HSE 2016, SCOEL 1996). It is a strong respiratory, ocular and skin irritant. CNESST (2019) concluded that MEA is a skin and respiratory sensitiser, but this opinion has been disputed (HSE 2001 and 2016).

Supporting Information

Short-term inhalation exposure to MEA vapour results in localised respiratory irritation. The pivotal study for derivation of a short-term EAL is the sub-acute duration rodent study submitted as evidence in support of an application under REACH (HSE 2016) with a No Observed Adverse Effect Concentration (NOAEC) of 10 mg/m³. No correction for continuous exposure is applied because irritation is considered a concentration-dependent effect. The short-term EAL of 0.4 mg/m³ as a 1-hour mean is obtained by dividing the NOAEC by an uncertainty factor (UF) of 25.

The critical health effects from long-term inhalation exposure are considered to be respiratory irritation and neurobehavioral toxicity. The pivotal study for derivation of a long-term EAL is the same sub-acute rodent study used for the short-term EAL (HSE 2016). The long-term EAL of 0.1 mg/m³ as a 24-hour mean is obtained by dividing the NOAEC of 10 mg/m³ by a UF of 100. Although no UF for sub-acute to chronic duration is required because irritation is considered a concentration-based effect, an additional UF was included to take account of uncertainty over long-term effects.

References

<u>CNESST, 2019. Agents causing occupational asthma with key references.</u> <u>COMMISSION DES</u> <u>NORMES, DE L'ÉQUITÉ, DE LA SANTÉ ET DE LA SÉCURITÉ DU TRAVAIL, QUÉBEC,</u> <u>CANADA.</u>

HSE, 2016. Substance Evaluation Report for 2-aminoethanol, Version 2. Health and Safety Executive.

SCOEL, 1996. Recommendation from the Scientific Committee on Occupational Exposure Limits for Ethanolamine. SCOEL/SUM/24.

8. Naphthalene (CAS Number 91-20-3)

Naphthalene is the smallest and most volatile polycyclic aromatic hydrocarbon (WHO 2010). It is a combustion product from fossil fuels, which are released from industrial and domestic heat and power sources and from vehicle exhausts. It is an important component of creosote, a commonly used wood preservative, and was used historically in mothballs.

Adverse effects from exposure to naphthalene have been reviewed by a few authoritative bodies (ATSDR 2005, US EPA 1998, and WHO 2010). Most evidence for the toxicity of naphthalene comes from animal experiments. The principal health concerns are respiratory tract lesions, including respiratory tract carcinogenicity demonstrated in animal studies, and haemolytic anaemia in humans (WHO 2010).

Regulatory Guidelines

Recommended Environmental Assessment Level in Air

Long-term EAL	3 μg/m³ as a 24-hour mean
Short-term EAL	None (insufficient evidence)

Supporting Information

Long-term chronic HBGVs have been proposed by ATSDR (2005), US EPA (1998), and WHO (2010). They were all based on a lowest observable adverse effect level (LOAEL) for respiratory toxicity in rodents from 2-year inhalation studies. Variation in the final guidelines were in part the result of differences in use of toxicokinetic models and adjustments as well as the chosen UF. A long-term EAL of 0.003 mg/m³ as a 24-hour mean is recommended to protect the general public, which is based on the chronic MRL proposed by ATSDR (2005). Its derivation is also consistent with the recently proposed indoor air quality guideline (IAQ) for the UK (Shrubsole et al. 2019).

There was insufficient evidence on which to derive a short-term EAL.

References

ATSDR, 2005. Toxicological profile for naphthalene, 1-methylnaphthalene, and 2methylnaphthalene. TP 67.

SHRUBSOLE C., DMITROULOPOULOU S., FOXALL K., GADEBERG B., DOUTSI A., 2019. IAQ guidelines for selected volatile organic compounds (VOCs) in the UK. BUILDING AND ENVIRONMENT, 165, 106382.

US EPA, 1998. Chemical Assessment Summary for Naphthalene CASRN 91-20-3.

WHO, 2010. Guidelines for Indoor Air Quality: Selected Pollutants. ISBN 978 92 890 0213 4.

9. N-nitrosodimethylamine (CAS Number 62-75-9)

N-nitrosamines are hydrocarbons with the generic chemical formula of (R_1R_2) -N-N=O, where R_1 and R_2 are alky groups, which are formed primarily by reaction of amines with oxidising agents including chlorine disinfectants, nitrites, and atmospheric nitrogen oxides. They have been detected in flue gases from carbon capture systems, which use amine-based solvents as reagents (SEPA 2014). N-nitrosodimethylamine (NDMA) is one of the most widely studied and has been detected in cosmetics, food, medicines, and drinking water (IPCS 2002).

N-nitrosamines are potent carcinogens (NIPH 2011, IPCS 2002) with epidemiological and animal studies reporting associations between exposure and cancers of the stomach, bowel, liver, kidneys, nasal cavity, and lungs. However, most available data for NDMA concerns its oral toxicity and evidence on other adverse effects is limited.

Regulatory Guidelines

None	

Recommended Environmental Assessment Level in Air

Long-term EAL	0.0002 μg/m³ as an annual mean
Short-term EAL	None (insufficient evidence)

Supporting Information

Carcinogenicity is the critical health effect from long-term chronic exposure to NDMA, although limited inhalation data is available. While other organisations have based their HBGVs on oral exposure, there is concern that NDMA is more potent via the inhalation route. The recommended long-term EAL of 0.2 ng/m³ as an annual mean is derived from a Benchmark Dose Level (BMDL₁₀) of 0.023 mg/m³ (a new analysis of data on the incidence of tumours in the naval cavity in rodents from an inhalation study by Klein et al. 1991), adjusted for continuous exposure, divided by an appropriate margin of safety of 10,000.

There was insufficient evidence on which to derive a short-term EAL.

References

IPCS, 2002. N-Nitrosodimethylamine, Concise International Chemical Assessment Document 38. Geneva: International Programme on Chemical Safety, World Health Organization.

KLEIN R.G., JANOWSKY I., POOL-ZOBEL B.L., SCHEMZER P., HERMANN R., AMELUNG F., SPIEGELHALDER B., ZELLER W.J., 1991. Effects of long-term inhalation of Nnitrosodimethylamine in rats. IARC SCIENTIFIC PUBLICATIONS, 105, 322 – 328. NIPH, 2011. Health Effects of Amines and Derivatives Associated with CO2 Capture: Nitrosamines and Nitramines. Norwegian Institute of Public Health: Oslo.

SEPA, 2014. Review of amine emissions from carbon capture systems. Version 2.01. Scottish Environment Protection Agency: Stirling.

10. Tetrachloroethylene (CAS Number 127-18-4)

Tetrachloroethylene, tetrachloroethene, perchloroethylene, or PERC is a readily volatile, colourless liquid at room temperature and pressure with an ether-like odour (WHO 2010). It is a widely used industrial chemical as a raw material from hydrofluorocarbons, a degreaser and an industrial solvent. It is used in the manufacture of metal parts, textiles, paint removers, printing inks, adhesives, fragrances and in specialised cleaning fluids and dry-cleaning agents.

Adverse effects from exposure to tetrachloroethylene have been reviewed by several authoritative bodies (ATSDR 2019, US EPA 2012, and WHO 2010). The main health effects reported in human and animal studies from inhalation exposure are cancer and non-carcinogenic effects including irritation (ocular, respiratory tract, and skin), and toxicity to CNS, liver and kidneys (WHO 2010). Recent reviews focus on its neurotoxicity.

Regulatory Guidelines

None

Recommended Environmental Assessment Level in Air

Long-term EAL	40 μg/m³ as a 24-hour mean
Short-term EAL	None (constrained by compliance with the long-term EAL)

Supporting Information

Long-term chronic HBGVs have been based on various endpoints including kidney toxicity, carcinogenicity, and neurotoxicity. Recent reviews by ATSDR (2019) and US EPA (2012) have concluded that neurotoxicity is the most sensitive effect. A long-term EAL of 0.04 mg/m³ as a 24-hour mean is recommended to protect the general public, which is based on the chronic MRL proposed by ATSDR (2019). It is also consistent with the recently proposed IAQ for the UK (Shrubsole et al. 2019).

Short-term exposures to higher concentrations have resulted in neurotoxicity at blood concentrations similar to those seen following chronic exposure (ATSDR 2019). Therefore a short-term EAL is not recommended.

References

ATSDR, 2019. Toxicological Profile for Tetrachloroethylene. TP 18.

SHRUBSOLE C., DMITROULOPOULOU S., FOXALL K., GADEBERG B., DOUTSI A., 2019. IAQ guidelines for selected volatile organic compounds (VOCs) in the UK. BUILDING AND ENVIRONMENT, 165, 106382.

US EPA, 2012. Chemical Assessment Summary for Tetrachloroethylene (Perchloroethylene); CASRN 127-18-4.

WHO, 2010. Guidelines for Indoor Air Quality: Selected Pollutants. ISBN 978 92 890 0213 4.

11. Trichloroethylene (CAS Number 79-01-6)

Trichloroethylene or trichloroethene is a volatile, colourless liquid with a sweet ethereal odour (WHO 2010). It is mainly used for vapour degreasing and cold cleaning of manufactured metal parts and for industrial dry cleaning, paper and textile printing, the production of printing inks, extraction processes, and paint production.

Adverse effects from exposure to trichloroethylene have been reviewed by several authoritative bodies (ATSDR 2019, US EPA 2011, WHO 2010). The main targets of its toxicity in humans and laboratory animals are the CNS, the liver and kidneys, the immune system, the male reproductive system and the developing foetus. Available human data supports an association between exposure and cancers of the kidneys, liver, and the lymphatic system.

Regulatory Guidelines

None

Recommended Environmental Assessment Level in Air

Long-term EAL	2 μg/m³ as an annual mean
Short-term EAL	None (constrained by compliance with the long-term EAL)

Supporting Information

Long-term chronic HGBVs have been proposed by ATSDR (2019), US EPA (2011), and WHO (2010), which are based on various endpoints including developmental toxicity and carcinogenicity. A long-term EAL of 0.002 mg/m³ as an annual mean is recommended to protect the general public,

which is based on the unit risk calculated by US EPA (2011) for cancers of the kidneys, liver, bile duct, and Non-Hodgkin lymphomas at an ELCR of 1 in 100,000. The approach is consistent with the derivation of the recently proposed IAQ for the UK (Shrubsole et al. 2019).

Short-term exposure to higher concentrations results in neurotoxicity (ATSDR 2019). However, the available evidence is limited and existing guidelines exceed any daily or hourly limits derived from practical compliance constraints imposed by the long-term EAL. Therefore a short-term EAL is not recommended.

References

ATSDR, 2019. Toxicological Profile for Trichloroethylene. TP 19.

SHRUBSOLE C., DMITROULOPOULOU S., FOXALL K., GADEBERG B., DOUTSI A., 2019. IAQ guidelines for selected volatile organic compounds (VOCs) in the UK. BUILDING AND ENVIRONMENT, 165, 106382.

US EPA, 2011. Chemical Assessment Summary for Trichloroethylene CASRN 79-01-6.

WHO, 2010. Guidelines for Indoor Air Quality: Selected Pollutants. ISBN 978 92 890 0213 4.

12. Vinyl Chloride (CAS Number 75-01-4)

Vinyl chloride, chloroethene, or chloroethylene is a colourless and flammable gas with a slightly sweet odour (NAC/AEGL 2012). It is heavier than air and accumulates close to the ground. It is a high volume industrial chemical used as a monomer in the production of PVC plastics.

Adverse effects from exposure to vinyl chloride have been reviewed by several authoritative bodies (ATSDR 2006, US EPA 2000, WHO 2000). The CNS and the liver are the primary targets for acute and chronic exposure, respectively. It is a human carcinogen associated with cancers of the blood vessel linings at sites including liver and lungs.

Regulatory Guidelines

None

Recommended Environmental Assessment Level in Air

Long-term EAL	10 μg/m³ as an annual mean
Short-term EAL	1,300 μg/m³ as a 24-hour mean

Supporting Information

Long-term chronic HBGVs have been proposed by ATSDR (2006), US EPA (2000), WHO (2000), and the industry REACH Dossier. They were based either on liver toxicity (non-cancer endpoint) or carcinogenicity, with the latter being the most sensitive effect. At an ELCR of 1 in 100,000, the HBGVs are in the range 0.002 to 0.02 mg/m³. A long-term EAL of 0.01 mg/m³ is recommended to protect the general public, which is based on the unit risk calculated by WHO (2000).

Short-term exposures to higher concentrations of vinyl chloride results in symptoms of CNS depression and other neurological effects (ATSDR 2006, NAC/AEGL 2012). A short-term EAL of 1.3 mg/m³ as a 24-hour mean is recommended to protect the general public, which is based on the acute MRL proposed by ATSDR (2006) for delayed ossification in mice offspring.

References

ATSDR, 2006. Toxicological Profile for Vinyl Chloride. TP 6.

NAC/AEGL, 2012. Acute Exposure Guideline Levels for Selected Airborne Chemicals. Volume 11. ISBN 0-309-25481-7.

US EPA, 2000. Chemical Assessment Summary for Vinyl Chloride, CASRN 75-01-4.

WHO, 2000. Air Quality Guidelines for Europe, Second Edition.

Abbreviations and Definitions

AEGL	Acute Exposure Guideline Levels for Hazardous Substances. They are threshold exposure limits for the general public and are applicable to emergency exposure periods ranging from 10-minutes to 8-hours.
AEGL-2	An air concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects, or an impaired ability to escape.
AQS	Air Quality Standard
ATSDR	Agency for Toxic Substances and Disease Registry
ВМС	Benchmark Concentration
BMD	Benchmark Dose
BMDL	Lower 95 Percentile Confidence Level of the Benchmark Dose
CNS	Central Nervous System
ELCR	Excess lifetime cancer risk. It is defined as the estimated probability of an individual developing cancer over a lifetime as a result of exposure to a chemical. It is an "excess" cancer risk because there is already a background risk (about one in four) of an individual getting cancer. A minimal excess lifetime cancer risk is typically defined in the range of 1 in 10,000 to 1 in 1,000,000. In developing EALs, the default is 1 in 100,000.
EPAQS	Department of the Environment Expert Panel on Air Quality Standards (disbanded)
HBGV	Health-Based Guidance Value
HSE	Health and Safety Executive
IARC	International Agency for Research on Cancer

IAQ	Indoor Air Quality Guideline
IPCS	International Programme on Chemical Safety (World Health Organization)
LOAEL	Lowest Observable Adverse Effect Level
MRL	Minimal Risk Level is defined as an estimate of the amount of a chemical a person can eat, drink, or breathe each day without a detectable risk to health. MRL values are developed for health effects other than cancer.
NAC/AEGL	National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances
NOAEC	No Observed Adverse Effect Concentration
RfC	Reference Concentration is defined as an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure for a chronic duration (up to a lifetime) to the population
	(including sensitive sub-groups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is generally use in the US EPA assessments of non-cancer effects.
UF	(including sensitive sub-groups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is generally use in the US
UF WEL	(including sensitive sub-groups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is generally use in the US EPA assessments of non-cancer effects.
	 (including sensitive sub-groups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is generally use in the US EPA assessments of non-cancer effects. Uncertainty Factor Workplace Exposure Limit is defined as a concentration in air that protects workers from toxic substances either over a short-term – a short term exposure limit (STEL, 15 minutes) or long-term – a time weighted average

Appendix 2 Stack emissions monitoring: carbon capture and storage (amine scrubbing)

As Carbon Capture and Storage (CCS) is a relatively new technology, we are providing guidelines below for the monitoring and testing of emissions from CCS facilities, for operators to apply as they begin commissioning individual installations.

- location and facilities must be compliant with Environment Agency Technical Guidance Note (TGN) M1 (available from <u>www.mcerts.net</u>)
- if droplets are present, sampling must be carried out isokinetically
- MCERTS accreditation is required for specified methods, where available, unless agreed in writing.

The following sampling and testing protocols should be used for CCS stack emissions monitoring:

- Homogeneity assessment (EN 15259 plus Method Implementation Document (MID) for EN 15259). If the stack gas is homogeneous at the sample plane, then single point sampling is permitted.
- Stack gas velocity and volumetric flow rate EN 16911-1
- Oxygen (if required) EN 14789
- Ammonia EN ISO 21877 or procedural requirements of EN 14791 (Sulphuric acid (H₂SO₄) absorber solution)
- Amines procedural requirements of CEN TS 13649 (silica gel tubes) or use procedural requirements of EN 14791 (Hydrochloric acid (HCI) absorber solution). Consider analysis for the following:
 - o 2-ethanolamine (MEA)
 - Methyl diethanolamine (MDEA)
 - Diethanolamine (DEA)
 - o Ethylamine
 - o Methylamine
 - o Dimethylamine
 - Nitrosamines CEN TS 13649 (Themosorb/N sorbent cartridge) or use procedural requirements of EN 14791 (Sulphamic acid (H₃NSO₃) solution). Consider analysis for the following
 - N-nitrosodiethanolamine (NDELA)
 - o N-nitrosodimethylamine
 - o N-nitrosomorpholine
 - o N-nitrosomethylethylamine
 - o N-nitrosodiethylamine
 - N-nitrosodiisopropylamine
 - o N-nitrosodiisobutylamine
 - o N-nitrosodipropylamine
 - o N-nitrosodibutylamine
 - o N-nitrosopiperdine
 - o N-nitrosopyrrolidine
 - o N-nitrosodibenzylamine
- Formaldehyde CEN TS 13649 (silica gel tube) or US EPA M316 (Deionised (DI) water or change to DNPH)

- Acetaldehyde CEN TS 13649 (silica gel tube) or US EPA M316 (DI water or change to DNPH)
- TGN M22 or CEN TS 17337 (Fourier Transform Infrared (FTIR) analyser) may be used as an alternative method to those above, unless isokinetic sampling is required. This provides real time continuous data for periods of several hours or longer.

For further information on any of the monitoring protocols above, please contact <u>EAL.consultation@environment-agency.gov.uk</u>.

Glossary

CCS	Carbon Capture and Storage	
CEN	European Committee for Standardisation	
DNPH 2,4-Dinitrophenylhydrazine (Brady's reagent, Borche's reagent)		
EN	European Standard	
FTIR	Fourier Transform Infrared	
H ₃ NSO ₃	Sulphamic acid	
H_2SO_4	Sulphuric acid	
HCI	Hydrochloric acid	
ISO	International Standards Organisation	
MCERTS	Environment Agency Monitoring Certification Scheme	
MID	Method Implementation Document	
TGN	Technical Guidance Note	
TS	Technical Specification	
US EPA	United States Environmental Protection Agency	

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