Summary of responses to our 2012 public consultation "Hierarchy for the derivation of new Environmental Assessment Levels (EALs) to air"

November 2015

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We operate at the place where environmental change has its greatest impact on people's lives. We reduce the risks to people and properties from flooding; make sure there is enough water for people and wildlife; protect and improve air, land and water quality and apply the environmental standards within which industry can operate.

Acting to reduce climate change and helping people and wildlife adapt to its consequences are at the heart of all that we do.

We cannot do this alone. We work closely with a wide range of partners including government, business, local authorities, other agencies, civil society groups and the communities we serve.

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Foreword

This document summarises our response to issues raised through our public consultation entitled "Derivation of new Environmental Assessment Levels (EALs) to Air". The consultation ran from 19th December 2011 to 1st April 2012, and in a limited number of cases was extended on request for a further four weeks to 30th April 2012.

We use 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.

This consultation was designed to identify a new hierarchy for the derivation of new EALs following the change by the Health and Safety Executive in their appraisal of the occupational exposure of workers. Substances found in the workplace that previously were assigned an Occupational Exposure Limit (OEL), were assessed by HSE prior to being reassigned a Workplace Exposure Limit (WEL). OELs were once the primary source of EALs, however the reduction in substances assigned a WEL meant the number that could retain an EAL were significantly reduced, down from over 400 to less than 100. Since occupational exposure was part of the original hierarchy for the derivation of EALs it was necessary to establish a new hierarchy. Only then could new EALs be derived for use by us in our environmental permitting activities.

Our proposal to establish the base of the new hierarchy on chemical toxicity rather than occupational exposure prompted a series of questions to which we received eleven responses. The responses came from industries regulated through the Environmental Permitting Regulations 2010, from fellow regulators, from bodies responding on behalf of public health and from other interested parties.

Once this document is published and the hierarchy established, new EALs will be derived for use by us in our EPR permitting activities. Prior to using any new EALs a further round of public consultation will be held where we will ask for comments on proposed substance specific EALs, which we will then consider before their adoption.

Executive summary

H1 is our principal horizontal guidance note that cuts across all functions regulated by us under the Environmental Permitting Regulations 2010. H1 advises operators applying for a bespoke permit under the Environmental Permitting Regulations on the appropriate measures to use to manage health and environmental risks from the operation of their activity.

Launched in modular form in April 2010, H1 now includes an Overview document supported by eleven technical annexes. The Overview document serves to guide readers only to the annexes that relate to their activities, thereby streamlining risk assessments undertaken in support of the permitting process.

We use 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. EALs are located within Annex F of H1.

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, 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.

The consultation included eighteen questions. Whilst the thrust of the consultation was to seek responses in respect of the technical issues arising from a change to a hierarchy based upon chemical toxicity, we were also keen to learn how readers felt the consultation had operated in its electronic form and how it had been managed. This document is a summary of the consultation. It includes the questions we have posed, a summary of the comments we received and our responses to the issues raised.

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Acknowledgements

We would like to thank all those who participated in this H1 public consultation. Their names are included in Appendix 1. In particular, we would like to thank the Centre for Radiation, Chemicals and Environmental Hazards, part of Public Health England for their contribution to this document.

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1.1 Summary of responses to our public consultation "Hierarchy for the derivation of new Environmental Assessment Levels (EALs) to air."

Emissions to air from major industry are regulated by us through the provisions of the Environmental Permitting Regulations 2010 (formerly the Pollution Prevention and Control Regulations). We compare predicted ambient pollutant concentrations with environmental assessment levels (EALs) when assessing the acceptability of proposed emissions and best environmental options.

The derivation of EALs had previously followed a hierarchy of data sources published within earlier versions of H1. These included sources such as the UK's Expert Panel on Air Quality Standards (EPAQS), EU Directives or the World Health Organisation. However, EPAQS was merged into the Department of Health's Committee on the Medical Effects of Air Pollutants (COMEAP) in 2009 and so in the future the Environment Agency will be looking to this group and other government bodies of similar scientific standing for its advice.

Occasionally substances are identified in impact assessments submitted to us for which we do not have an EAL. So to enable us to carry out its permitting activities some new EALs may have to be derived from other sources.

Although occupational exposure was the largest single source of EALs it was one of the lower tiers of the old derivation hierarchy. As a result of the new HSE policy on occupational exposure, we took the view that the make-up of the hierarchy should be reviewed. Whilst the top half of the hierarchy remains largely unchanged, the previous reliance on EALs derived from Occupational Exposure Levels through the use of generic safety factors has moved to an approach based more closely on the specific characteristics (toxicity) of the substance. We have also focused on those substances reported through our Pollution Inventory. It was our proposed changes to the structure of the hierarchy for deriving EALs that we sought views on.

To encourage a response we couched the changes in a series of eighteen questions. Presented in electronic format, promoted on our website and via email to interested parties, we asked respondents to reply in writing and send their replies into us over the internet or by post to a central address. Most respondents chose the electronic route.

In their responses the chemical industry wholeheartedly supported the use of REACH as a source of new EALs. Whilst we acknowledge the role played by REACH, and its potential for deriving new EALs, we have identified some circumstances where we feel our in-house method may be more appropriate. Meanwhile health professionals thought the proposed hierarchy seemed appropriate. They considered the adoption of existing health-based guidelines for concentrations of contaminants in air as the basis for EALs to be pragmatic.

Some of our questions focused on the science behind the various methodologies within the hierarchy. As a consequence we did receive requests for clarification on a number of technical issues behind the science and these are answered in the specific sub-sections of the report.

1.2 The Consultation Questions

The questions asked were:

Question 1: Are you in agreement with the proposed hierarchy discussed in Section 5? If not please tell us how you would improve it.

Question 2: Annex 4 contains a list of substances encountered on the Environment Agency's Pollution Inventory for which no EAL is currently available. Are there any other substances for which you feel an EAL should be derived? Please justify each nomination.

Question 3: Are there any further authoritative evaluations that should be considered aside from those listed in Section 7. If so please tell us.

Question 4a: Do you agree that the proposed method for the derivation of EALs for chemicals with a toxicological effect threshold (Section 7.1) is the most appropriate way forward in the development of revised EALs? If not please tell us what alternative would you propose and why?

Question 4b: Do you agree that the proposed method for the derivation of EALs for chemicals with a toxicological effect threshold (Section 7.1) is the most scientifically valid way forward in the development of revised EALs? If not please tell us what alternative would you propose and why?

Question 5a: Do you agree that the proposed method for the derivation of EALs for genotoxic carcinogens (Section 7.2) is the most appropriate way forward in the development of revised EALs? If not please tell us what other method could you propose and why?

Question 5b: Do you agree that the proposed method for the derivation of EALs for genotoxic carcinogens (Section 7.2) is the most scientifically valid way forward in the development of revised EALs? If not please tell us what other method could you propose and why?

Question 6: 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 EAL for genotoxic carcinogens? If you believe an alternative level of risk is appropriate please tell us what this should be and why?

Question 7: Where a "BMDL10 and large assessment factor" approach is used to derive EALs for genotoxic carcinogens, is 10,000 the most appropriate factor to use? If not please tell us what other factor would you recommend and why?

Question 8: Do you consider the proposed default averaging times for genotoxic carcinogenesis and most threshold effects are appropriate? If not please can you suggest defaults that might be appropriate to other endpoints?

Question 9: In section 7.4 do you support the Environment Agency proposal to include a Relative Source Contribution in its Hazard Characterisation Method for chemicals where the critical effect has a threshold? If not, please give your reasons.

Question 10: Do you support the Environment Agency proposal not to include an RSC in its Hazard Characterisation Method for chemicals where the critical effect is not systemic (e.g. sensory irritants) or does not have a threshold (eg genotoxic carcinogens)? If not, please give your reasons.

Question 11: When there are few data on public exposure by other routes do you support the proposed RSC default of 50%? If not, please tell us what other defaults could you justify?

Question 12: In section 8 do you think that our proposal to use REACH DNELs/DMELs derived for the "humans via the environment" exposure route is justified and legitimate as a source of EALs? If not please tell us what alternative would you propose and why?

Question 13: Do you feel that the potential use of IOELVs to derive environmental exposure is a valid and scientifically robust approach? If not please tell us what alternative would you propose and why?

Question 14: Do you support our proposed approach to the handling of DNELs/DMELs supplied to the ECHA ahead of publishing the values? If not please tell us what other approach would you propose and why?

Question 15: Do you support the use of our proposed in-house method for the derivation of new EALs where data is not available to us via the REACH process? If not please tell us what alternative would you 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?

1.3 Responses to questions one to eighteen

This section summarises the responses to the questions in the consultation.

Question 1: Are you in agreement with the proposed hierarchy discussed in Section? If not please tell us how you would improve it.

Summary

Generally speaking, trade bodies rejected the proposed hierarchy. Their preference was to use data that was less than 5 years old and to adopt a level of data scrutiny that could provide a robust indicator of potential health impacts. As a consequence the application of the Calabrese and Kenyon method, and to some extent our own methods, were considered less robust than the development of Workplace Exposure Limits (WELs) and European Air Quality Guidelines. REACH regulations were promoted by trade bodies as a primary data source. However another regulator pointed out that the REACH method for calculating the Derived Minimal Effect Level (DMEL) uses animal data to produce a numerical risk of cancer, an approach not recommended in the UK. Meanwhile health professionals thought the proposed hierarchy seemed appropriate and considered the adoption of existing health-based guidelines for concentrations of contaminants in air as the basis for EALs to be pragmatic.

1.1 A trade body challenged the appropriateness of using data more than 5 years old in a method positioned higher up the hierarchy.

Our response: Ideally we would like all EALs to be derived using methods at the top of the hierarchy but that has not been possible. So we have to use methods lower down and in some cases the source data from which the EALs were derived are older than five years. For example EU Limit Values were in force from early 2010 and some of the Air Quality Standards from 2005, and to date nobody has produced values to challenge the rigor of those standards. Within H1 we use such standards as absolute values, for example in assessing emissions of sulphur dioxide, oxides of nitrogen and particulate we do not take account of any exceedance permitted by those standards. For these reasons we have not put a time limit on sources of data and information that can be used in deriving new EALs.

1.2 The use of EPAQS data was not supported by one trade body as they suggested there is no clear mechanism for updating their existing standards as the group is no longer in existence.

Our response: We do not propose changing existing EPAQS standards for the current list of EALs, unless new evidence is found which supports such a move. In such situations we would consult government health professionals before proposing any change. Such changes would likely become part of a further round of public consultation before they were implemented.

1.3 A consultant asked if new EALs will be ranked in terms of their reliability/rigor, depending on the source data/position within hierarchy on which they are based?

Our response: Within our consultation document we have set out the changes we propose to make to the existing hierarchy for the derivation of new EALs. On the occasion where an EAL may be derived from more than one source within the hierarchy then the higher method within the hierarchy will hold sway.

1.4 A consultant suggested that EU manufacturers and importers of chemicals have vested interests in EALs being less stringent. And that reliance on data from these bodies is to be questioned.

Our response: We have said in our consultation document that Chemical Safety Reports submitted under REACH will be reviewed to ensure the information provided is adequate before the data is used to derive new EALs.

1.5 It was argued by one trade body that since the EPAQS committee was no longer in existence the use of Calabrese and Kenyon data, which the committee had previously approved, could not be supported.

Our response: Any EAL derived using the Calabrese and Kenyon method would be subject to consultation with government health professionals and the wider public before being implemented into the list of EALs.

1.6 It was observed by one consultant that European Environmental Quality Standards (EQS) should be the first priority as they are the only standards that can require an operator to go beyond BAT.

Our response: European Union (EU) Limit Values have the status which can require a regulator to impose permit standards beyond Best Available Techniques (BAT). However, EU Limit Values for air are subject to a political process in their derivation and therefore may not be based solely on scientific considerations. Air Quality Standards derived by EPAQS are based on scientific evidence, with particular reference to levels of airborne pollution at which no or minimal effects on human health are likely to occur. UK air quality standards or objectives do not require the regulator to go beyond BAT in their permitting activities.

1.7 By supplementing/supplanting an EQS for a substance with another value derived in the UK, a consultant argued that we potentially leave ourselves open to legal challenge and being accused of 'gold plating' regulation.

Our response: EPAQS standards are health based and so provide an appropriate source of data from which to derive EALs.

1.8 A difference in the risk level associated with the DNEL as opposed to the DMEL was highlighted by a consultant. They added that we should define what level of risk is acceptable and work from there.

Our response: Because they are derived for different types of toxicological effect, it would be difficult to define a comparable level of acceptable or tolerable risk across both DNELs and DMELs. DNELs are based on a "safety assurance" approach of ensuring that exposures are below an effect threshold. DMELs are derived for substances for which it is not possible to develop a DNEL because there is understood not to be a threshold for the critical effect (that is, there is considered to be a theoretical risk at any level of exposure).

Similarly, the method of deriving EALs for carcinogens (a non-threshold effect) are not always directly comparable: for example, a quantified estimate of cancer risk from a human study is not readily equitable with a margin of exposure approach to data from an animal study.

1.9 A trade body observed that excluding EU air quality limit values could lead to the inclusion of multiple assessment criteria (EALs and air quality standards) for individual pollutants and create unnecessary complications within the permitting process.

Our response: Some EU Limit Values and AQ objectives are based on a percentile compliance approach and so are not in a suitable format for use as an EAL. Moreover EU Limit Values have a different legal status compared with EALs so we assess their impact separately. See also our response to question 1.6.

1.10 It was argued by a trade body that to continue deriving EALs from WELs would provide continuation of a methodology familiar to the majority of stakeholders. This was supported by the lack of any published evidence to suggest an approach based on Occupational Exposure Limits (OELs) had not provided a high level of protection for human health in the locality of industrialised plant.

Our response: The derivation of Workplace Exposure Limits (WELs) included consideration of what could practicably be achieved within the workplace. We note that for most substances deriving EALs from WELs is not as protective of human health as EALs derived via our new hierarchy.

1.11 One trade body asserted the EU intended for the content of validated REACH dossiers to be used to address the potential toxicological impact of those substances on the general population. Since that was the stated aim of the Environment Agency why should it wish to circumvent the objectives of the REACH process.

Our response: We will consider REACH data once we have reviewed a sample of Chemical Safety Reports and are satisfied with their recommendations.

1.12 One operator highlighted the difference in transparency between the approach based on WELs and that of Calabrese and Kenyon (C & K) method. Signalling the lack of any track record for use of the C & K method in the UK, they suggested it was overtly conservative leading to the generation of EALs which were not achievable.

Our response: It is known that the Calabrese and Kenyon methodology produces low values for EALs. , However we note that for most substances EALs derived from WELs are not as protective of human health as EALs derived using our new hierarchy.

1.13 The same operator proposed a new hierarchy as follows:

- UK Expert Panel on Air Quality Standards
- EC Air Quality Directives - limit values and guidelines
- WHO Air Quality Guidelines for Europe
- DN(M)ELS derived using risk assessment guidance to support REACH
- Health & Safety Occupational Exposure Limits
- Environment Agency Tolerable Concentration in Air (TCA) methodology
- Environment Agency Criteria Values for inhalation
- Tolerable Concentration in Air using the Calabrese & Kenyon method

Our response: Please see our responses to questions 1.9 and 1.10 above. In addition, whilst the REACH methodology may be used to generate a large number of EALs quickly, there may be occasions where a particular substance features regularly within our permit determinations and in such situations we would want to use our in-house methodology to derive an EAL using a more in-depth review of the evidence. This

would place our in-house methodology higher within the hierarchy as proposed in our consultation.

1.14 A fellow regulator suggested that whilst the inclusion of REACH was appropriate as a source of information for deriving EALs, the methodology for producing DMEL is based on a quantitative risk assessment which produces a numerical estimate of cancer from animal data, and such an approach is not recommended in the UK.

Our response: We acknowledge that one of the two methods available to derive DMEL under REACH, linear extrapolation from animal bioassay data, is not recommended by the most recent advice from the UK Committee on Carcinogenicity (COC) on risk characterisation methods. We would therefore only consider DMELs that had been derived used the application of an assessment factor (10,000) to a suitable point of departure (BMDL10) that is consistent with UK advice on the derivation of minimal risk levels. We agree also that the REACH dossiers are an appropriate source of information for use in the derivation of EAL.

1.15 Health professionals advised that only health criteria values (HCVs) (based on threshold effects), recommended following the revised guidance described in our 2009 publication 'Human Health Toxicological Assessment of Contamination in Soils' should be used in this hierarchy.

Our response: We agree with health professionals that older health criteria values (prior to 2009) derived using the old CLR9 report for the development of Soil Guideline Values are not appropriate for the derivation of EALs. Only health criteria values published since 2009 using the updated methodology outlined in SR2[1] report will be considered.

1.16 It was observed by health professionals that when the proposed use of an EAL is for safety assurance (predicting that proposed releases are not a risk to public health) then the different sources of EALs is unlikely to be problematic. However, the potential inconsistency between EALs derived using different methods and types of data source might be important when appraising the best environmental option, or in evaluating risks to health if the predicted environmental concentrations exceed an EAL.

Our response: In assessing applications where background levels of pollutant are significant we may choose to use our in-house methodology to derive new EALs as described in answer 1.13.

1.17 Where compliance with an EAL derived using the Calabrese and Kenyon method was impractical, health professionals suggested that a fuller evaluation of the epidemiological and toxicological evidence might allow a less precautionary extrapolation from study data to tolerable concentration.

Our response: Where we have proposed an EAL based on the Calabrese and Kenyon method it would be discussed with health professionals prior to any public consultation on its adoption.

1.18 Clarification was sought by a trade body on why substances have been selected for a particular route for setting an EAL. They observed that acrylonitrile has a REACH

[1] https://www.gov.uk/government/publications?keywords=Human+health+toxicological&publication_filter_option=all&topics%5B%5D=all&departments%5B%5D=environment-agency&official_document_status=all&world_locations%5B%5D=all&from_date=&to_date=&commit=Refresh+results

DMEL, yet the Environment Agency has published their own EAL derived using an in-house method.

Our response: Please see our response to question 1.13.

1.19 The use of a method other than REACH in deriving an EAL for acrylonitrile prompted a trade body to strongly recommend the setting up of a formal and independently verified process to approve the methodology, new EALs and their subsequent updating. They identified the existing Committee on Toxicology as a suitable option and highlighted the need for input from industry in the process.

Our response: We are aware of the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). We will consult with Public Health England, Centre for Radiation, Chemicals and Environmental Hazards (CRCE) when deriving and updating new EALs. It does not envisage that the government's independent expert advisory committees such as COT or the Committee on Carcinogenicity in Food, Consumer Products and the Environment (COC) would be routinely involved in this process. However, it is possible that advice on specific aspects of the toxicological or epidemiological data and its interpretation may be sought from such committees on occasion. Prior to the introduction of any new EAL we would carry out a new consultation on its adoption in the usual way.

1.20 It was suggested by a consultant that in the absence of any assessment criteria for a particular substance, environmental impact assessments may continue to refer to EALs based on the Health and Safety Executives OELs.

Our response: If a new EAL is thought necessary we would look to see if another substance released through the same pathway and subject to the same controls which posed a bigger risk was included and use that. If that was not the case we would compare the predicted process contribution against background levels and thereby identify the significance for control for that specific pollutant release. Until a new hierarchy for the derivation of new EALs is in place the old hierarchy stands.

1.21 Within the text we proposed consulting other government committees (in place of EPAQS) because of their expertise in evaluating the effects of chemicals in air on public health. A consultant asked would these government committees be free from the need to consider practicality/politics in the setting of air quality assessment criteria?

Our response: EPAQS was merged into the Department of Health's Committee on the Medical Effects of Air Pollutants (COMEAP) in 2009. So in the future the Environment Agency will be looking to this group and other government bodies of similar scientific standing for its advice. In undertaking this work such groups are independent in thought and develop recommendations after reviewing the evidence.

1.22 Within the text we proposed reviewing Chemical Safety Reports prepared under REACH before adopting them as the basis for EALs to ensure that the information provided is adequate. A consultant supported this proposal as in their opinion industry has an interest in less stringent air quality assessment criteria being adopted.

Our response: We note this opinion and hopes the wider public are reassured by our proposals.

1.23 It was pointed out by a consultant that EPAQS did not adopt the Calabrese and Kenyon method for setting air quality standards for the UK, so the limitations of the Calabrese and Kenyon approach must be appreciated.

Our response: EPAQS agreed the Calabrese & Kenyon method could be used as an interim measure in the absence of other information, provided the information used was brought up to date and, where appropriate, UK or European evidence was included. We have updated it and reviewed it, recognising the limitations of the methodology.

1.24 In preparing the Health Risk Assessment Guidance for Metals (HERAG) a trade association highlighted the great deal of care their industry had taken in evaluating available data for quality and relevance and especially in using the services of expert scientists in each facet of the guidance. They asked if the Environment Agency has sufficient expertise to be able to evaluate existing toxicological data in a similar scientifically robust manner?

Our response: Prior to proposing any new EALs for use in its regulatory activities, we will work with health professionals with expertise in the field of toxicology.

1.25 The same trade association noted that within the consultation document there was no reference in the case of metals to biologically essential metals and differentiating those from non-essential metals. It added that in some cases this resulted in proposals for an EAL far, far below the necessary daily intake for certain essential elements.

Our response: The UK Expert Group on Vitamins and Minerals (EVM) has said that since vitamins and minerals are essential for human health, it is not appropriate to assess them in the same way in which other chemicals added to food are assessed. However, since there is much evidence that excessive intakes of some vitamins and minerals can cause harm, it is not appropriate to exclude essential nutrients from the safety assessment that is applied to other chemical substances which are added to food.

Whether an element is essential to human health depends not only on the level of intake (the dose) but also its chemical form and route of entry into the body. Most nutrients are beneficial when ingested as part of a varied nutritional diet. Nutrients differ from other chemical substances in that they are essential for human health, so that adverse effects can result from intakes that are too low as well as too high. Where the margins between necessity and toxicity are narrow, application of conventional methods of risk assessment, such as would be used in the establishment of an acceptable daily intake, could result in recommended safe levels which would be below those that are essential. This would occur because of the use of uncertainty factors, which are applied when extrapolating data from laboratory animals to humans or from small human studies to the general population. Due to differences in daily nutrient requirements, there is also the chance that a beneficial dose for someone with a high nutritional requirement may be excessive to someone with a low nutritional requirement. The EVM reviewed a number of generic schemes to resolve this but concluded that it was too complex an issue for a single scheme to accommodate it. EVM decided that each essential element would need to be considered individually on the basis of its available data and we would suggest that a similar consideration would be prudent to use for inhalation exposures.

1.26 A trade body did not agree with the proposed hierarchy for the derivation of new EALs or Tolerable Concentrations in Air. They suggested the issue was not whether it is always or even generally preferable to use the EPAQS, but whether the EPAQS is the best source or even an appropriate source of reference for the particular substance involved. They cited the example of beryllium, where references, later than the 2001 reference they claimed was used by EPAQS in their 2009 Metals and Metalloids publication, were available that questioned the conclusions drawn by the initial reference on the same data source.

Our response: EPAQS did review documents up to 2006 on beryllium but the most relevant document was dated 2001.

1.27 The same trade body went on to say that the publication of many new epidemiology studies assessing the carcinogenic potential of beryllium published since 2006 can be reviewed by reference to the 2012 study by Boffetta et al. and that REACH dossiers on beryllium and beryllium oxide submitted in December 2012 are beyond the timeframe of the EPAQS review and should be considered.

Our response: In addition to our response in 1.26 we will periodically review EALs as science and our knowledge of the effect of chemicals on human health develops.

1.28 Finally they contested that the recommendations of EPAQS or any other authoritative evaluation listed in the hierarchy should be evaluated in the context of existing ambient air quality standards and general population exposure levels.

Our response: We take advice and data from various sources to regulate industrial installations to protect human health.

Question 2: Annex 4 contains a list of substances encountered on the Environment Agency's Pollution Inventory for which no EAL is currently available. Are there any other substances for which you feel an EAL should be derived? Please justify each nomination.

Summary

A small number of new substances were identified in addition to those with an EAL on the current Pollution Inventory list. Substances listed on the Pollution Inventory were not thought to be inclusive of all substances included within permit applications. Focus on the Pollution Inventory was seen by one respondent only as a need for prioritisation and not exclusivity.

2.1 A consultant thought it wrong for us to limit the derivation of new EALs to those substances that are in the Pollution Inventory. They added that whilst this may be a reason to prioritise their development it should not be used as a reason simply not to develop new EALs.

Our response: We will focus our efforts on substances we encounters through our regulatory activities. We have recently completed a public consultation on revisions to the Pollution Inventory which will influence the substances that require a new EAL. However, if pollutant returns to the Pollution Inventory are very small or non-existent, there seems little point in deriving new EALs for those substances.

2.2 The same consultant noted the Pollution Inventory does not cover all substances that could be released by an operator and also contains thresholds of releases for a number of categories of substances. In their opinion the list of substances for which an EAL is developed should be based on a review of all substances listed in permit applications by operators.

Our response: We have a duty to supply data on pollutant emissions to satisfy national and international reporting requirements. These include the European Pollutant Release and Transfer Register (E-PRTR), the Large Combustion Plant Directive, and the Montreal Protocol and Convention on Long-range Transboundary Air Pollution. Our experience of permitting since 2010 has indicated that if we focus our efforts on the substances reported to the Pollution Inventory we should cover all likely requests for substance EALs.

2.3 Going further the consultant suggested that a substance without an EAL would cause an operator to refer back to old versions of H1 or even E1, which would leave **us** with no basis on which to challenge the chosen EAL.

Our response: We recommend that all operators seeking EALs for substances which do not have an EAL listed in H1 should contact us for advice.

2.4 Our reasons for not deriving an EAL for dioxins and furans troubled one respondent. They questioned our assertion that the primary route for exposure for most other proposed EALs was via inhalation. They added that for an industrial emission where there are no allotments or gardens through which people grow vegetables and eat local produce**,** then inhalation by air will be the primary exposure. And in such circumstances it would be better to provide a means of assessing the significance of this exposure.

Our response: We are concerned that an EAL based on inhalation exposure only might be inappropriately reassuring, given that, in the majority of cases, exposure is

likely to be dominated by other pathways. Moreover, even if local foodstuffs are not consumed at present this may change in the future.

2.5 Another operator identified the lack of an EAL for dioxins and furans as problematic from a permitting perspective, adding that stakeholders expect to see these relatively common emissions (albeit at low concentrations) assessed within an application. They added that the lack of any screening criteria in relation to air concentrations or deposition to soil often left permit applicants with no choice but to carry out full food chain exposure modelling which they contested was highly disproportionate to risk. They proposed the following be considered:

An EAL for inhalation exposure, or a definitive statement in H1 that there is no perceived risk from inhalation exposure from these species; and **a** maximum deposition rate EAL in H1 to allow screening before carrying out full food chain exposure modelling.

Our response: We would expect that the need for food-chain modelling and assessment should be considered as part of the pre-application discussion.

2.6 One operator welcomed the shorter list of proposed substances as they thought it would allow a better focus on the exercise of deriving new EALs.

Our response: We welcome this support.

2.7 Responding to the needs for assessment of substances released to the environment as a result of carbon capture projects, a trade body suggested that as a first step in a consultative process we should compile a list of the most common amine and amine degradation products associated with emissions from carbon capture and storage plant for which EALs are required.

Our response: We will develop EALs for both amines and amine degradation products, so that we have data available to evaluate the environmental impacts of carbon capture and storage (CCS) plant which use amine scrubbers to remove carbon dioxide.

For amines we will establish the EAL for 2-aminoethanol (commonly known as monoethylamine or MEA) (CAS No. 141-43-5) and for diethylamine (DEA) (CAS No. 109-89-7).

For the class of amine degradation products known as nitrosamines, we will establish the EAL for N-Nitrosodimethylamine (NDMA) (CAS No. 62-75-9).
For the class of amine degradation products known as nitramines, we will identify the compound of greatest concern and establish its EAL.

2.8 A fellow regulator identified two substances for consideration:

Bisphenol A (CAS No. 80-05-7) - the human exposure to which is primarily through diet, but other sources include air, dust and water; and

N-Nitrosodimethylamine (NDMA) (CAS No. 62-75-9) - emissions from emerging carbon capture technology.

Our response: The release of Bisphenol A was previously recorded in our Pollution Inventory returns from waste water treatment plants, it was not identified as a release to air. From 2013 it is no longer recorded in the Pollution Inventory.

For NDMA see above response (2.7).

Question 3: Are there any further authoritative evaluations that should be considered aside from those listed in Section 7. If so please tell us.

Summary

The European Chemicals Agency (ECHA) was identified by industrialists and a UK trade body as an important source of reference data. And it was felt that the IRIS database from the United States should only be considered if there is no European source of health values. Health Canada was suggested by health professionals, who also advised that a periodic review of data sources would be necessary to ensure new sources were not overlooked.

3.1 One trade association believed what they described as 'the disseminated robust summaries on the ECHA (European Chemicals Agency) website' should be considered. They added the US Environmental Protection Agency IRIS database should only be considered for checking for recent data if there is no other European source of health values.

Our response: In terms of the use of REACH documentation within the newly proposed hierarchy please see our response to question 1.13. UK, European and international evaluations have been prioritised ahead of evaluations in the IRIS database.

3.2 Health professionals identified 'Health Canada' as a source of 'authoritative national evaluations'. They suggested that the Environment Agency should consider updating its list of authoritative evaluations periodically to ensure that it represents the most robust, relevant and up to date sources.

Our response: We look at a wide range of sources for guidance and evaluations and the list is not prescriptive. We will consider authoritative evaluations from wherever they arise, although we tend to focus on UK or European reports as their approach is often more closely aligned to our circumstances. If Health Canada provided satisfactory information we would consider it.

3.3 Data within REACH dossiers was identified for consideration by one trade body together with data regarding the protectiveness of existing ambient air quality standards.

Our response: In terms of our use of information within REACH dossiers please see our response to question 1.13. Within the newly proposed hierarchy wehave shifted the emphasis from standards which may be subject to political and social considerations and moved towards an approach based upon the toxicity of chemicals and their effects on human health.

3.4 One operator suggested that data summaries disseminated by ECHA and derived from REACH registration dossiers should be given priority. They highlighted the more recent SCOEL SUM documents as being more detailed than their predecessors and health based, and on that basis welcomed the potential consideration of IOELV documentation.

Our response: We set out our proposed use of REACH documentation in response to question 1.13. In its consultation we asked for information in relation to the derivation of individual Indicative Occupational Exposure Limit Values (IOELVs) but nothing was received. However, we will consider on a case-by-case basis any IOELV used by the

Scientific Committee on Occupational Exposure Limits (SCOEL) in the derivation of derived no effect levels (DNELs).

3.5 The operator added that whilst regulatory reviews from other bodies may provide additional sources of information and references to original papers, it should be recognised that the conclusions of such reviews and the interpretation of studies (e.g. US EPA IRIS) are made within specific legal and political context which may not be relevant in the context of UK EALs.

Our response: We recognise the limitations of reviews undertaken by other bodies as a result of the context in which they are developed.

Question 4a: Do you agree that the proposed method for the derivation of EALs for chemicals with a toxicological effect threshold (Section 7.1) is the most appropriate way forward in the development of revised EALs? If not please tell us what alternative would you propose and why?

Question 4b: Do you agree that the proposed method for the derivation of EALs for chemicals with a toxicological effect threshold (Section 7.1) is the most scientifically valid way forward in the development of revised EALs? If not please tell us what alternative would you propose and why?

Summary

There was a split in responses here: industrialists thought REACH delivers all that is required, whereas health professionals and fellow regulators supported our proposal.

4.1 Health professionals supported the chosen starting point for the proposed method as a review of existing authoritative evaluations. They reflected that the proposed method was similar to the toxicological approach used in deriving health criteria values (HCVs) in the assessment of land contamination as described in our 2009 publication on the 'Human Health Toxicological Assessment of Contaminants in Soils', SC05002/SR2. See https://www.gov.uk/government/publications?keywords=Human+health+toxicological&publication_filter_option=all&topics%5B%5D=all&departments%5B%5D=environment-agency&official_document_status=all&world_locations%5B%5D=all&from_date=&to_date=&commit=Refresh+results

Our response: We welcome this show of support.

4.2 A fellow regulator commented that the proposed method for the derivation of EALs for chemicals with a toxicological threshold was both appropriate and scientifically valid, but they questioned the availability of toxicological data for all priority substances for which a Tolerable Concentration in Air (TCA) will be derived. They thought it unlikely that authoritative evaluations would provide the required toxicological data needed to calculate TCAs for all relevant substances.

Our response: Within Annex 5 of the consultation document, we have set out the factors proposed for developing TCAs. However, it may be that the supply of adequate toxicological data will be a factor in the choice of substances considered for determination of a TCA and then an EAL.

4.3 One trade association did not believe an additional method was justified, because in their view the REACH guidance methodology already provides one.

Our response: We consider the REACH process provides a framework within which a DNEL/DMEL may be produced. Our in-house methodology uses the same framework and explains how we will apply it.

4.4 An industrialist thought that whilst the general principles indicated seemed reasonable there was no need for this to be carried out where for most substances a REACH dossier was available via the ECHA website. They added the REACH dossier included determination of a DNEL/DMEL for the general public, hence there was no need to use the proposed methodology. In circumstances where a REACH dossier did not exist then a uniform process could be operated by applying the REACH methodology.

Our response: Please see response to question 4.3 above.

4.5 One trade association thought the use of uncertainty factors was neither scientifically valid nor appropriate. They added that the general use of uncertainty factors, particularly the universal, non-differential use of uncertainty factors defied science. They reminded us that the word "extrapolation" means "beyond the evidence" and went on say that science by definition resides in the observable range. "Conjecture, including calculations, outside the observable range for either risk or exposure, is by definition, an extra-scientific process ("ESP"). ESPs are used in science for hypothesis generation, but hypotheses can only be tested through observation. ESPs should not be used for setting acceptable ambient air concentrations by the Environment Agency."

Our response: When using uncertainty factors we will be advised by health professionals with responsibility for the protection of public health.

Question 5a: Do you agree that the proposed method for the derivation of EALs for genotoxic carcinogens (Section 7.2) is the most appropriate way forward in the development of revised EALs? If not please tell us what other method could you propose and why?

Question 5b: Do you agree that the proposed method for the derivation of EALs for genotoxic carcinogens (Section 7.2) is the most scientifically valid way forward in the development of revised EALs? If not please tell us what other method could you propose and why?

Summary

Again there was a split in responses: industrialists suggested there was no need for any additional methodology beyond that already available via REACH, whereas health professionals identified parallels with our derivation of health criteria values and fellow regulators supported our proposals as being scientifically valid.

5.1 In response to question 5a health professionals our starting point in carrying out a review of existing authoritative evaluations. They added that the approach outlined in Figure A2 of Annex 5 indicated a preference for quantitative assessments based on human data, if sufficient data are available. Where there was a deficit in human data the application of a large uncertainty factor to appropriate animal data could be used. This was similar to the toxicological approach used in deriving Health Criteria Values (HCVs) in the assessment of land contamination within the Environment Agency's report "Human Health Toxicological Assessment of Contaminants in Soils, 2009" SC05002/SR2.

Our response: Support from health professionals for our proposed position on derivation of EALs for genotoxic carcinogens is welcomed.

5.2 Responding to questions 5a and 5b an industrialist thought that whilst the general principles indicated seemed reasonable there was no need for this to be carried out where for most substances a REACH dossier was available via the ECHA website. They added the REACH dossier included determination of a DNEL/DMEL for the general public, hence there was no need to use the proposed methodology. In circumstances where a REACH dossier did not exist then a uniform process could be operated by applying the REACH methodology.

Our response: We accept that the REACH methodology could be used to derive a set of new EALs quickly. However we concluded that we may find a small number of substances that affect the determination of a group of permits and in such instances it may require a more robust basis for making decisions. In these circumstances we would turn to its in-house methodology, which is higher up the hierarchy, but it anticipated that its use would be limited to a few substances.

5.3 Responding to questions 5a and 5b a trade association did not agree that an additional method was justified as the REACH guidance methodology was already available. They added that in the acrylonitrile supporting document we proposed methodology did not take account of all available data, for example the REACH DNEL.

Our response: At the time of preparation of the acrylonitrile document the REACH DNEL for this substance was not available. The acrylonitrile document was intended to act as an illustration of how our approach would be applied.

5.4 It was concluded by a fellow regulator that the proposal for the derivation of EALs for genotoxic carcinogens was scientifically valid. They also identified the use of an indicative tolerable risk of 1 in 1,000,000 (10^{-6}) in the context of pollution prevention as appropriate. However**,** they added the dose corresponding to that risk level may be below the limit of detection for some substances and so impractical to regulate.

Our response: We welcome the support of our fellow regulator.

5.5 Approaches based on the calculation of T25s was not favoured by health professionals. However, they recognised that they are permitted under REACH and Part IIA of the Environment Protection Act (EPA) and that, where the data did not allow use of a more scientifically valid point of departure for extrapolation such as BMDL10, use of T25 might offer a pragmatic alternative by using an uncertainty factor of the order of 10,000 (10^4).

Our response: Our preference will be to derive Tolerable Concentrations in Air based on suitable human data. However, there may be occasions where such data is not available and reliance upon animal data becomes necessary. In such cases we are proposing to include a safety factor of 25,000 and advice would be sought as appropriate.

Question 6: 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 EAL for genotoxic carcinogens? If you believe an alternative level of risk is appropriate please tell us what this should be and why?

Summary

Our proposal on lifetime excess cancer risk was supported by a fellow regulator. Health professionals recognised the consistency with the assessment of public radiation risk and that it was consistent with the REACH proposal for protection of the public. However, whilst industrialists also supported the use of REACH, they preferred a case by case assessment of the risk posed by their operations.

6.1 It was the view of a fellow regulator that where assessment is based on human data, a calculated lifetime excess cancer risk of 1 in 1,000,000 (10^{-6}) is appropriate but may be difficult to measure because ambient environmental concentrations posing that level of risk may be too low to quantify.

Our response: We welcome the support of a fellow regulator in their consideration of a lifetime excess cancer risk for members of the public resulting from exposure to chemical substances. The point about measuring low ambient levels of pollution consistent with a defined level of risk is noted.

6.2 It was recognised by health professionals that the risk level proposed for use in deriving EALs (10^{-6}) was similar to that used for the regulation of public radiation risk. It was also consistent with that proposed within REACH as an appropriate level of protection offered to the general public (for non-occupational exposure). They qualified the proposal by saying the screening risk from historical contamination of land under Part IIA of EPA, in making decisions on whether remediation might be necessary, was 10^{-5}.

Our response: We note this distinction between historical contamination and the assessment of future pollution impacts.

6.3 However, a trade body was not happy with our proposed risk level of 10^{-6} for the derivation of EALs, adding that this issue had been dealt with on a case by case basis within each Chemical Safety Report submitted in response to the REACH regulations.

Our response: Data within REACH dossiers will be considered once we are satisfied as to the robust scientific nature of the content of these submissions.

6.4 It was noted by an industrialist that the proposed risk level was often suggested as a basis for decision making. However, they identified critical factors in applying this in practice as the robustness of the epidemiology database and the methodology used to derive the estimate of cancer risk. They suggested that a case by case review of the data was appropriate and that the REACH dossiers provided a useful starting point.

Our response: Please see our response to question 6.3.

Question 7: Where a “BMDL10 and large assessment factor” approach is used to derive EALs for genotoxic carcinogens, is 10,000 the most appropriate factor to use? If not please tell us what other factor would you recommend and why?

Summary

Whilst industrialists preferred a case by case approach to risk assessment as defined within the REACH dossiers, health professionals added guidance on how safety factors should be applied to the derivation of EALs when derived from animal data. A fellow regulator sought guidance on our proposal.

7.1 A view expressed by a consultant was that whatever factor is used it should equate to the same risk level as for the other substances.

Our response: In adopting our approach, we aim for a minimal or negligible risk to human health, taking into account the type and quality of available toxicological data. Due to the considerable uncertainties in extrapolating from animal data, it is not appropriate to calculate quantitative estimates of risk to human health and therefore it is not possible to compare or equate the approach taken to animal data (point of departure (POD) /10,000) with a cancer risk estimate derived from good quality human data. The approaches used by us are broadly consistent with those recommended by COC in recently published guidance for estimates of minimal risk.

7.2 Disagreeing with our proposal a trade association stated this had been dealt with on a case by case basis within each Chemical Safety Report in REACH.

Our response: Please see our response to question 6.3.

7.3 It was noted by an industrialist that the source cited is often suggested as a basis for decision making. But they added there are indications, even with genotoxic carcinogens, that mechanistic factors can implicate threshold effects. As such a case by case review of data is appropriate and the REACH dossier provides a useful starting point.

Our response: Please see our response to question 6.3.

7.4 The Environment Agency were advised by health professionals that in 2005 the European Food Safety Authority's (EFSA) Scientific Committee concluded that a margin of exposure (MOE) of 10,000 (10^4) or higher between exposure and a BMDL10 from an animal study would indicate low concern from a public health point of view, noting that risk management decisions were at the discretion of the appropriate authority. They observed that in the case of EALs based on extrapolation from human data, the Environment Agency is regarding an excess lifetime cancer risk of 10^{-6} as indicative of a level of risk that can be regarded as negligible in relation to the Environmental Permitting Regulations (EPR). They added to be consistent with this approach when using animal data, an uncertainty factor of 100,000 (10^5) should be applied if the point of departure on the dose-response curve is a BMDL10 and 250,000 (2.5×10^5) if a T25.

Our response: We welcome this advice provided by health professionals and also notes that the margin of exposure should not be directly considered as equating to an excess lifetime cancer risk.

7.5 We were advised by a fellow regulator that BMDL10 is a point of departure that causes a 10% change in response and statistically takes account of the whole dose-

response curve. They added that threshold toxicity is inherent in BMDL10 and provides an approximation of a No Observed Adverse Effect Level (NOAEL) (ie. threshold toxicity). They queried why we have proposed to use BMDL10 to assess genotoxic carcinogens (ie. non-threshold substances)?

Our response: The proposed approach is consistent with recent guidance on risk characterisation issued by the UK Committee on Carcinogenicity and methods proposed by ECHA under REACH. Threshold toxicity is not inherent in a BMDL10. A BMDL can be used for tumour data or for any other endpoint. It is defined at the lower 95% confidence bound on the dose that corresponds to a specific change (x%) in response compared to the (modelled) response in control animals. Both the European Food Safety Authority (EFSA) and the World Health Organization (WHO) recognise the use of the BMD approach for all endpoints including carcinogenicity. COC guidance on use of BMD for both threshold and non-threshold effects is available in its guidance statement on Risk Characterisation, and further information on the BMDL itself will be published in its guidance statement on Points of Departure and Potency Estimates, which is currently being drafted. We acknowledge that other requirements such as the use of best available techniques will continue to apply.

7.6 The regulator also asked whether the application of the 10,000 (10^4) uncertainty factor to BMDL10 was our way of making BMDL10 data represent a carcinogenic dose? They added why not use a dose descriptor T25 instead?

Our response: The proposed approach is consistent with recent guidance on risk characterisation issued by the UK Committee on Carcinogenicity (COC) for developing pragmatic minimal risk levels. The 10,000 used with a BMDL10 represents a suitable margin between the Point of Departure (POD) and a level of exposure which would result in a minimal risk; it parallels the Margin of Exposure (MOE) approach where a margin of 10,000 on a BMDL10 from an animal study is considered to be unlikely to be of concern.

Question 8: Do you consider the proposed default averaging times for genotoxic carcinogenesis and most threshold effects are appropriate? If not please can you suggest defaults that might be appropriate to other endpoints?

Summary

There was general support for our proposal.

8.1 A trade association and two industrialists thought the proposed timings were appropriate. One industrialist went further and noted that the ADMS is the primary tool used for dispersion modelling in the UK and has the capability to handle averaging periods from one minute and above.

Our response: We welcome this vote of confidence in its proposal. It notes the consultee's preferred use of the Atmospheric Dispersion Modelling System (ADMS) but considers that whilst meteorological data is packaged in an hourly timeframe we would want to see validation of the use of this tool for predictions based upon a one minute averaging time.

8.2 A consultant was also supportive of this proposal, but added that the same principal holds true for the other pollutants and that EALs should be quoted for the time periods over which the effect occurs. They added that this should be made clear in H1 and the software, something which was not done in earlier versions of the document where a blanket 1 hour averaging period was applied in relation to short term releases.

Our response: Currently the screening assessments in H1 are based on hourly, monthly or annual assessments. Conversions from hourly to other timescales can be undertaken using the values in Table 2.1 of Annex F.

8.3 Support for the use of a 24 hour averaging time in relation to genotoxic carcinogenesis was given by a fellow regulator, together with a recommendation for the use of shorter averaging times for irritant effects.

Our response: We recognise that for irritant effects shorter averaging times may be appropriate. However, we would propose to use an annual average in relation to genotoxic carcinogenesis.

8.4 Health professionals advised that averaging times should be appropriate to the critical health-based exposure/endpoint. But whilst they anticipated a 24-hour averaging time would be appropriate for health-based comparators designed to protect against, or minimise critical effects from, chronic exposures, they noted that the proposal contained no reference to short term EALs. They added that assessing permit applications or compliance on the basis of daily, or, particularly annual averages alone might not be sufficiently health protective, especially where emissions fluctuate over time or where acute toxicity might be a risk. They asked for continued dialogue with the Environment Agency over this issue of acute toxicity.

Our response: We note the important point being made here about acute toxicity and looks forward to working with health professionals in the future development of short term EALs to protect human health.

Question 9: In section 7.4 do you support the Environment Agency proposal to include a Relative Source Contribution in its Hazard Characterisation Method for chemicals where the critical effect has a threshold? If not, please give your reasons.

Summary

Industrialists thought the use of the Relative Source Contribution (RSC) unnecessary and this was supported by health professionals when the toxicological data originated from a human study. A fellow regulator supported the proposal but advised against the inclusion of background concentrations for non-threshold substances.

9.1 A trade association considered the use of RSC unnecessary as it was already part of the conservative process involved in the derivation of Direct No Effect Levels (DNEL).

Our response: We understand that RSC is not included in the derivation of the route-specific DNEL. Its proposal is to include RSC only where the critical health effects are systemic and to limit the minimum contribution from air to total exposure to 50%, which it considers to be a proportionate response.

9.2 A fellow regulator sought clarification that an RSC default value of 50% would be used in the derivation of EALs from Derived No (Minimal) Effect Levels (DN(M)EL).

Our response: We are proposing to use 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.

9.3 The same regulator expressed their support to this proposal as RSC incorporates background exposure into Tolerable Concentrations in Air (TCA) for threshold substances. They advised that background concentrations should not be considered for non-threshold substances so that non-threshold substances can be reduced to as low as reasonably practical.

Our response: We agree that it would not be consistent with current practice to apply an RSC in the derivation of EALs for genotoxic carcinogens.

9.4 It was the view of an industrialist that whilst there may be some circumstances where use of RSC might be justifiable, in general the conservative nature of the DNEL derivation suggested this was not a matter for concern.

Our response: A small exceedance of a DNEL for short time periods is generally undesirable but the potential adverse effects need to be considered on a chemical-by-chemical basis and to be protective of the most sensitive members of the population. Variability between chemicals in the magnitude of uncertainty factors applied to the Point of Departure (POD) and differences in the steepness of the dose-response curve means that it is often difficult to quantify the increased risk to health from exceeding a DNEL or other criteria. These values represent our best scientific attempts at identifying the threshold at which exposure poses a negligible or tolerable risk to health and as a clear starting point its view is to seek to manage risks to health by controlling exposures to around or below this level.

9.5 Support for the use of RSC was provided by health professionals when the critical toxicological data from which the EAL is derived are taken from an animal study. This being to ensure the total exposure from all sources is tolerable. However, they added that where the toxicological data is from a human study, the subjects can be assumed to have experienced intake from other sources and so there was no need to account for these other exposures in the risk assessment by using an RSC.

Our response: Use of RSC depends on a thorough understanding of the evidence on which the Tolerable Concentration in Air is based. Whether the underlying data is from occupational epidemiology or animal experiments, application of the RSC will be considered on a chemical-specific basis taking into account such factors as raised by the consultee.

Question 10: Do you support the Environment Agency proposal not to include an RSC in its Hazard Characterisation Method for chemicals where the critical effect is not systemic (eg sensory irritants) or does not have a threshold (eg genotoxic carcinogens)? If not, please give your reasons.

Summary

All responses to this question were supportive of our proposal.

10.**1** Confirming the application of an RSC as being appropriate where the health-based endpoint was systemic, a fellow regulator was able to agree with us that it need**s** not be applied in the risk assessment where the critical effect is local (e.g. sensory irritation). They added the proposal not to apply an RSC to the assessment of genotoxic carcinogens was consistent with the approach taken in many other risk assessment regimes, including our 'Human Health Toxicological Assessment of Contaminants in Soils, 2009'.

Our response: The support and useful background information provided here are noted.

Question 11: When there are few data on public exposure by other routes do you support the proposed RSC default of 50%? If not, please tell us what other defaults could you justify?

Summary

Although only three responses, one offered support for the proposal, one offered limited support and one no support at all.

11.1 A trade association was unable to support this proposal. They felt the Relative Source Contribution (RSC) default of 50% was not needed as it was already built in through the conservative nature process of the derivation of DNELs.

Our response: Please see our response to question 9.1

11.2 It was suggested by an industrialist there may be some circumstances where use of an RSC might be justifiable. However, they hoped that in many cases where no specific data on public exposure exists, generic reasoning could be used to determine if the extra precaution associated with an RSC was necessary. They again suggested the conservative nature of DNEL derivation would indicate this was unlikely to be of concern.

Our response: We believe it is reasonable to consider whether or not the RSC should be applied, particularly if studies suggest contributions via other routes of exposure are unlikely.

11.3 Although in support of this proposal, a fellow regulator asked in circumstances where the background exposure was too small should the Tolerable Concentration in Air (TCA) value remain unaltered?

Our response: We will consider such cases on a chemical-specific basis taking into account the quality of the background data, potential variability, the consequences for exposure exceeding the TCA (that is, how steep is the dose response curve) and the practicability of applying it.

Question 12a: In section 8 do you think that our proposal to use REACH DNELs/DMELs derived for the “humans via the environment” exposure route is justified as a source of EALs? If not please tell us what alternative would you propose and why?

Question 12b: In section 8 do you think that our proposal to use REACH DNELs/DMELs derived for the “humans via the environment” exposure route is legitimate as a source of EALs? If not please tell us what alternative would you propose and why?

Summary

There was general support for this proposal.

12.1 There was support for this proposal from two industrialists, one of whom said they had outlined in responses to other questions that REACH derived DNELs/DMELs provide what they said was an 'obvious and preferred basis for deriving EALs'.

Our response: We recognise the work performed by registrants in assessing their data and providing DNELs/DMELs, subject to an independent check that the values are appropriate for EAL purposes.

12.2 Health professionals suggested that where a detailed characterisation of the hazards posed to health by a chemical was recently undertaken under REACH then it seemed sensible to make use of it. Commenting on our aim to undertake a review of this industry-led proposal which they thought would avoid duplication of effort, they thought this action would ensure an independent evaluation of the DN(M)ELs considered for use as EALs. However, they added it was important to ensure that individuals undertaking this work carried the appropriate knowledge and expertise.

Our response: We note the advice and support given here by health professionals.

12.3 In response to question 12a a fellow regulator supported the proposal adding it was justified in terms of ambient environmental exposure, but not occupational exposure.

Our response: We note the advice and support given here by a fellow regulator.

12.4 In response to question 12b, the fellow regulator added that if "legitimate" means proved and tested, then the proposal to use REACH DN(M)ELs derived for ambient air exposure is legitimate, as it has been used by international agencies such as the World Health Organisation (WHO).

Our response: We accept this description of the word "legitimate" and notes the use of DN(M)ELs by the WHO.

12.5 A trade association believed the proposal to be a legitimate one as a primary source of information. They thought that if a value was to be questioned then justification should be provided.

Our response: We will consider the values and provide comments on those we choose not to accept.

Question 13a: Do you feel that the potential use of IOELVs to derive environmental exposure is a valid approach? If not please tell us what alternative would you propose and why?

Question 13b: Do you feel that the potential use of IOELVs to derive environmental exposure is a scientifically robust approach? If not please tell us what alternative would you propose and why?

Summary

Health professionals sought confirmation of our proposals on the use of IOELVs and a fellow regulator offered guidance on the use of IOELVs in deriving EALs for the wider community. Industrialists offered guidance on when an IOELV could be used in deriving new EALs.

13.1 Responding to both parts of this question a trade association felt able to support the Environment Agency's proposal not to use IOELVs for environmental exposure.

Our response: This support is noted.

13.2 In response to question 13a it was the view of a fellow regulator that since IOELVs protect workers between the ages of 16 and 65, whereas EALs cover the wider environment (including children, the elderly and those with compromised health) IOELVs should not be adopted directly as EALs.

Our response: We would not expect IOELVs to be adopted directly as EALs because of their basis in occupational exposure.

13.3 In response to question 13b a fellow regulator agreed the proposal was valid.

Our response: We note this agreement with our proposal.

13.4 Responding to question 13a an industrialist agreed that use of an IOELV directly as an EAL would not be appropriate. However, they added the basis of a REACH DNEL could rely on data and arguments used in setting an IOELV. Taking a wider view they suggested that where exposures occur that are not covered by a REACH substance registration then if an IOELV existed it could form a valid starting point for an EAL.

Our response: We accept that the assessment used in setting an IOELV could provide one input to the derivation of an EAL.

13.5 Adding to their comments on question 13a, the industrialist noted that in the context of using IOELVs within REACH, the text in the H1 consultation document was misleading. The text "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" they considered too restrictive. They stated that "Reach allows the IOELV to be used providing there are no new data pertinent to the validity of the IOELV."

Our response: We note this response.

13.6 Health professionals were unclear as to what Environment Agency's proposals were in regard to the use of Indicative Occupational Exposure Limit Values (IOELVs).

They explained that if IOELVs can be obtained, the evaluations underpinning IOELVs were likely to provide useful evidence from which EALs could be derived. They added that in their opinion use of IOELVs might be appropriate within the Calabrese and Kenyon methodology and use of IOELVs would be preferable to Binding Occupational Exposure Limit Values (BOELVs) whose derivation might be influenced by socio-economic and technical factors.

Our response: This advice is noted.

Question 14: Do you support our proposed approach to the handling of DNELs/DMELs supplied to the ECHA ahead of publishing the values? If not please tell us what other approach would you propose and why?

Summary

Industrialists did not support this proposal; a fellow regulator offered qualified support and health professionals sought information on the resource implications for them if they were to support the Environment Agency in a review of this data.

14.1 Our approach was not supported by a trade association who explained the Community Rolling Action Programme (CoRAP) process already provided a means of evaluation under REACH.

Our response: We recognise that substance evaluation under the CoRAP will be the principle means for EU regulators to evaluate the contents of registration dossiers. For prioritised substances, we will wait for the evaluation report, provided that relevant toxicological end points were included in the reasons for CoRAP listing. However, it is unlikely that all of the substances requiring EALs to be set will be prioritised for evaluation in the first few years of the process. Substance evaluations may also be targeted, so might not always address those end points of most interest to us for EAL purposes. If we are to use the information available in the REACH registrations, it will need to review dossiers separately for those substances not included on the CoRAP.

14.2 For most substances of interest an industrialist thought the proposal was irrelevant as ECHA had disseminated data on high volume (>1000 te/year/legal entity) substances and those substances identified as carcinogenic, mutagenic or toxic for reproduction (CMRs). In the absence of REACH data they thought the REACH methodology should be applied to available data.

Our response: We will need to assess the basis for the derivation of the DNEL/DMEL. This information will not usually be publicly available (since it is contained in the Chemical Safety Report (CSR)). If we are not able to access the CSR, it could perform an independent assessment using the REACH methodology. Our in-house method uses the same framework as the REACH methodology.

14.3 Our proposal was supported by a fellow regulator when applied to threshold substances, but they advised that DMELs were based on quantitative risk assessments (animal data). They asked how should this be reconciled to fall within the approach recommended for use in the UK? However, they added that if DMELs were to be derived from human data they would support it.

Our response: We acknowledge that one of the two methods available to derive DMEL under REACH, linear extrapolation from animal bioassay data, is not recommended by the most recent advice from the UK Committee on Carcinogenicity (COC) on risk characterisation methods. We would therefore only consider DMEL that had been derived using the application of an assessment factor (10,000) to a suitable point of departure (BMDL10) that is consistent with UK advice on the derivation of minimal risk levels. We agree also that the REACH dossiers are an appropriate source of information for use in the derivation of EAL.

14.4 In adopting this approach health professionals sought guidance on the scale of input that was likely to be requested of them. If unable to provide the required level of support they suggested we should first undertake a screening approach using suitably qualified and experienced individuals before consulting the health professionals.

Our response: We are grateful for this offer of support. It is difficult for us to estimate the resource we would need from health professionals to complete this task. There is a deficit of about forty substances which currently are reported to our Pollution Inventory and do not have an EAL. Using our new hierarchy we would derive this list of missing EALs and then engage with health professionals on the proposed values. Once we had agreement on our proposals we would consult the public.

Question 15: Do you support the use of our proposed in-house method for the derivation of new EALs where data is not available to us via the REACH process? If not please tell us what alternative would you propose and why?

Summary

Industrialists thought there was no need for another methodology as the REACH methodology was already available, a fellow regulator supported the proposal and health professionals sought clarification on our proposal.

15.1 A fellow regulator considered our in-house method was appropriate.

Our response: We welcome this support to our proposal.

15.2 However, a trade association felt there was no need for an alternative method as the REACH methodology could be used to derive an EAL.

Our response: We accept that the REACH methodology could be used to derive an EAL and have included it within the proposed hierarchy. But where data is not provided through REACH an alternative data source will be needed.

15.3 An industrialist thought it best not to complicate matters by introducing another (local UK) method. They bolstered this by adding that in such circumstances the same methodology used in REACH could be applied to the relevant data and to do so would result in a more uniform approach.

Our response: We consider that REACH provides a framework for assessment, but it is not a tightly defined methodology. Our in-house method is based on the REACH approach but indicates how the overall methodology should be applied to the derivation of EALs.

15.4 Clarification was sought by health professionals on which method (our in-house or Calabrese and Keynon), would be used to derive the Tolerable Concentration in Air. They added that once clarification was provided they would welcome the opportunity to comment.

Our response: Our in-house method would be used.

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.

Summary

Industrialists looked for the option of arbitration where they did not support the value of any future EAL, a trade association sought clarification on the future scope of new EALs, and specific issues were raised in relation to beryllium.

16.1 An opinion expressed by a consultant was that derivation of EALs should be consistent with the regulatory framework for environmental permitting and to accept the use of EU Limit Values where they are available. (EQS in the IPPC Directive). Thereafter the starting point should be by defining the acceptable level of risk and deriving EALs to that level. They offered the opinion that such an approach would deliver a consistent set of EALs, which would not be influenced by the information available at the time the review was carried out.

Our response: Some EU Limit Values and Air Quality Objectives (AQO) are based on a percentile compliance approach and so are not in a suitable format for use as an EAL. Moreover EU Limit Values have a different legal status compared with EALs so we assess their impact separately. It is not our responsibility to define an appropriate level of risk, and whilst the consultant's proposal is sensible it feels it would be very difficult to put into practice. Our needs to use a common end point (for example, a NOAEL or similar benchmark) depending on the nature of the substance and its effects on human health.

16.2 We were asked by a trade association if it was its intention to expand the derivation of new EALs to include the protection of vegetation and ecosystems.

Our response: In determination of EPR applications we, in consultation with conservation agencies, use critical levels and critical loads. It has no current plans to extend these values.

16.3 It was noted by an industrialist that tolerable concentrations in air (TCA) were to be derived in-house by us with advice from the Health Protection Agency. They asked that this be an open process, so that the derivation of TCAs is clear, and that it is undertaken in consultation with Industry, who should be able to explain the basis and data within the relevant REACH dossier. Furthermore, a mechanism should be available to refer any contentious points forward to bodies such as the Committee on Toxicity (COT) or Committee on Carcinogenicity (COM).

Our response: Our in-house method uses the same framework as the REACH methodology and we published our document on acrylonitrile to inform the 2012 public consultation. We aim to publish four additional documents on the derivation of Tolerable Concentrations in Air (antimony, dimethylformamide, trichloroethylene and vinyl chloride monomer). Prior to us adopting any new EALs it will consult widely with industry, health professionals, and the general public to give everyone an opportunity to comment on the specific proposals.

16.4 The industrialists also observed that compared to limits based on a health based approach for some substances the current limits appear over conservative.

Our response: Users are asked to provide evidence in support of these claims.

16.5 Finally, they highlighted the lack of a reference as to how the impact of proposed new EALs will be taken into account. They asked if a formal consultation process will

be put in place in advance of the introduction of new proposals and will there be an appeals process should new EALs be unjustifiably low?

Our response: It is our intention to consult before introducing any new EALs. It remains a decision for the operator of any listed activity to appeal against any EPR permit conditions should they so choose.

16.6 Focusing on what they described as the difference in the physico-chemical and toxicological properties of beryllium metal, compounds and alloys, a trade association suggested the current classification of all beryllium compounds into one group was not consistent with the requirements of REACH. They quoted testing protocols used in compiling the REACH dossier which they maintained demonstrated that beryllium metal was not a skin irritant, eye irritant, acute inhalation toxin, a skin sensitiser or orally toxic as currently described.

Our response: An operator or its representatives may ask us to review any current EAL on the basis of new scientific information about the toxicity of a substance. We would normally consult Public Health England for advice on the data submitted and then decide on the way forward. It is possible that advice on specific aspects of the data and its interpretation may be sought from the government's independent expert advisory committees on occasion. We remind operators that EALs are not legally binding standards, but tools it uses for permitting activities under the Environmental Permitting Regulations. However, EALs are protective of human health and any exceedance or significant contribution towards an exceedance is unlikely to be looked upon favourably.

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

Summary

As they had not been directly emailed one trade association was not happy in the way this consultation had been managed. Another trade association pointed to failings within the future derivation of new EALs. One operator asked why we had chosen to publish its document on the Tolerable Concentration in Air for acrylonitrile.

17.1 One trade association was not happy with how this consultation had been managed. Quoting a lack of adequate preparation, a failure to recognise the significant amount of work already carried out by the HERAG project, the information obtained through REACH and the highly specialised nature of the task. They thought the circulation list was very limited and were of the opinion that the complex evaluation in the consultation required an understanding of toxicology unlikely to be found in many of the consultees. They added it was their considered view the consultation did not meet the criteria laid down in the Government Code of Practice for Consultations.

Our response: We are sorry that the Non-Ferrous Alliance (NFA) was not consulted directly on this consultation. At the start of the consultation, we had over 1,200 organisations on our stakeholder list and that included the Aluminium Federation who notified the NFA of the consultation. Our stakeholder list has since been reviewed and the NFA added, which should ensure they are contacted directly in the future.

17.2 The consultation was seen by another trade association as lacking in two respects:

- Lack of evidence of an impact assessment being undertaken; and
- Proposals for changing EALs has not been set in the context of the incoming Industrial Emissions Directive (IED).

Our response: Within section 3.1 of the consultation we set out its proposals for future EALs and the commitment to undertake a detailed assessment of costs once REACH dossiers were received and validated. This review has not yet been undertaken by us. Tighter emission limit values within BAT Conclusions documents, produced as part of the IED, should make compliance with EALs more likely.

17.3 A consultant suggested that if our website that hosted the consultation was upgraded to take the latest version of Internet Explorer the system would be improved enabling responses to be made directly to the website.

Our response: This point is acknowledged.

17.4 It was not clear to one operator why we chose to publish a copy of their acrylonitrile document that explained how our in-house Hazard Characterisation Method was to operate.

Our response: We identified 5 substances of higher priority for which a tolerable concentration in air would be determined. The consultation document explained the in-house method and we chose, somewhat arbitrarily, to publish the acrylonitrile document as an example from the five that were in draft form. It was hoped that by

publishing this document we would inform the consultation.

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

Summary

Apart from the comment in question 17.1 recipients cited our website, notification through their trade association, or via direct email contact from us.

1.4 References

Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment. COC/G 06 – Version 1.0 (2012)

ECHA (2010) Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health. Version 2.

HSE (2011) EH40/2005 Workplace Exposure Limits 2nd edition, available via: www.hsebooks.co.uk

H1 Horizontal Guidance Note. Environment Agency 2011 available via: H1 Environmental risk assessment for permits: overview and annexes - Publications - GOV.UK

The Environmental Permitting (England and Wales) Regulations 2010 SI 675 London: The Stationery Office

1.5 List of abbreviations

AALG	Ambient Air Level Goal, from Calabrese and Kenyon method
BMD	Benchmark Dose - dose level associated with a pre-specified (small) change in response
BMD10	Central estimate of the Benchmark Dose for a 10% response above background
BMDL10	Lower limit of the 95% confidence interval on the BMD10
COC	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment
COMEAP	Committee of Medical Experts on the Effects of Air Pollution
CoRAP	Community Rolling Action Programme
COSHH	Control of Substances Hazardous to Health
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
DEFRA	Department for the Environment, Food and Rural Affairs
DMEL	Derived Minimal Effect Level
DNEL	Derived No Effect Level
EAL	Environmental Assessment Level
ECHA	European Chemicals Agency
EPAQS	Expert Panel on Air Quality Standards
EPA	Environmental Protection Act 1990
EPR	Environmental Permitting Regulations 2010
EQS	Environmental Quality Standard
EU	European Union
EVM	UK Expert Group on Vitamins and Minerals
HERAG	Health Risk Assessment Guidance for Metals
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	US Environmental Protection Agency's Integrated Risk Information System
IVL	Indicative Limit Value
LOAEL	Lowest observed adverse effect level
MoE	Margin of Exposure - estimated human exposure divided by the reference point (usually the BMDL10).
NOAEL	No observed adverse effect level - standard approach for evaluating dose-response data for threshold effects.
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
POD	Point of Departure
REACH	Registration, Evaluation, Authorisation and restriction of CHemicals) Regulations 2006
RP	Reference Point - a dose that does not result in biologically significant effects
RSC	Relative Source Contribution
SCOEL	Scientific Committee on Occupational Exposure Limits
Stochastic effect	Probability of developing a tumour depending upon the dose received
TCA	Tolerable Concentration in Air
TDI	Tolerable daily intake
US EPA	US Environmental Protection Agency
WEL	Workplace Exposure Levels
WHO	World Health Organization

1.6 Appendix 1

Table of respondents to this consultation

Association of Electricity Producers (AEP)
BP Chemicals Limited
Beryllium Science & Technology Association
Bureau Veritas UK Ltd
Chemical Industries Association
EDF Energy
INEOS Nitriles
Non-Ferrous Alliance
Peter Brett Associates LLP
Public Health England, Centre for Radiation, Chemical & Environmental Hazards
Scottish Environment Protection Agency (SEPA)

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