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# Guidance on information requirements and chemical safety assessment

## Chapter R.14: Occupational exposure estimation

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**Guidance on information requirements and chemical safety assessment**
**Chapter R.14: Occupational exposure estimation**

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## PREFACE

This document describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, and the chemical safety assessment. It is part of a series of guidance documents that aim to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1] and its amendments as of 31 August 2011.

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006).

## DOCUMENT HISTORY

| Version | Comment | Date |
|---|---|---|
| Version 1 | First edition | May 2008 |
| Version 2 | The material on worker exposure models in Part D of IR&CSA guidance (Chapter 5.3 and Appendix D-1 pp. 63-64) introduced to Chapter 14.4. | May 2010 |
| Version 2 | In the text on exposure models "steps to run the tool" have been removed, as they were not considered helpful in written guidance. | May 2010 |
| Version 2 | Section 14.4.7 on the ECETOC TRA worker tool for exposure estimation at Tier 1 has undergone a major revision and updating, with the inclusion of the new version of Ecetoc TRA worker model | May 2010 |
| Version 2 | The text on other models (Stoffenmanager, Riskofderm, ART) has been updated | May 2010 |
| Version 2 | The text on EMKG-Expo-Tool has been edited | May 2010 |
| Version 2 | The text on measurement data has been updated (R 14.4.4 and R14.4.5) | May 2010 |
| Version 2 | A new section R14.4.6 on short term exposure data has been introduced | May 2010 |
| Version 2.1 | Corrigendum:<br>(i) replacing references to DSD/DPD by references to CLP<br>(ii) further minor editorial changes/corrections | November 2012 |

## GUIDANCE FOR IMPLEMENTING THE UPDATES

Most of the updates in this guidance provide additional tools and parameters to support occupational exposure assessment and exposure scenario building under REACH, or are of an explanatory or an editorial nature.

A registrant having already finalised the occupational exposure estimation based on Chapter R.14 as published in May 2008 may therefore wish to take the following advice into account:

- Carefully read the document history to be informed on what has been updated;
- Check whether the changes in the guidance put into question
    - the scope of the exposure assessment and scenarios already worked out, and
    - the outcome of the risk characterisation related to these exposure scenarios.

  If the conclusion of the check is that neither is put into question, it is unlikely that the adaptation of the already existing Chemical Safety Report to this guidance update is of high priority.

## CONVENTION FOR CITING THE REACH REGULATION

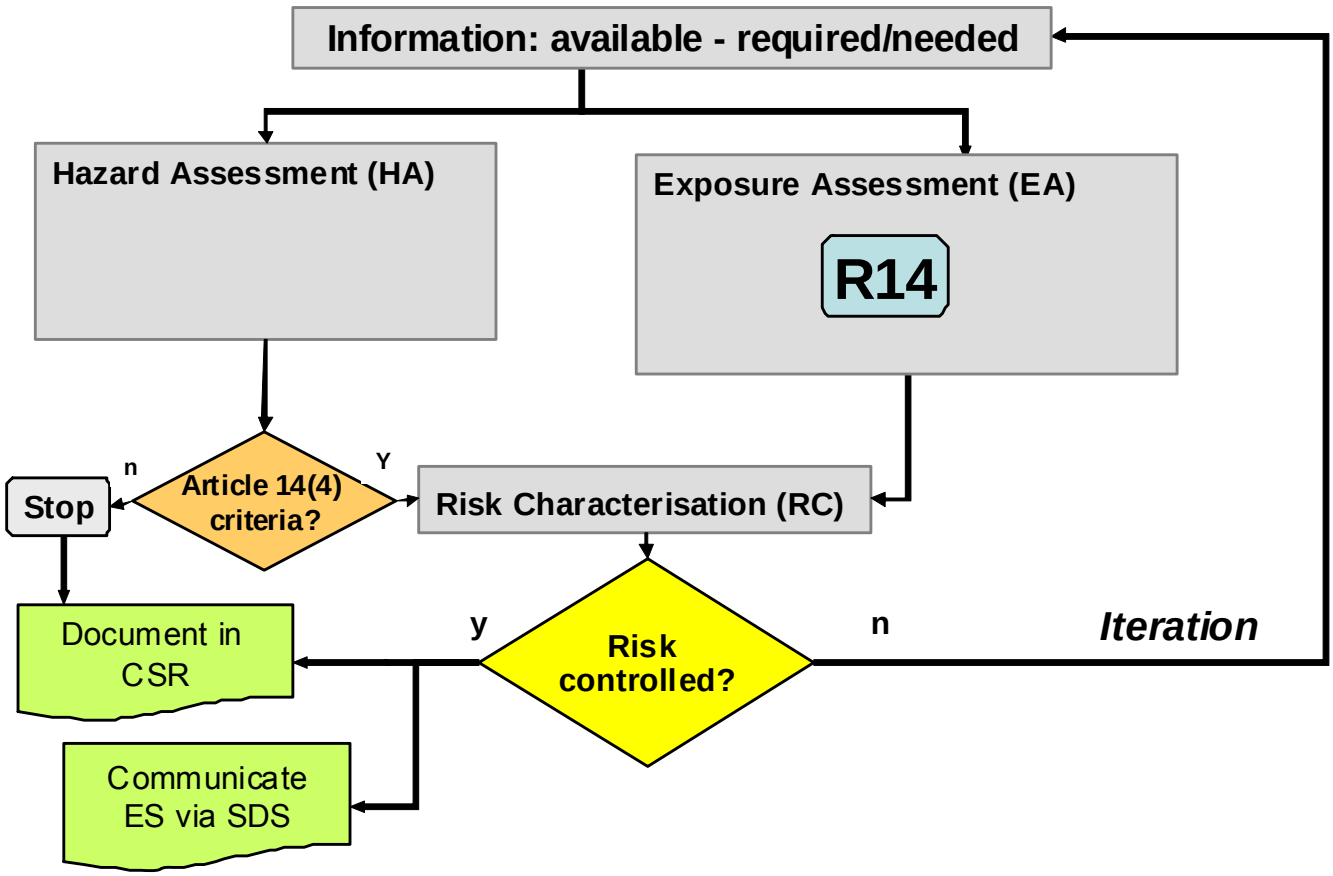
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

## TABLE OF TERMS AND ABBREVIATIONS

See Chapter R.20

## PATHFINDER

The figure below indicates the location of Chapter R.14 within the risk assessment process.



# TABLE OF CONTENTS

**R.14 OCCUPATIONAL EXPOSURE ESTIMATION ..... 1**

**R.14.1 Introduction ..... 1**

**R.14.2 Types and routes of exposure ..... 1**

**R.14.3 Determinants of occupational exposure and RMMs ..... 3**

**R.14.4 Exposure estimation with measurements and modelling approaches ..... 4**

R.14.4.1 Introduction ..... 4

R.14.4.2 Workplace exposure assessment rating criteria ..... 5

R.14.4.3 Core information requirements ..... 7

R.14.4.4 Use of measured data ..... 8

R.14.4.5 Selection and interpretation of measured data ..... 9

R.14.4.6 Acute exposures ..... 16

R.14.4.7 Use of exposure estimation tools ..... 19

R.14.4.8 ECETOC TRA tool for occupational exposure ..... 20

R.14.4.9 EMKG-Expo-Tool ..... 26

**R.14.5 Higher Tier exposure assessment ..... 34**

R.14.5.1 Stoffenmanager exposure model ..... 34

R.14.5.2 RISKOFDERM dermal model ..... 36

R.14.5.3 Advanced REACH Tool (ART) ..... 39

**R.14.6 References ..... 43**

## Tables

Table R.14-1: Workplace exposure assessment rating criteria ..... 6
Table R.14-2: Indicative number of measurements needed to determine confidently that the true RCR is below 1 ..... 11
Table R.14-3: Multiplying factors to generate acute reasonable worst-case value from full shift values ..... 18
Table R.14-4: General fugacity table ..... 22
Table R.14-5: Help on fugacity selection criteria ..... 22
Table R.14-6: Fugacity classifications for process temperature / melting point relations (PROCs 22-25 (metals) only) ..... 23
Table R.14-7: Modifiers for duration of activity ..... 24
Table R.14-8: Influence of the concentration in mixtures ..... 24
Table R.14-9: Output of ECETOC TRA worker exposure estimation ..... 25
Table R.14-10: Definition of dustiness bands ..... 28
Table R.14-11: Definition of volatility bands ..... 28
Table R.14-12: Scale of use bands/one batch ..... 29
Table R.14-13: Exposure potential bands (EP)* ..... 30
Table R.14-14: Control strategies ..... 30
Table R.14-15: Predicted exposure ranges ..... 32
Table R.14-16: Output of EMKG-Expo-Tool ..... 33
Table R.14-17: Calculated evaporation times for T = 20°C (gloves) and T = 30°C (skin) ..... 46
Table R. 14-18: Factor for multiplication of the full shift reasonable worst case estimate to derive short-term reasonable worst case estimate ..... 49

## Figures

Figure R.14-1 Ratios between 95th percentiles of different averaging times and 75th percentiles of full shift values, relative to the GSD of the full shift values ..... 47
Figure R. 14-2 Ratios between 99th percentiles of different averaging times and 75th percentiles of full shift values, relative to the GSD of the full shift values ..... 47
Figure R.14-3 Ratios between 95th percentiles of different averaging times and 90th percentiles of full shift values, relative to the GSD of the full shift values ..... 48
Figure R.14-4 Ratios between 99th percentiles of different averaging times and 90th percentiles of full shift values, relative to the GSD of the full shift values ..... 48

## Appendices

Appendix R.14-1 Evaporation rate ..... 45
Appendix R.14-2 Derivation of short term inhalation exposure (reasonable worst case) ..... 47
Appendix R.14-3 Control guidance sheet numbering system and an example “weighing of solids” ..... 50

# R.14 OCCUPATIONAL EXPOSURE ESTIMATION

## R.14.1 Introduction

This chapter provides support for estimating occupational exposures. It describes what information is needed for the assessment at the different levels (Tiers) and how to deal with it. The first Tier exposure estimations are meant to be conservative and may be well above actual exposure levels. The higher Tier exposure estimations are much more specific and require more detail for the estimation parameters and exposure determinants. The higher Tier estimations also require much more knowledge on the confidence that can be related to the estimation (see Chapter R.19).

Attention is given to:

- Collection of exposure information for establishing (the final) exposure scenarios (ESs)
- Information needs for different Tiers
- Estimation or calculation of exposures

For occupational exposure, the following stages of the life cycle of a substance are mainly relevant[2]:

- **Manufacturing**: Chemical synthesis of the substance and its use as a chemical intermediate;
- **Formulation**: Mixing and blending into a mixture;
- **Industrial use**: Application of the substance, mixture/product in an industrial process;
- **Professional use**: Application of mixtures/products in skilled trade premises.

In the following sections an overview of the elements that need to be focussed on in an occupational exposure assessment, as they are required for REACH implementation, will be presented. The following elements need particular attention:

- Types and routes of exposure (Section R.14.2)
- Determinants of occupational exposure (Section R.14.3)
- Exposure assessment with measurements and modelling approaches (Section R.14.4)
  - Core information requirements (Section R.14.4.3)
  - Use and selection of measured data (Section R.14.4.4 and Section R.14.4.5)
  - ECETOC TRA (Section R.14.4.8)
  - EMKG-Expo-Tool (Section R.14.4.9)
- Higher Tier exposure assessment (Section R.14.5)

## R.14.2 Types and routes of exposure

Substances in the workplace may come into contact with the body and possibly enter the body by inhalation, by contacting and passing through the skin (dermal route), or sometimes by swallowing (ingestion). Exposure to a particular substance should normally be understood as meaning external exposure. This can be defined as the amount of the substance ingested, the amount in contact with the skin, and/or the amount inhaled (which is represented by the airborne concentration of the substance in the breathing zone of a worker). It does not usually refer to concentrations within the body, which are determined by the amount of the substance absorbed from the digestive system, respiratory system, or entering the body through the skin. Information

[2] Other life stages may be relevant as well (e.g. the waste stage) and should be assessed when relevant

on the exposure should therefore clearly indicate whether the exposures under discussion are external or internal.

Exposure can be considered as a single event, as a series of repeated events or as continuous exposure. In the exposure assessment the levels of exposure, either from measured or modelled data, need to be considered, as well as other parameters such as duration and frequency of exposure. Exposure assessments should be planned taking into account both acute and chronic effects and local and systemic effects caused by the substance. Task-based scenarios can be appropriate for exposure assessment for both acute and chronic effects. Exposure to substances causing local effects may also be of interest and should be described where appropriate.

Inhalation exposure

For many substances and exposure situations the main route of exposure is by inhalation. Exposure by inhalation is a function of the concentration of the substance in the breathing zone atmosphere and is normally presented as an average concentration over a reference period. For comparison with hazards after repeated or continuous exposure, a reference period of a full shift (normally 8 hours) is generally used. If the substance has the potential to cause acute health effects or if exposure is of intermittent short durations it may also be relevant to identify and evaluate exposure over shorter periods.

The exposure assessment can be based on exposure during specific tasks which may be carried out over varying time periods. Inhalation exposure may occur due to gases and vapours, as well as aerosols (liquid and solid (including fumes, dust, fibres)) which may be present in the ambient air. It is difficult to assess exposure to aerosols properly, as the particle size may vary with time and place and particle size determines the degree of uptake in the body by inhalation (through the lungs) and by ingestion (through the oral route). In some first Tier models, dustiness is used as a surrogate for the emission potential of solids and solid-particle aerosol exposure.

Inhalation exposure can be described by the concentration of the substance in air, and the duration and frequency of exposure. It is generally expressed in ppm (parts per million) or amount per unit air volume inhaled, averaged over the duration of relevant task or shift (e.g. $mg/m^3$ 8 hour time-weighted average (TWA)).

Dermal exposure

The dermal route may be the main route of exposure for some substances or exposure situations. Substances may have local effects on the skin or may have the ability to penetrate (even intact) skin and become absorbed into the body. Two terms can be used to describe dermal exposure:

- potential dermal exposure is an estimate of the amount of contaminant landing on the outside of work-wear and on the exposed surfaces of the skin. It is the sum of the exposure estimates for the various body parts, including hands and feet;
- actual dermal exposure is an estimate of the amount of contamination actually reaching the skin. It is mediated by the efficiency and effectiveness of clothing worn and work practices used to minimise transfer of contamination from work-wear onto the skin.

Potential dermal exposure is the most frequently used indicator.

Absorption through the skin can result from localised contamination, e.g. from a splash on the skin or clothing, during manual work situations, e.g. when mixing and loading, taking samples, spraying a substance, or in some cases from exposure to high ambient air concentrations. Dermal absorption can be affected by a number of factors, including the amount and concentration of the substance, presence of other substances that may facilitate the absorption, the area and location of exposed skin (for example higher absorption through face skin compared to that through the palms of the hand), the duration and frequency of exposure and person-specific properties, e.g. the general condition of the skin.

There are three major routes of dermal contamination: by deposition (from air), by direct contact with the contaminant (e.g. immersion, splashes), and by contact with contaminated surfaces.

Transfer of contamination from hands to other parts of the body may be an important part of skin exposure. Contaminated clothing can also be a source of exposure particularly of the hands when removing contaminated work clothing and/or PPE. Dermal exposure is generally expressed in terms of the mass of contaminant per unit surface area of the skin exposed.

Oral exposure

Ingestion (oral) exposure may occur in many situations where there is exposure to aerosols (see above under inhalation) and where contaminated skin or clothing may lead to exposure due to contact with the mouth region. To some extent, it may be controlled by straightforward good hygiene practices such as segregating working and eating facilities and adequate washing prior to eating. These matters are normally dealt with through general welfare provisions in national health and safety legislation and established good industrial hygiene practices in companies.

Exposure through ingestion is therefore generally not considered further in the assessment of workplace exposure. However, the potential for exposure via ingestion should be kept in mind when considering uncertainties in the exposure assessment as a whole. There are no accepted methods for quantifying exposure by ingestion as such. In specific cases a possible assessment of ingestion exposure can be made using the algorithms available in ConsExpo (www.consexpo.nl ); see also Chapter R.15). Another approach is to consider biological monitoring, where all routes of uptake are integrated and accounted for (see Section R.14.4.4).

## R.14.3 Determinants of occupational exposure and RMMs

Worker exposure depends on characteristics of substances, products, processes, tasks/work activities, conditions and RMMs used. To enable proper worker exposure estimation the following types of information are needed in relation to the source of the exposure and the exposure determinants:

- where is the substance used? (including description of processes, activities and products);
- characteristics of the substance: physical state, vapour pressure, dustiness (e.g. powder, pellets);
- the composition of mixtures (preparations)[3] and articles (including approximate percentages);
- possible hazardous impurities in the substance (see Guidance for identification and naming of substances under REACH);
- how is the substance used? (including description of work activities/tasks leading to exposure, quantities used);
- approximate percentage in process materials and finished products;
- the nature of exposure, i.e. the operational conditions (including type and approximate frequency and duration of tasks, duration and frequency of exposures);
- what risk management measures (technical/personal) are (to be) used when the activities are carried out? (please refer to Chapter R.13 for further details); this includes information to show that any personal protective equipment (PPE) recommended is suitable, well-fitted and maintained, and is used as a last resort (i.e. other control options are used to the extent possible);
- recommendations regarding appropriate management systems to ensure that the measures to limit or prevent exposure are correctly applied (e.g. duration of exposure is minimised and PPE is used correctly).

For Tier 1 estimations, the level of detail required in the above types of information can be limited. It should be related to the necessary choices of inputs to be made for the Tier 1 tool. For higher

3 Also referred to as formulations or chemical products

Tiers many additional details will be necessary for the exposure estimation (see Sections R.14.4 and R.14.5).

Product related RMMs, e.g. reducing the dustiness by converting a powder into an oil-coated powder, into granules, etc. can be implemented by the producer whereas site-specific RMMs are to be implemented by the DU. The hierarchy of the RMMs (STOP-principle, i.e. Substitution, Technical measures, Organisational measures, and/or Personal measures) is generally applied at the DU level. The technical, organisational and personal RMMs which the M/I recommends for DUs should be practical and proportionate to the anticipated risk. For details the reader is referred to the Guidance on Risk management measures and operational conditions, Chapter R.13, including the introduction to the RMM Library.

## R.14.4 Exposure estimation with measurements and modelling approaches

### R.14.4.1 Introduction

Human occupational exposure estimations should be based on the following core principles:

- Exposure estimations should be based upon sound scientific methodologies. The basis for conclusions and assumptions should be explained and any arguments presented in a transparent manner.
- Exposure estimations should describe exposure during defined activities under the operational conditions and risk management measures (RMMs) relevant for the exposure scenario. Such scenarios should be representative of the exposure in the full exposure scenario, including, where relevant, particular subpopulations. Specific attention should be paid to subpopulations or subsets of broad and generic exposure scenarios. The exposure estimation should, where possible, present both reasonable worst-case and typical exposures. The reasonable worst-case is regarded as the level of exposure which is exceeded only in a small percentage of cases. To address the reasonable worst-case, it is recommended to select the 90$^{th}$ percentile of the exposure distribution over the whole spectrum of likely circumstances of use in a particular scenario (see also Paustenbach 2000). The reasonable worst-case should not include extreme use or misuse, but can include the upper end of normal use as it is recognised that control of exposure may be poor or non-existent. Exposure which results from accidents, malfunction or deliberate misuse should not be addressed. Cleaning and maintenance, if carried out regularly and frequently, should be included in normal use.
- Actual exposure measurements, provided they are reliable, representative for the scenario under scrutiny, and robust in terms of sample size, are preferred to estimates of exposure derived from either analogous data or from the use of exposure models.
- Exposure estimates should be developed by collecting all necessary information (including that obtained from analogous situations or from models); evaluating the information (in terms of its quality, reliability etc.), thus enabling sound estimates of exposure to be derived. These estimates should preferably include a description of any uncertainties relevant to the estimate.
- In carrying out the exposure estimation the risk management/control measures (RMMs) that are already in place should be taken into account (for details see Chapter R.13 and Guidance D). Consideration should be given to the possibility that, for parts of the exposure scenarios, risk management/control measures which are required or appropriate for one part of the exposure scenario may not be required or appropriate for another (i.e. there might be sub-scenarios legitimately using different RMMs which could lead to different exposure levels).
- Exposure should normally be understood as external exposure which can be defined as the amount of substance ingested, the total amount in contact with the skin (which can be calculated from exposure estimates expressed as mg/cm$^2$) and/or either the amount inhaled or the concentration of the substance in the atmosphere, as appropriate. The exposures may have to be differentiated into short-term or long-term exposures and compared with the respective

DNELs. For each separate assessment the RCR (= risk characterisation ratio, quotient of exposure level and DNEL) has to be determined. For the estimation of DNELs see Chapter R.8.

- The overall RCR will be the sum of the RCRs (= the sum of inhalation and dermal RCR).

In cases where an EU Indicative Occupational Exposure Limit (IOEL) exists, the registrant may, under certain conditions, use the IOEL in place of developing a DNEL (for further information see Chapter R.8, Appendix R.8-13: Deriving DNELs, when a community/national occupational exposure limit (OEL) is available).

Exposure could be a single event, a series of repeated events, or a continuous exposure. The duration and frequency of exposure, the routes of exposure, workers' habits and work practices as well as the technological processes need to be considered. In scenarios where a person is potentially exposed to the same substance from different products – typically related to combined exposure at a workplace and as a consumer, e.g. in hobbies – exposure scenarios reflecting these concomitant exposures should be assessed in the exposure estimation in the risk characterisation step (see further Guidance Part E).

For estimation of exposure, the following preferential hierarchy should be applied to exposure data for estimation of exposure levels:

- measured data, including the quantification of key exposure determinants;
- appropriate analogous data, including the quantification of key exposure determinants;
- modelled estimates.

Of course, this hierarchy only reflects the situations where the measured data are representative and robust. In many cases, a combination of measured data and modelling approaches may lead to the most appropriate assessment. An uncertainty analysis can help to indicate those exposure determinants with the largest influence on the risk (see Chapter R.19 on uncertainty analysis).

### R.14.4.2 Workplace exposure assessment rating criteria

Available workplace exposure data should have a central role in the process for exposure estimation. Information sources include documentation and workplace measurements collected both by manufacturers and downstream users to fulfil the provisions of the Chemical Agents Directive (98/24/EC). Such data, if of a suitable quality and supported by sufficient information to enable them to be seen as representative of any particular exposure scenario, will reflect real-life conditions better than any modelled representation. To use the exposure measurements in the process of exposure scenario development, a number of factors (IPCS 2008) have to be taken into consideration:

- are the data appropriate for the scenario being investigated?
- are the data supported by sufficient contextual information so that their relevance to the scenario can be determined?
- have the data been obtained using appropriate sampling and analytical techniques to ensure the necessary sensitivity?
- are sufficient data points available to consider the measurements as representative for the scenario being evaluated?

There is extensive guidance on how to develop and implement exposure monitoring strategies to evaluate the effectiveness of recommended risk management advice available (CEN 1995) and on how to report information (OECD 2003). Generally, the process for developing any exposure scenario would not normally require exposure monitoring to be initiated, but, rather, the process needs to take adequate account of available exposure data for the substance. If no data exist, data on analogous and modelled sources can be used with expert judgment.

Table R.14-1 shows a summary of principles for evaluating the usefulness and appropriateness of available exposure data and information in order to determine both reasonable worst-case and

typical exposure values (edited from Money and Margary 2002). The aim of these criteria is to enhance the confidence with which data can be used. If the basis for the exposure assessment is very poor, the table suggests a conclusion that there is a need for more information. Some of the most relevant iterations needed for the development of the exposure scenarios are also indicated in the table.

Table R.14-1: Workplace exposure assessment rating criteria

| Data characteristics | Comments & interpretation |
|---|---|
| **High quality data**<br><br>**Actual measurement data** of high quality, e.g. personal exposure data (including that obtained by biological monitoring) that are representative of the scenario being described; which have been collected and analysed according to recognised (e.g. CEN or equivalent) protocols; and that are available as sets of raw data supported by information on key exposure determinants. | This form of data is likely to enable a decision on whether or not there is safe use.<br><br>There may be a need for more information, if key activities in the exposure scenario are not covered by measurement data presented.<br><br>Data confidence is high. |
| **Medium quality data**<br><br>**Analogous measurement data** of a similar quality to the above and which describe exposures that derive from:<br>• other substances having similar exposure characteristics[4] (e.g. volatility, dustiness) and/or<br>• other comparable activities considered likely to provide a reliable estimate of exposure for the scenario in question.<br><br>**Actual measured data of intermediate quality** e.g. data that have been consolidated and where only basic statistics are available to support them; where data have been obtained using non-standard protocols; where data cannot be described as being fully representative of the exposure scenario; obtained from static sampling which can be shown to reasonably represent personal exposures, etc. | This form of data is likely to enable a decision whether or not the use is safe. A conclusion that there is a need for more information may be appropriate when the estimated exposure levels are close to the DNEL.<br><br>Data confidence is good and this should positively affect the interpretation of the data. |
| **Medium to low quality data**<br><br>**Predicted exposures** derived from suitable models and using input criteria/values that are relevant for the scenario and are derived from generally accepted sources.<br><br>**Actual data of lesser quality,** e.g. where data are | To reflect the increased uncertainty of data, this might lead to the conclusion that there is safe use only if the exposure level is clearly lower than the DNEL. With Tier 1 modelled data in the region of the DNEL the safety of use is less certain.<br><br>Data confidence remains acceptable, |

[4] The judgement on similarity must be provided in the CSR.

| Data characteristics | Comments & interpretation |
|---|---|
| only available from compliance monitoring or static sampling; where limited information on key exposure determinants is available.<br><br>**Analogous data of intermediate quality,** e.g. conforming to the definition for actual data contained in above, but where only basic statistics are available to support them or where data points may be insufficient to suggest representativeness. | particularly when the exposure assessment is derived from an extensive range of sources.<br><br>Exposure data derived from compliance monitoring are often biased towards high-end exposures. This in-built bias should be taken into consideration. |
| **Low quality data**<br><br>**Exposure data arising from sources not addressed in any of the above classes**. For example, this may include data obtained from non-appropriate static sampling; circumstances where input data for models are inadequately defined or some biological monitoring data which have been used to predict airborne exposure levels. | Cannot be used to reach the conclusion that there is safe use. The conclusion that there is a need for more information, and/or interaction steps is the preferred option. The conclusion that the use is not safe may otherwise be indicated.<br><br>Data confidence is questionable and these data alone cannot usefully be used to describe risk. However, such data can be useful in helping to interpret those scenarios for which some exposure data may be deficient and in guiding decisions on the scope and type of additional information needed |

### R.14.4.3 Core information requirements

The following determinants need to be known already for Tier 1 exposure scenarios:

- physical state of the substance
- physical state of the product handled
- vapour pressure (for liquids)
- different levels of “dustiness” (for solids) (see also Table R.14-5)
- the concentration of the substance in the mixture
- the level of containment
- efficiency of local exhaust ventilation (LEV)
- duration of activity
- what is done with the substance, covering parameters related to: energy exerted on the substance or product, surface area of source in contact with air, if very limited amounts handled. (This is an example of a determinant most likely to be very important for a higher Tier assessment.)

PPE is generally not considered, even when it might be used, for the first exposure estimation which focuses on potential exposure. Exceptions are situations where the work cannot be carried out without PPE, for instance the use of gloves when handling corrosive substances, which cannot otherwise be used without serious health risks, or the use of respirators when working with asbestos.

The exposure-reducing effect of PPE is considered as a next step (See Chapter R.13).

### R.14.4.4 Use of measured data

It is important to recognise that available workplace exposure data have a role not only in the process for developing any Exposure Scenario (ES), but also in evaluating the effectiveness of the recommended risk management measures (RMMs). As the Exposure Scenario describes those RMMs and operational conditions (OCs) sufficient to control workplace exposure to below the DNEL of the substance, workplace exposure monitoring constitutes a valuable tool for helping DUs to determine the integrity and validity of the exposure control advice received from further up the supply chain. Extensive guidance has been developed on how exposure monitoring strategies can be developed and implemented to evaluate the effectiveness of recommended risk management advice (CEN 1995). Generally, the process for developing any Exposure Scenario would not normally require new exposure monitoring to be initiated, but, rather, the process needs to take adequate account of available exposure data from actual, analogous and modelled sources.

The purpose of the exposure assessment in a Chemical Safety Assessment is to assess the exposure levels that relate to the described Operational Conditions (OC) and Risk Management Measures (RMM) in the Exposure Scenario. Because exposure, even in relatively well-defined situations, has substantial variability, it is important to assess the so-called 'reasonable worst-case' exposure level. This is a level at the higher end of the exposure distribution in the Exposure Scenario that may occur in specific circumstances leading to higher exposures than the expected averages within that Exposure Scenario, e.g. high production rates or high temperatures with limited natural ventilation. Such a reasonable worst-case level will occur in a minority of the cases within the Exposure Scenario, but is realistic. It excludes cases which are clearly outside the scope of the Exposure Scenario, such as exposures after serious accidents or exposures in situations where workers do not follow the instructions or do not use the required RMM. By using the reasonable worst-case value instead of the maximum or worst-case value the influence of occasional outliers in exposure distributions is reduced.

The ideal situation would be that sufficient exposure measurements are available for a defined Exposure Scenario to enable a judgment to be made that the chosen RMMs (and OCs) are adequate (see Chapter R.13) to control exposures to levels below the DNEL. However, such a judgment implies that a) sufficient data are available that are representative of the range of conditions that any Exposure Scenario might be expected to cover, and b) that the quality of the data are such that their inherent uncertainty is not too large to usefully apply the data. In this respect, there are no 'hard rules' that define what constitutes 'an adequate number of exposure measurements' that should be available for developing any Exposure Scenario; it is only correct to assume that ESs that reflect broad and general or generic activities are likely to require more than those which relate to a specific situation.

Although measured data may be available for many uses of common substances, especially those that are perceived as posing a risk, this will not be the case for uncommon uses or infrequently encountered chemicals. However, suitable measured data for analogous substances and/or modelled estimates of the exposure may be available. In many situations, different forms of exposure data will be available and it will be necessary to combine these in a manner that respects both their inherent qualities as well as the preferred hierarchy that available data should have within the process for ES development.

In the following, the person making judgements on measured data is called the "assessor", since this may be a person representing a manufacturer or importer (M/I), a formulator, a sector specific organisation, or a single company. In many cases, measured data will be taken into account. These data may be gathered from:

- a database of measured data; such a database could be owned by the registrant (e.g. data on measurements during manufacture) or by a government or research institute (e.g. data from compliance testing of research);
- surveys of occupational exposure (e.g. for a substance, for a branch) found in the public domain;
- data gathered by the manufacturer/importer/supplier/trade association of a substance outside the public domain.

The measurement data may be related to the substance as such (which is preferred) or to analogous substances. In addition, the measured data may present either exactly the situation of the scenario or an analogous situation (e.g. gluing instead of brush painting). For the purpose of exposure assessment, analogous data are either data based on similar operations, using the same substance or data based on the same operation, but for similar substances. It is considered that most substances will have analogous 'markers', i.e. substances that can be used if data on the assessed substances are not available or are insufficient. Whilst not providing equivalent reliability in terms of their status in the hierarchy of preferred data (Table R.14-1), such data on 'markers' provide information which is more valuable than that obtained from modelled estimates.

When using data from analogous substances, the M/I must ascertain that his estimation gives a result on the safe side. For example, an estimation based on data from a more volatile substance is on the safe side, while an estimation based on data from a less volatile substance is not on the safe side – it may lead to an underestimation of risk. For example, suppose that an exposure estimate is required for the use of xylene as a cleaning solvent in the printing industry and no (or little) measured data are available. If data are available describing the same activity for another solvent (possessing similar physico-chemical properties, and somewhat higher volatility e.g. toluene), then these data can be considered analogous and used in the manner described in more detail in Table R.14-1. However, the estimation of toluene exposure based on xylene exposure should not be done, as toluene is clearly more volatile. Volatility is a very important parameter for inhalation exposure and comparability should be justified. Similarly, if an exposure estimate needs to be made for discharging e.g. zinc oxide powder, but no data can be identified, then it is acceptable to use the data for another dusty solid which is handled in a similar manner. In such a case attention should be given to comparability in dustiness or, if information on dustiness is not available, on particle size as a surrogate of dustiness[5] .

To assist in the interpretation of measurement data, or in the generation of modelled data, good quality, specific information on the processes in which the substances are used, is required. It will enable exposures to be characterised sufficiently to obtain the best estimate of exposure via all routes. For this purpose, certain core information requirements on determinants have been defined (see Guidance Part D). These should be sought and incorporated into any exposure estimation, regardless of whether or not there are supporting measured data available. The assessor will need to carefully consider all available relevant information. Even when measured data are not available, assessors still need to have all of the descriptive data in order to use exposure models.

### R.14.4.5 Selection and interpretation of measured data

General aspects

Measured data should be representative for the exposure scenario they are applied to. It is recommended to check whether or not data are available from different sources, including branch-specific projects, risk assessments carried out under the Existing Substances Regulation, and the scientific literature. Exposure data are collected for many different purposes, including compliance with national health and safety legislation. The suitability of any data used needs to be assessed as the purpose for which it was collected may affect how it can be used in a REACH exposure assessment.

M/I may have to consider the use of their substances in several branches or, in special cases, for only one DU. Each situation may have different requirements in relation to the measured data. In the first case, they will have to be representative for the whole branch, whereas in the second case the data only need to represent the situation in a single company.

5 Particle sizes of produced solids and dustiness in practical use is not very well related, so the use of data from substances of comparable particle size results in more uncertainty than the use of data from substances of comparable measured dustiness.

When using data from broad exposure situations, care should be taken that the data are indeed representative of the exposure situation to be assessed. When e.g. data are used from a data set described as "gluing", it should be evaluated whether the specific types of gluing to be assessed in the CSA are indeed sufficiently covered by the types of gluing in the measured data set. Issues to be evaluated include the similarity in technology (e.g. level of automation), similarity in scale of the processes (gluing small parts is quite different from gluing flooring in offices) and the potential subgroups within the broad data set that could be better described by their own specific Operational Conditions, Risk Management Measures and resulting exposure levels. For manufacturing processes of chemical products a differentiation may be warranted e.g. between general operations, loading and unloading activities and maintenance work.

Where exposure measurements are available, it should be possible to link them to the OCs and RMMs described in an Exposure Scenario. The information could be expected to include:

- Raw data reflecting personal exposures (comprising single data points) listing: measured concentration; units of concentration; sampling duration; duration and frequency of relevant exposures; description of sampling; analytical methods and tasks undertaken during the monitoring period.
- Where necessary, annotations explaining apparent anomalies. Data should cover personal exposures over the working shift and/or describe short-term and/or peak exposures where acute hazards exist and/or where major tasks are undertaken which could give rise to significant exposure. Data collected using static samplers should only be used in the exposure estimation if there is sufficient information provided to demonstrate how they reflect personal exposures or that they provide a conservative estimate of personal exposures (*i.e.* that in this situation personal exposure levels would be lower than results from static samples). Air samples should be taken at breathing zone height and in the immediate vicinity of workers. If there is a large quantity of pooled and statistically evaluated data available, these data may be used provided that the methods used to do this and reasons for using data from static sampling are made clear. The raw data should be available for the assessor (and for the evaluator of the exposure assessment) to examine them if needed.
- Details that enable the reliability and representativeness of the data to be confirmed have to be assessed. These include considerations such as:
    - Quality assurance information providing evidence that data have been collected and analysed according to officially recognised protocols and methods, e.g. ISO/IEC 17025:2005, to describe the requirements for the quality assurance information, the data collection, the quality of the protocols, inter-laboratory quality assurance, the sampling strategy, etcetera, clearly.
    - When and why were the data obtained?
    - Do the data cover the use(s) including processes, activities and RMMs defined in the exposure scenario?
    - What were the conditions at the time of the measurement, e.g. normal or abnormal?
    - Were the data collected according to general requirements for the measurement of occupational exposure to chemical agents e.g. EN 482:2012 (CEN 2012) and measurement strategy e.g. EN 689 (CEN 1995) and validated analytical methods?
    - Do the data reflect past or present practice within the industry?
    - Do the data reflect conditions in one company or are they representative of the industry?

<u>Inhalation data</u>

Generally, at least 6 data points should be presented to adequately describe the exposure of a single work activity within one company, but many more (and generally no less than 12) would be considered necessary for an activity that was undertaken in a sector of industry. The exact number of data points needed for the risk assessment very much depends on the confidence in the data,

specifically in the representativeness and level of 'fit' between the data set and the situation to be assessed, as well as on the margins between DNELs (or DMELs) and the measured exposure levels (see Table R.14-2). The quality of an assessment based on only a discrete measurement data set depends on the sample size, the spread in the data and the homogeneity of the dataset (probably related to the variances in the exposure scenario). The confidence related to the estimated value taken for the exposure is higher with larger sample sizes and more narrow distributions. The broadness of scope of the situations measured and their 'fit' to the situation to be assessed is also very important. Assessing exposure for broad exposure situations needs much more data to ensure sufficient coverage of the broad situation and to enable evaluation of potentially relevant subsets. Another important factor is the difference between the surrogate exposure level and the limit value involved (the appropriate DNEL), called the RCR. Table R.14-2 presents a practical example of how to estimate how many data are needed to ensure that the data is robust enough to provide sufficient confidence that the true reasonable worst-case value is below the DNEL. It should be noted that data from one company is unlikely to be representative of a whole industrial sector.

Table R.14-2 suggests some rules of thumb on the number of data points needed for sufficient confidence in the estimates based on the dataset. The different levels of variation and/or uncertainty in the exposure data and the size of the derived risk characterisation ratio (RCR) drive the desirable number of data points to ensure that there is a high confidence in a true RCR below of 1 (loosely based on a table in Milz et al., 2006).

**Table R.14-2**: Indicative number of measurements needed to determine confidently that the true RCR is below 1

| | | RCR : <1 - 0.5 | RCR : <0.5 - 0.1 | RCR : <0.1 |
|---|---|---|---|---|
| | | N | N | N |
| Variation and uncertainty in the data$ | Low^ | ~20-30 | 12-20 | 6-12 |
| | Moderate + | ~30-50 | ~20-30 | 12-20 |
| | High* | >50 | ~30-50 | ~20-30 |

N= number of samples
RCR = Risk Characterisation Ratio
$ Variation and/or uncertainty can be caused by on the one hand true variation in exposure (as indicated by a measure of variation) and on the other hand by lack of knowledge about how representative the data are for the situation to be assessed.
* **High**: a high geometric standard deviation (GSD) in the measured data (e.g. > 3.5) or the representativeness of the data is suspected to be significantly uncertain for the situation to be assessed.
+ **Moderate:** a moderate GSD (e.g. 2 – 3.5) and/or the representativeness of the data is questionable.
^ **Low** : a low GSD (e.g. < 2) and the data can be considered representative for the situation to be assessed.

The use of Table R.14-2 is illustrated by the following examples. If the (expected) variation in the exposure is high and/or if the uncertainty regarding the representativeness of the dataset is high and if the RCR based on the estimated reasonable worst-case value is close to 1, a high number of data points (e.g. > 50) is needed to provide sufficient confidence that the real RCR is below 1. However, if the dataset is known to exactly fit the exposure scenario, there is limited variation in the exposure and the RCR based on the estimated reasonable worst-case is between 0.5 and 1, a dataset of 12 to 20 data points provides sufficient confidence in a true RCR < 1.

In order to obtain representative inhalation exposure measurements the duration and time of the monitoring should be carefully chosen. In addition, the data should be capable of properly representing exposure throughout the whole of the time-weighted average reference period (normally 8-hour).

Ideally, in order that data can be viewed as being representative for the exposure scenario, they should be collected using randomised sampling strategies. Information collected using non-random strategies, e.g. worst-case sampling as part of a compliance programme, will be biased, for the purposes of exposure assessment. Whilst such data can be useful in describing some exposure scenarios, it should only be used if sufficient contextual information is available.

The bias in the data should be acknowledged. Any significant bias within the data should be identifiable, at least in qualitative terms, and dealt with where appropriate. Bias alone should not exclude data from consideration; e.g. the removal of high-end exposures due to leaks, spills, etc. It should be identified and acknowledged.

*Particle size*

If exposure to dusts takes place, an indication of the particle size distribution of the dust should be provided. This information is useful for the estimation of uptake through inhalation, because the biological uptake – and resulting systemic availability of the substance - may depend on the deposition location in the airways. This deposition location in turn depends on the particle size distribution. The percentages of inhalable dust (100 micrometers or less), respirable particles (10 micrometers or less) and ultrafine or nanoparticles (below 100 nm (0.1 µm)) are very relevant for health effects. For measured data on dusts, as a minimum the size selection characteristics of the sampling methods used should be provided.

Dermal data

Many of the factors which influence other forms of exposure, such as the way a job is done, environmental conditions, and human factors introduced by the interface between workplace and operator, also influence the magnitude of potential dermal exposure. Contamination will rarely be evenly distributed over the body. In some cases it will occur on areas well protected by personal protective equipment (PPE) or clothes, whereas in other cases the exposed skin, or even areas beneath protective clothing, may be contaminated. Knowledge of the distribution of contamination on the body may lead to a more effective risk assessment. Ideally real representative exposure data should be used to assess the health risks arising from dermal exposure.

The approach to assessment of dermal exposure is to use measurement data for scenarios when they are available (including use of analogy reasoning) and to use appropriate models if measured data on the scenario are not available.

Measured dermal exposure data should include information on: surface area sampled ($cm^2$); mass of contaminant (mg); mass per unit area ($mg/cm^2$); duration of sampling/exposure (minutes); frequency of exposure (number of times per day that separate exposure situations occur, e.g. number of batches produced per day); duration of exposure periods; sampling method and the composition of any mixtures, with specific attention to the concentration of the assessed substance. This information should be complemented by a description of the tasks during the performance of which the exposure occurs.

Supporting information should include details of workwear worn, differentiating between general workwear and protective clothing and equipment, and details of personal hygiene. Potential

exposure from unclean general workwear (that actually represents exposure from previous exposure situations) should not influence the results that need to be used for specific exposure scenarios.

There are not many measurement data for dermal exposure. A good source is the RISKOFDERM project that has resulted in large number of measurements, reports and publications. The project also resulted in development of an expert model for estimating potential dermal exposure (see Section R.14.5.2).

During handling of corrosive or hot substances the use of protective gloves and other equipment, such as face shields, aprons and good work practices are required. As a result, direct dermal contact occurs only occasionally. Therefore, repeated substantial daily dermal exposure is unlikely. For properly labelled corrosives, the emphasis in the CSR and ES should be on the presentation of adequate risk management measures, rather than on the assessment of the risks from dermal exposure. However, effects due to other properties of the substance may need to be assessed. If during the use of a corrosive substance mixture diluting/mixing occurs which results in a mixture without corrosive properties then dermal exposure to this mixture should be assessed, i.e. repeated dermal exposure cannot be disregarded.

For highly volatile substances, dermal exposure is reduced because of the shortened retention time of the substance on the skin. In Appendix R.14-1 an equation for calculating the evaporation time is given. The evaporation time should be considered in relation to the absorption rate to provide an indication of the relative percentages of external contaminants that are either absorbed by or evaporate from the skin.

This exposure reducing effect due to evaporation cannot be considered if workers have continuous direct contact with the substance. Furthermore, to take the fast evaporation of a substance into account, non-occlusive dermal exposure has to be the predominant exposure situation. However, there are scenarios (e.g. production and further processing in the chemical industry) for which the unhindered evaporation of substances from the skin (or the protective clothes) is likely.

Biological monitoring

When available, biological monitoring data can be used within the exposure assessment. It can add value to the exposure assessment process by providing information that enables a better understanding of the nature and extent of the total exposure, through all exposure routes. Biological monitoring information serves as an additional data point that helps to both better characterise exposure and further reduce the uncertainty surrounding the effectiveness of control measures in the workplace, including PPE. However, biological monitoring information requires careful interpretation by experienced practitioners. Sufficient information must be provided to show the relevance of the biological monitoring data to the substance, jobs and/or tasks. The half-lives of substances measured by biological monitoring determine whether or not a measured result is representative of a day's exposure or a longer period. For example, in some cases taking one blood sample at the end of the day is appropriate, whilst in other cases a full day pooled urine sample (24 hours) should be used.

Biological monitoring information reflects actual exposure, i.e. it indicates that exposure has occurred and that absorption into the body has taken place. However, together with further information (e.g. point and time of the sampling) it sometimes indicates the primary route of exposure or the relative proportions that different exposure routes contribute to total dose.

Biological monitoring information should be seen as equivalent to other forms of exposure data (i.e. as having neither greater nor lesser importance than) e.g. airborne contaminant measurements. Biological monitoring data must also meet all of the quality requirements that relate to other forms of exposure information. That is, it must be of a high quality and representative for the circumstances it is intended to describe. For a number of compounds, biological monitoring is well established and described (in terms of methodology, analytical quality assurance and control parameters and pharmacokinetics). For the majority of substances however, methodology is still

under development and essential features, such as quality control standards and programmes are lacking.

It should also be remembered that biological monitoring results reflect an individual's total exposure to that substance through any relevant route and from any source, i.e. from consumer products, and/or from the environment and not just occupational exposure. In the case of confounding variables it may difficult to link biological monitoring data to specific Exposure Scenarios, even though in many cases occupational exposure is the most influential.

For biological monitoring data a number of parameters should at least be mentioned. These include the exact parameter measured, the sampling strategy (e.g. spot sample at the end of the working day, or 24 hour sample), the biological half-time of the measured substance and any information that may help in the interpretation of the data. Biological monitoring data should be presented with the same core information as data on inhalation or dermal exposure to enable proper interpretation of the outcome in relation to working conditions. Where available, established relations between biological monitoring levels and inhalation (or dermal) exposure levels should be presented. A clear presentation of the meaning of the biological monitoring data in relation to inhalation and dermal exposure levels, exposure duration and possible health outcomes should be provided.

In order to make use of biomonitoring data, it is necessary to compare measured data to either a DNEL for the relevant biomarker or to an external DNEL. Where comparisons are being made to an external DNEL it is necessary to have data to indicate the relationship between levels of the biomarker and the external dose metric on which the external DNEL is based. The toxicokinetic properties (e.g. absorption percentages) that form the basis for the relationship between the biomarker and external dose metrics should be clearly described. The comparison of biomonitoring data with DNELs is further described in Chapter R.8.

Uncertainty and statistics

There are various uncertainties relating to occupational exposure assessment. These are:

- measurement uncertainties (including those arising from the sampling method);
- selection of measurement results;
- uncertainties of model results;
- assessment uncertainties.

If any of the sources of uncertainty or variability are ignored or at least some indication of their likely impact on the final assessment is not given, this will lead to assessments which will have doubtful precision and accuracy. All of these uncertainties and variabilities need to be considered along with the uncertainties related to the interpretation of the toxicological data in the process of risk assessment. Uncertainties, specifically if they relate to the representativeness and appropriateness of measurement data in relation to the Exposure Scenario to be assessed, can in some cases be compensated for by using a more conservative estimator (see also Chapter R.19).

The quality of exposure information and its applicability to the assessment process requires careful evaluation before it is incorporated into an exposure assessment. This evaluation should always be carried out using the expertise of occupational hygienists, rather than applying simple conventions or the rigid use of statistical methods. For example, account will normally need to be taken of the conditions under which the information has been collected, in order to establish how representative this information is, and hence the relevance and weight it will have within the exposure estimation process. Information collected when work processes go wrong may not be truly representative for routine operations, even though the data may be used to draw other conclusions on a variety of conditions. Conversely, large quantities of information collected on a substance from the routine operation of manufacturing plant will almost certainly not represent many downstream uses of the same substance.

Relevant expertise is also needed to enable proper use of statistics from measured data. For exposure estimates, the comparison of chronic DNELs or DMELs with the reasonable worst case full shift exposure level is needed. What level represents a reasonable worst case in measured data sets depends on the data set. In general, it is a level in the higher part of the exposure distribution. It should be chosen to ensure that the value is still very likely to be relevant as a long term estimate for most workers, also in cases where broad scenarios contain (potentially unknown) subgroups of workers that have a systematically higher exposure within the boundaries of the Exposure Scenario. Since broad scenarios will be described by just a few parameters of OCs and RMMs, there is ample room for subgroups to exist.

Evaluating potential differences between subgroups can be very useful to prevent on the one hand underestimating risks (if the higher exposure of a subgroup is masked by many lower exposure levels of other subgroups) and on the other hand overly conservative requirements put on OCs and RMMs (if certain RMM are e.g. only needed for a high exposure subgroup and not for the total exposed population). Based on such analysis the registrant may choose to develop a separate exposure scenario for the highly exposed subgroup.

If the registrant intends to base the exposure assessment on sets of measured data, some general rules should be considered when selecting the representative value (for the reasonable worst case) from the exposure distribution:

- Evaluate whether the available exposure data set is generally adequate for deriving an exposure estimate that reflects the conditions of use described in the exposure scenario. If yes, select the appropriate percentile.
- It is recommended to select the 90$^{th}$ percentile of an exposure distribution reflecting the whole spectrum of conditions of use described in a particular exposure scenario.
- Under particular conditions other percentiles may appear applicable as well. A justification should be provided in the CSR.
    - It may for example be appropriate to use a 75$^{th}$ percentile if the measured data set represents only the worst case situation but is applied to characterise a broader range of conditions, and where the real percentage of exposures exceeding the selected value will be much lower than 25% (see Example R.14-1).
    - Another case for possible use of lower percentile could be a well defined, high quality data set referring to homogenous (narrow) exposure conditions, characterised by a risk characterisation ratio clearly below 1 and being fully representative for the OC and RMM described in the exposure scenario.

The 50$^{th}$ percentile or median of measured data is not recommended as the estimator for worker exposure in a chemical safety assessment.

**Example R.14-1: Exposure estimations in different settings**

An Exposure Scenario is ‘rolling and brushing of paint containing substance X’. The paint can be used throughout Europe, both indoors and outdoors and in all seasons. A paint containing substance X can contain a relatively high or a relatively low percentage of X (e.g. between 5 and 30 %). The Exposure Scenario should cover all possibilities. The worst case situation within the scenario may be workers using paint with 30 % of X indoors in the summer in Southern Europe.

A large dataset is available that presents measured data from measurements in Europe, where no information is available on percentage of X in the paint, on the area in Europe where measurements were taken or on the temperatures at the times of measurement. In this case a high percentile (e.g. 90$^{th}$ percentile) of the exposure distribution should be used as a reasonable worst case.

If, however, there is a very specific data set for workers in Southern Europe using paints with high percentages (30 %) of X, and the scenario is meant to also cover situations with lower expected exposures (low percentage of X in paint used and low temperature during measurements) the use of a lower percentile, such as the 75$^{th}$ percentile could be considered. All the data available and assumptions made in the handling and interpretation of the results, need to be justified and documented in the CSR.

Another parameter that cannot generally be recommended is the maximum of a data set. Since worker exposure tends to have a skewed (often lognormal) distribution, there is generally a small possibility of a very high exposure level. Many large data sets have one or two high values and therefore a very high maximum. This maximum level is not representative of the reasonable worst case and will overestimate the risks. Of course, if the maximum of a large representative data set is clearly below the DNEL, the conclusion of safe use can also be drawn by using the maximum as estimator for the exposure level. Such a maximum could be related to high exposure values representative for a specific sub-group, which may warrant a specific exposure scenario.

### R.14.4.6 Acute exposures

Exposure to some substances may lead to acute health effects. If a substance is classified for acute effects and 'peak exposure' is likely to occur, an acute DNEL should be derived (Chapter R.8). Exposure situations without 'peak exposure' (i.e. an acute exposure level clearly higher than the related full shift exposure level) are very rare. Therefore, in most cases a classification for acute effects should lead to an acute DNEL. In order to provide a relevant estimate of exposure the assessor should request acute exposure data. If such data are available they should be evaluated in the same way as described earlier. Where the data are of sufficient quality and reliability they can be used to provide a reasonable worst case and typical value for acute exposure. In the risk assessment the comparison should be made with a relevant DNEL, e.g. an acute DNEL.

The relevant duration of 'acute exposure' and 'acute DNEL' is not specifically defined. Very short durations (seconds to minutes) are only seldom assessed and then mostly by direct reading instruments. On the other hand, the closer the relevant exposure duration is to a full shift, the less relevant a differentiation between acute and full shift exposure is.

For inhalation exposure peak exposure could generally be considered to be the exposure averaged over 15 minutes (Chapter R.8). This corresponds well with the STEL value (short term exposure limit) for 15 minutes exposure duration used in the worker protection legislation (EC 2000). The documentation of the measured data should always include the sampling time as accompanying information.

The aim of assessing acute exposures may differ from that of normal 8 h exposure assessment. The type of acute effects should be taken into account in assessing short term exposure. For substances that may cause lethal effects after a single acute exposure, exceeding certain values cannot be allowed at all. It might be important to detect the high peak exposures for e.g. respiratory sensitisers. For substances whose acute effects being transient and not very severe are not the first signs of long-term effects, a certain probability of occurrence may be considered acceptable. Because acute effects may occur immediately after exposure, after a brief period following exposure or after only one or a few consecutive exposure events, the exposure estimator to be compared with the acute DNEL should generally be a high percentile of the exposure distribution of acute exposure measurements e.g., the 95$^{th}$ percentile could be suggested as the reasonable worst-case estimator of short term exposure for effects that are reversible and not severe.

Acute exposure measurement data, due to their nature, are more variable than corresponding full shift exposure levels in the same situation. Acute exposure values are also related to each other, especially acute exposure values measured just before or just after each other. Based on this knowledge, the relation between parameters of acute and full shift exposure distributions have been calculated (Kumagai and Matsunaga 1994). The 95$^{th}$ percentile of 15 minute exposure data is about twice the 90$^{th}$ percentile and 4 times the 75$^{th}$ percentile of full shift data collected for the same situation.

Measurements of acute exposure can often be aimed at tasks or conditions with the highest expected exposures. In this case, similar numbers of measurements are needed as for full shift exposures. However, when moments of high exposure are difficult to predict and acute exposure measurements are taken randomly during a shift, more measurements are needed. Generally, a minimum number of 20 short term exposure measurements is recommended for a reasonably certain estimation of the 95$^{th}$ percentile of the acute exposure distribution. For data sets with a rather uncertain fit to the Exposure Scenario, with a known very large variability or with a reasonable worst case close to the short term DNEL, substantially higher numbers of measurements may be needed to consider the data set a robust data set.

#### R.14.4.6.1 Estimating acute short term inhalation exposure

This chapter gives guidance on how to estimate reasonable worst-case acute inhalation exposure levels when only full shift exposure levels or estimates are available. Because of concern related to chronic health effects caused/contributed to by exposure for airborne substances, occupational exposure limits are mainly set for full shift (8 hour) exposure. Therefore in many worker situations only full shift exposure levels or estimates are available. Exposure models, e.g. ECETOC TRA, also focus on full shift exposure levels. If acute effects are also of concern, an estimation of the acute exposure levels is also needed for the risk assessment. It is possible to extrapolate full shift exposure levels or estimates to derive acute exposure estimates (see the above paragraph on acute exposure measurement data). This statistical extrapolation can be used for substances with less severe and generally transient acute effects, but not for those with severe acute effects, e.g. death after short term exposures.

The basis for the extrapolation from full shift exposure estimates to acute is the fact that most exposure distributions tend to be (more or less) lognormal and that the geometric mean (GM) and Geometric Standard Deviation (GSD) of such distributions with different averaging times are related (Kumagai and Matsunaga 1994). Percentiles of lognormal distributions can be calculated from the GM and GSD and therefore the percentiles of distributions with different averaging times are also related. The percentile to be used as reasonable worst case estimator is not a fixed percentile, neither for full shift nor for acute exposure data. For full shift estimates, based on the (uncertainty) of the data and the assumed fit of the estimated situation to the situation under assessment a 75$^{th}$ to 90$^{th}$ percentile could be used. For acute exposure estimates, due to the acute nature of the effects, a relatively high percentile would probably be needed.

Acute reasonable worst-case values can be derived from full shift values by using a multiplication factor. This factor depends on the conservativeness of the reasonable worst-case short term value required, i.e. on the percentile of the acute exposure distribution that is considered to be the reasonable worst-case value. It also depends on the percentile that was used as reasonable worst-case value for the full shift and on the variability within the Exposure Scenario in the full shift exposure levels. A number of default factors have been derived, based on equations from Kumagai and Matsunaga (1994) with corrections for autocorrelation relevant for the extrapolation between the short term (15 minutes) averaging time and the full shift. In Table R.14-3 the factors by which the full shift reasonable worst case should be multiplied to estimate an acute reasonable worst case value are presented. The relationship between 95$^{th}$ or 99$^{th}$ percentiles of 15-minute exposure distributions and 75$^{th}$ or 90$^{th}$ percentiles of 8-hour distributions are complex curves, depending on the GSD of the 8-hour distribution (Appendix R.14-2). In most cases the curve increases with GSD, but the curve relating 95$^{th}$ percentile of 15-minute exposure with 90$^{th}$ percentile of 8-hour exposure peaks at low GSDs. Therefore the extrapolation factor for high GSDs is in this case lower than for low GSDs.

**Table R.14-3**: Multiplying factors to generate acute reasonable worst-case value from full shift values

*(Based on calculations using equations from Kumagai and Matsunaga (1994))*

| Situation | Full shift reasonable worst case = 75th percentile | | Full shift reasonable worst case = 90th percentile | |
|---|---|---|---|---|
| **Acute (15 minute average estimator** | **95th percentile** | **99th percentile** | **95th percentile** | **99th percentile** |
| Not very high variability (default)[a)] | 4 | 20 | 2 | 6 |
| Very high variability[b)] | 6 | 40 | 1.5 | 10 |

[a)] In general there is substantial variability in worker exposure levels. Use these values when the variability is unknown, but there is no reason to assume that the variability is very high, or if the GSD of the full shift exposure distribution is up to 6.

[b)] In some cases day to day variation in exposure is very high, e.g. when activities generally require limited opening of systems and manual intervention, leading to generally very low exposures, but some activities that occur infrequently require opening of systems and manual intervention, leading to very much higher exposures. Use these values if this is the case or if the GSD of the full shift exposure distribution is above 6.

Full shift estimates in the ECETOC TRA are assumed to represent the 90th percentile of the exposure distribution. It is also assumed that in general the variability will not be very high. Therefore, it is recommended to multiply a full shift ECETOC TRA estimate by a factor of 2 to estimate the 95th percentile or a factor of 6 to estimate the 99th percentile of the related short term exposure distribution. For full shift estimates with models providing percentiles of the output distribution (e.g. Stoffenmanager) the factor to be used depends on the percentile used for the full shift estimate.

The above mentioned method should not be used if it is clear that acute exposure levels are not lognormally distributed, e.g. if there is only one 15 minute exposure period on each day with no exposure during the remainder of the day. In such cases specific estimates should be based on data or model estimates for the specific exposure periods. Further guidance on assessing acute inhalation exposure is presented in Appendix R.14-2.

#### R.14.4.6.2 Acute dermal exposure assessment

Inhalation and dermal exposure as well as the methods to assess the exposures have different characteristics. Therefore, the derivation of short term exposure estimates for dermal exposure is not similar to that for inhalation exposure.

For possible systemic effects caused by dermal exposure, consecutive or repeated short term sampling is often not feasible. Dermal contamination on the surface of the skin may in real life be variable over a shift, due to a complex combination of contamination and decontamination processes. This would lead to a possible 'peak internal dose'[6] if there is a high dermal absorption rate (in µg/cm$^2$/min) during, or briefly after, periods of higher contamination of the skin. If the dermal absorption rate is low, the effect of variation in dermal exposure will not be transferred to internal exposure because the variation will be flattened out before absorption takes place: the contaminant will stay on the skin until it is finally removed (intentionally or by incident) or absorbed. In these cases internal peak doses will rarely occur.

6 The terms 'peak exposure' and 'short term exposure' are not precisely defined, leading to possible differences in interpretation. In this paragraph 'short term' and 'peak' exposure are considered to be similar and are defined as a clearly higher exposure than the full shift average occurring over short periods, e.g. from a few minutes up to an hour.

Most existing dermal exposure measuring methods, with the exception of special techniques, remove what is on the skin (or on sampling media on the skin) at the moment of sampling. Monitoring of short term dermal exposure levels necessitates special expertise in skin exposure assessment and good knowledge of the activity being studied.

Dermal exposure models derive either exposure levels for the full exposure period or contamination levels in mg/min, which should be multiplied by the duration of exposure to calculate exposure estimates for the full exposure period. They do not deliver values that can be used for 'time weighted averaging' over repeated samples.

Based on the methods and characteristics of dermal exposure, it is pragmatic to assume that short term exposure to the skin will give rise to lower exposure levels and internal doses than if the skin were repeatedly or continuously exposed for a full shift. On this basis, it would be precautionary to use long-term dermal exposure values to assess the risks for systemic effects that occur from short term dermal exposures. The long-term dermal exposure value should be compared with DNELs derived for systemic effects for long-term dermal exposure.

Exposure estimation for local effects on the skin uses other units (µg/cm$^2$) and is driven to a greater extent by the concentration of the assessed substance in the contamination reaching the skin than by the total contamination over the full exposed area. The exposure associated with the maximum percentage of substance in the product should therefore be used as the basis for estimating acute local skin effects.

### R.14.4.7 Use of exposure estimation tools

The currently available tools for first Tier occupational exposure estimation have been developed to be at the same time simple-to-use and inherently conservative. They are therefore best used as initial screening tools i.e. they enable a defined range of OCs and RMMs to be identified and evaluated quickly.

In principle the determinants listed in Section R.14.4.3 need to be known for Tier 1 exposure assessment modelling and description of exposure scenarios (the relevant input data depends on the model used). In the following section the preferred Tier 1 tool (ECETOC TRA) is described in Section R.14.4.8. In Section R.14.4.9 another first Tier tool, the EMKG-Expo-Tool is described. In Section R.14.5 higher level assessment tools are presented.

Limited comparisons of the tool-predicted exposure with available measured data (independent data-sets) show a reasonable correlation for all the tools described in more detail in the following sections. Nevertheless, there is room for improvement. This is especially the case for inhalation exposure to particulates or aerosols, which is more complicated to model and predict. Moreover particulates have not been investigated as much as volatiles, leading to a more uncertain prediction of exposure, including potential underestimation of worst case exposure concentration for particular activities (or process categories).

If use activity/process categories are one of the input parameters (determinants of exposure) choosing the most appropriate activity/process category for a given activity at company level is the individual choice of the user. These choices and potential mistakes related to them also impact on the "validity" of an exposure prediction.

Registrants need to be aware that exposure prediction based on the tools described in this guidance cannot be considered as finally "validated" in a strict sense. Experience in using the tools and increased availability of more exposure information over the next few years will lead to further development of the tools and the related models. Comparing the results with measured data or using more than one model in parallel for prediction reduces the uncertainty in risk characterisation in a practical assessment case.

### R.14.4.8 ECETOC TRA tool for occupational exposure [7]

This section describes the methods employed in the determination of exposure for the worker aspects of the ECETOC Targeted Risk Assessment. ECETOC developed the approach to assess the health and environmental risks from the supply and use of chemicals. This section presents the methodologies developed to estimate inhalation and dermal worker exposures. The ECETOC TRA assessment is also provided in an integrated version which allows the user to perform worker, consumer or environmental assessment via one interface. All ECETOC TRA tools can be downloaded free of charge, after completing the download request form from http://www.ecetoc.org/tra. The integrated version can also be used to carry out batch calculations: calculating several exposure scenarios at once (for workers, consumers and the environment) in a batch mode.

For occupational exposure the ECETOC approach uses established exposure prediction models (EASE with documented modifications by industry experts) but introduces a more precise, structured and simplified approach in order to make it amenable to a more rapid assessment and to a wider user community. The approach also uses the common practice in the workplace that, by using a suitably conservative exposure prediction model which leads to a demonstration of low risk for a specific scenario of use, eliminates the subsequent need to collect and use measured exposure data for another assessment of the same scenario.

The concept for the worker exposure was to provide the user with the risk assessment methodology that selects the Process Categories (PROCs) for the broad sector of use (either industrial or professional) of a substance, and then enables further modifications by selecting exposure control (Risk Management Measures). For guidance on the type of RPE leading to the required reduction in exposure the tool refers to COSHH Essentials sheets, available at: http://www.oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf.

The assessment as an output is a simple description of the type and basic conditions of use which can then be translated into a calculated exposure using an exposure model. The calculation basis of the approach is a modified version of the EASE (Estimation and Assessment of Substance Exposure) exposure model version 2.0, developed by the UK Health and Safety Executive (HSE 2003). The following text gives a description of the ECETOC TRA tool (version 2010).

*Strengths*

- Clear structure
- The process categories (PROCs) as applied in use description in Chapter R12, can be easily linked to exposure estimates based on the TRA
- Ability to predict both inhalation and dermal exposures for any chosen scenario
- Duration of process/activity/operation unit is taken into account
- Exposure scenarios based on EASE and expert input from industry stakeholders
- The process type and the setting (industrial or professional) is taken into account in defining the effectiveness of the local exhaust ventilation
- The percentage of a substance in a mixture can be used to iterate the inhalation exposure
- The effect of respiratory protective equipment (RPE) is taken into account in inhalation exposure
- Results of the assessment can be saved for later modification
- There is the possibility to calculate several scenarios simultaneously.

7 Please note that a new version of the Tier 1 tool ECETOC TRA was released in 2012. However, the present corrigendum only addresses alignment with the CLP Regulation and minor editorial/changes and corrections. Thus, the reference to ECETOC TRA in the text are referring to the version 2.

*Limitations*

The ECETOC TRA for worker is a first Tier tool. It is therefore intentionally limited in scope and detail.

- It is not always easy to choose between 'industrial' and 'professional' use[8]
- The amount of product used cannot be taken into account
- Limited OC and RMM taken into account; e.g. no possibility to distinguish between automated (remote-controlled) and manual process
- The percentage of a substance in a mixture is not taken into account for dermal exposure (ECETOC 2009). The percentage of a substance in a mixture is not considered for solids
- Personal protective equipment for dermal exposure is not included
- The type of RPE providing a defined level of reduction are not specified in the tool
- The dermal exposure for some situations with local exhaust ventilation is underestimated compared to measured data (e.g. RISKOFDERM project). In the light of knowledge having become available since EASE was published, the LEV effect on dermal exposure assessment may sometimes be overestimated by the model

*Ways to compensate for limitations*

- Assume professional use if it is unclear whether a use best fits professional or industrial
- Recalculate the dermal exposure level for substances used in mixtures at concentrations below 100% outside the model by using the exposure modifying factors used in ECETOC TRA worker for inhalation exposure
- Recalculate potential dermal exposure to actual dermal exposure (to account for Personal Protective Equipment) outside of the model
- To be more confident on the dermal exposure prediction under LEV conditions, the assessor could continue with higher tier assessment (e.g., Riskofderm). He could also recalculate the dermal exposure level outside the tool by setting the effectiveness of the local exhaust ventilation regarding dermal exposure to "0" or any other value significantly below the 90 to 99% assumed in the TRA (to reach a conservative estimate).

*Applicability*

- Not applicable (directly) for non-mineral solids used at elevated temperature (e.g. molten).

*Status of validation*

- The output of the previous TRA tool has been validated against risk assessment results but not against measured exposure data sets. No systematic comparison between tool prediction and measured data sets have been published so far.

#### R.14.4.8.1 Input data

The input parameters for ECETOC TRA worker are

- Molecular weight (needed for recalculation from ppm to mg/kg bw/day and for the recalculation to mg/m³)
- Physical state of the substance (solid or not)

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[8] In many cases this choice is clear, but there are some situations in which the difference may not be obvious. E.g. spray painting in a car repair shop, repair and building work at industrial sites and work in a small 'wood working factory'. For more information, see ECETOC Report 107.

- Vapour pressure (liquids/gases) or dustiness (solids)
- Process Category (PROC)
- Whether the activity is industrial or professional
- Whether the activity takes place indoors or outdoors
- Presence of Local Exhaust Ventilation (LEV; only for indoor activities)
- Duration of the activity (in classes)
- Type of respiratory protection used
- Whether the substance is used in a mixture
- Concentration range of the substance in the mixture (in classes; only if used in a mixture).

In addition to these inputs that are needed to calculate exposures, some values also need to be entered for substance name, CAS number and short scenario name, as they are required by the software.

Vapour pressure and dustiness

All input data are captured in the tool on an input data screen. The vapour pressure and dustiness are used to categorise the material as to its fugacity (tendency of a substance to become airborne from a heterogeneous system) as defined in an availability banding for an initial assessment. The term 'volatility' will be used in the rest of the description as a proxy for 'fugacity'. The data are stored in the tool and used for assessment of worker exposures. For metals the fugacity is based on the relation between process temperature and the melting temperature of the metal. This is accounted for in the choice of PROCs. Tables R.14-4 – R.14-6 presents the categories used by ECETOC TRA.

**Table R.14-4**: General fugacity table

| Vapour pressure (kPa) | Dustiness | Fugacity |
|---|---|---|
| >=0.00001- <0.5 | Low | Low |
| 0.5 to 10 | Medium | Medium |
| >10 | High | High |

**Table R.14-5**: Help on fugacity selection criteria

| General description | Relative dustiness potential | Typical materials | TRA Selection Value |
|---|---|---|---|
| Not dusty | 1 | Plastic granules [a], pelleted fertilisers | **Low** |
| Slightly dusty | 10 - 100 times dustier | Dry garden peat, sugar, salt | **Low /Medium** [c] |
| Dusty | 100 - 1,000 times dustier | Talc, graphite | **Medium** |

| | | | |
|---|---|---|---|
| Very/extremely dusty | More than 1,000 times dustier | Cement dust, milled powders, plaster, flour, lyophilised powders, (process fumes [b]) | **High** |
| [a] Exposures to materials where a substance is contained and bound in a matrix (e.g. pigment within a plastic, filler within paint) should also be included in this category. Although the real exposure is actually determined by a combination of physical form and the bioavailability of the substance within the matrix, because the bioavailability is very low under such circumstances this will result in a low exposure potential. | | | |
| [b] Process fumes (e.g. rubber, welding, soldering) behave like gases and would be considered within this category if exposures to such complex mixtures are considered in any risk assessment.<br>[c] The user may choose between low and medium fugacity | | | |

**Table R.14-6**: Fugacity classifications for process temperature / melting point relations (PROCs 22-25 (metals) only)

| Process temperature* in relation to melting point | Fugacity |
|---|---|
| process temp < melting point | low |
| process temp ≈ melting point | moderate |
| process temp > melting point | high |
| * In drilling or "abrasion" techniques (e.g. grinding) the temperature of the "tool-material contact area" may be used instead of the process temperature. | |

Process categories (PROCs)

ECETOC TRA worker uses the PROCs (as presented in Chapter R.12) as a basic starting point for exposure estimation.

The parameters that provide options for iteration (alternative Operational Conditions or Risk Management Measures) are applied to each basic exposure estimate, and are those most likely to be encountered in use and/or easiest to implement in a workplace. These are:

- Operational conditions
  - Industrial or professional activity
  - Activity taking place indoors or outdoors
  - Duration of the activity
  - Percentage of substance used (if used in a mixture)
- Risk Management Measures
  - Presence of LEV
  - Use of Respiratory Protective Equipment

For each of the PROCs, the inhalation and dermal exposure estimation was made using the modified EASE model (HSE 2003). This was done for both solids and vapours (within the range of volatilities – low, medium and high – as defined by the model). Predicted exposure values were also calculated for each potential modifying factor or Risk Management Measure at each volatility/fugacity level. Historically EASE is known to over-predict exposures in some instances. Additional work comparing the output of the above exercise with known values of exposure for a variety of current workplace activities showed over- and under-prediction of exposures in many

cases. The reason for this is considered to be the fact that EASE relies upon historical exposure data from enforcement activities in known problem areas, rather than the typical/normal operations that are required for more routine risk assessment. For this reason the values from the output from EASE were reviewed and modified accordingly. The full rationale for each modification was recorded.

The estimated dermal applied dose for each scenario was determined by multiplying the EASE dermal output with the assumed dermal contact area (varying with scenarios). Values / assumptions can be viewed in a specific 'dermal' table in the spreadsheet and in the ECETOC report on the updated ECETOC TRA. It is assumed that no personal protection was in use and that dermal absorption/permeation was 100%.

Impact of working outdoors

A default reduction of the basic estimate for working outdoors is calculated by multiplying the basic estimate by a factor of 0.7. In other words: the outdoor exposure is 70% of the indoor exposure if all else is the same.

Limited exposure duration

To correct for much shorter exposure duration than a full shift ECETOC TRA worker uses correction factors to the basic estimate (which assumed that an activity is done full shift). The factors applied are given in Table R.14-7. For example, if the duration of an activity is 45 minutes, then the basic obtained exposure estimates are multiplied by a factor of 0.2, meaning that the exposure value is lowered by a factor of 5. This correction should only be applied for risks arising from long-term exposures.

**Table R.14-7**: Modifiers for duration of activity

| Duration of activity | Exposure modifying factor |
|---|---|
| > 4 hours | 1 |
| 1 - 4 hours | 0.6 |
| 15 min - 1 hour | 0.2 |
| < 15 min | 0.1 |

Impact of percentage of substance used in a mixture

Instead of a simple, but possibly not sufficiently conservative, direct multiplication of the basic estimate by the fraction of the substance in the mixture used, ECETOC TRA worker uses a different multiplication factor for bands of concentrations in mixtures. These factors are shown in Table R. 14-8.

**Table R.14-8**: Influence of the concentration in mixtures

| Concentration in mixture (w/w) | Exposure modifying factor |
|---|---|
| *Not in a mixture* | *1* |
| > 25% * | 1 |
| 5 – 25% | 0.6 |
| 1 – 5% | 0.2 |
| < 1 % | 0.1 |

| |
|---|
| * Highest concentration in 1999/45/EC the EU Dangerous Preparations Directive |

### R.14.4.8.2 An example of exposure derivation using ECETOC TRA worker

Table R.14-9 shows an example estimate and the output parameters of ECETOC TRA worker spreadsheet. The example clearly shows how the assessor may develop his assessment by correctly modifying input parameters.

**Table R.14-9:** Output of ECETOC TRA worker exposure estimation

| Worker Exposure report for Substance ABC (CAS NO. 00-00-1) | Exposure Estimate (Units ppm) |
|---|---|
| Medium fugacity | |
| **Exposure scenario (Roller painting)**<br>Process Category 10 - Roller application or brushing<br>Public Domain (Professional) activity<br>Initial Exposure Estimate | <br><br><br>100 |
| **Exposure modifiers**<br>The activity takes place **Indoors**<br>**Ventilation is present** with an assumed **efficiency of 80%**<br>The maximum duration of the activity is **1 - 4 hours**<br>**Respiratory Protection with a minimum efficiency of 90% is used**<br>Is this substance part of a mixture? Yes at 5 – 25% w/w<br>Assessment factor applied is 0.6 | <br>20<br>12<br>1.2<br><br><br>0.72 |
| **The Inhalation Exposure Estimate for this Exposure Scenario is** | **0.72 ppm** |
| Dermal exposures may arise from this Exposure Scenario and, assuming a maximal exposed skin area | 960 (sq cm) |
| Dermal exposures are estimated at | **1.37 mg/kg/day** |

### R.14.4.8.3 Further application: MEASE for metals and inorganic substances

A new tool (MEASE) has been developed to address first Tier exposure estimation of metals and inorganic substances. It combines the approaches from the ECETOC TRA tool, the EASE expert system and the health risk assessment guidance for metals (HERAG project) and generates first tier inhalation and dermal occupational exposure estimates. For inhalation exposure, the tool follows the PROC approach of the TRA tool and selects initial exposure estimates from three fugacity classes (low, medium, high). The fugacity classes are defined based on the physical form, the melting point of the metal, the temperature of the process, the vapour pressure and the selected PROC.

For dermal exposure, MEASE is based on the system of exposure bands of the broadly used EASE system. However, the generated exposure estimates are based on measured data from several metals, collated and plotted against the EASE exposure classes in the "dermal fact sheet" of the HERAG project. The MEASE tool deviates from ECETOC TRA in some basic assumptions and possible default parameters. As it is a new tool, no validation is available yet. The MEASE tool can be downloaded free of charge from http://www.ebrc.de/mease.html and the REACH metals gateway http://www.reach-metals.eu/

### R.14.4.9 EMKG-Expo-Tool

The exposure prediction model of the German EMKG-Expo-Tool[9] "Easy-to-use workplace control scheme for hazardous substances" is a generic tool that can be used to derive a Tier 1 inhalation exposure value for the workplace (EMKG, BAuA 2008). The tool was developed to help small and medium sized companies to comply with the Chemical Agents Directive. The EMKG-Expo-Tool is based on the banding approach of the COSHH Essentials originally developed by HSE (HSE 1999). While COSHH Essentials is seen as a qualitative approach to guide the assessment and management of workplace risks, the EMKG-Expo-Tool can also be used as a generic tool for assessing and comparing the level of exposure with limit values (OEL, DNEL). Hence the EMKG-Expo-Tool should be seen as an approach for filtering the non-risky workplace situations from those requiring detailed attention. The exposure assessment part is based on the banding approach of COSHH Essentials originally developed by HSE (HSE 1999). The tool only functions for inhalation exposure. The English version of the EMKG-Expo-tool is available on the BAuA website: (www.baua.de), http://www.reach-helpdesk.de/en/Exposure/Exposure.html.

The EMKG-Expo-Tool uses three input parameters: volatility or dustiness, amount of substance used, and control strategy. For solids, the dustiness of the substance is the principal physical property to be considered for the exposure potential. For liquids, 'volatility' is the key determinant. The amount used per batch or operation (small (g/ml), medium (kg/l) or large (tonnes/$m^3$)) is regarded to be the most important condition to be considered, as it impacts how the material is packaged, transported and used.

The control strategy is defined with factors that aim at exposure reduction (general ventilation, local exhaust ventilation, containment). These general control solutions are underpinned by a series of Control Guidance Sheets (CGS) which provide practical examples of control approach for common industrial unit operations such as weighing mixing and filling. Often these unit operations can be linked to a process category of the use descriptor system.

The tool predicts a lower and an upper value for the exposure range (in mg/$m^3$ for solids and ppm for vapours). In order to arrive at a conservative estimate the upper value of the exposure range should be used for the risk characterisation, i.e. the comparison with the DNEL-value.

*Strengths*

- Clear and user friendly structure
- Influence of amount of product is taken into account
- Iteration is possible by considering short term exposure, scale of use, control strategy
- Provides control strategies for a range of common tasks, e.g. mixing, filling etc.
- Control guidance sheets are available on the Internet, thus the use of the tool in connection with a use descriptor may lead to the identification of relatively detailed risk control guidance.

*Limitations*

- Can only derive inhalation estimates
- The exposure assessment parts are not visible to the user.
- The number of choices regarding the input values is relative limited, thus iteration is limited as well. E.g., the substance concentration (in products) is assumed to be 100%. The duration of exposure is assumed to be the shift length. If the activity is carried out for less than 15 minutes a day the next lower exposure range can be used.
- Not suited for gases (handled or released)

9 The acronym EMKG stands for "Einfaches Maßnahmenkonzept Gefahrstoffe".

- Should not be used for tasks where aerosols of unknown composition are formed (e.g. fumes, dusts are formed through abrasive techniques)
- Not suitable for CMR substances.

*Status of validation*

The exposure prediction model of COSHH Essentials was evaluated by comparison of predicted exposure ranges presented in Table R.14-15 with measured data, and by extensive peer review of the logic and content by experts (Maidment 1998). However, it was very difficult to find quality data for comparisons.

The German BAuA conducted the first and most complete evaluation of its exposure predictive model to date, based on 958 independent measurement data points (Tischer 2003 a, b). The primary empirical basis for the analysis was measurement data collected within several BAuA field studies. Some data were also provided by the chemical industry. It was found that for solids (powders) and medium-scale use of liquids, measured exposures were lower or within the predicted range. For the wide dispersive use of small quantities (millilitres) of solvent-based products (such as paint or adhesive), measured exposures sometimes exceeded the range of EMKG-Expo-Tool assessment.

Testing the COSHH Essentials model for three volatile organic chemicals at a small printing plant suggests that the tool works reasonably well both for short-term task-based and full-shift exposure measurements (Lee et al. 2009). Evaluation of the model with exposure measurements from 12 petroleum company workplaces in Japan found that the model tends to provide safe-sided judgements (Hashimoto et al. 2007).

Overall the conclusion, on the basis of the available evidence, is that the EMKG-Expo-tool is sufficiently conservative for a Tier 1 tool and can thus be used as such.

#### R.14.4.9.1 Input data

The following determinants are needed as input data:

- type of substance: solid/liquid
- dustiness or volatility (boiling point/vapour pressure)
- operational conditions (temperature, amount of substance/product used per task, size of the application surface)
- implemented RMMs (control strategy)
- exposure period (<15 min or ≥ 15 min)

Dustiness

For solids, the material's dustiness is the principal physical property that needs to be considered. In order to determine the dustiness, the user has to determine the dustiness subjectively on an observational or analogy basis. In total there are three dustiness bands defined as presented in Table R.14-10.

**Table R.14-10: Definition of dustiness bands**

| | |
|---|---|
| **High** | Fine, light powders. When used, dust clouds can be seen to form and remain airborne for several minutes. For example: cement, titanium dioxide, photocopier toner |
| **Medium** | Crystalline, granular solids. When used, dust is seen, but it settles quickly. Dust is seen on the surface after use. For example: soap powder, sugar granules |
| **Low** | Pellet-like, non friable solids. Little evidence of any dust observed during use. For example: PVC pellets, waxes |

These categories may introduce difficulties for the user as their boundaries are not clearly defined. For instance the transition from powders to granules and pellets forms a continuum with no clear-cut boundaries. This is also true for the evidence of dust clouds. In case of doubt the user should opt for the higher dustiness band.

Volatility

For liquids, volatility is the key determinant and the user needs information about the boiling point, or the vapour pressure at a stated temperature, and the process temperature. These variables are arranged in three discrete bands (Table R.14-11)

**Table R.14-11:** Definition of volatility bands

| Volatility band | Normal temperature (T ~ 20 °C) | Any operating temperature (OT) (°C) | Vapour pressure (kPa at OT) |
|---|---|---|---|
| **Low** | boiling point above 150 °C | b. p. ≥ 5 x OT + 50 | < 0.5 |
| **Medium** | boiling point between 50 and 150 °C | other cases | 0.5 - 25 |
| **High** | boiling point below 50 °C | b. p. ≤2 x OT + 10 | > 25 |

In the case of mixtures (preparations) the boiling point (or the partial vapour pressure if available) of the substance under consideration determines the volatility. When the combined exposure (the sum over all components) of a mixture has to be assessed, the model proposes to use the lowest boiling point of the range given for mixtures. This approach is frequently conservative because at the lower temperature end of this range the boiling point is likely to be close to the boiling point of its most volatile component.

Scale of use

In contrast to volatility and dustiness the impact of operational factors on the exposure potential is more diverse and cannot be accommodated in an easy to use model. The scale of use is regarded as the most important factor, since it impacts on how the material is packaged, transported and used (Table R-14-12). In total there are three categories:

**Table R.14-12:** Scale of use bands/one batch

| | |
|---|---|
| **Small** | grams or millilitres (up to 1 kilogram for solids or 1 litre for liquids) |
| **Medium** | kilograms or litres ( batch sizes between 1 and 1000 kilograms for solids and 1 and 1000 litres for liquids) |
| **Large** | tonnes or cubic metres ( batch sizes of greater than 1 tonne for solids and 1 $m^3$ for liquids) |

These categories are related to the corresponding batch or operation in which the material is handled. The total quantity of hazardous substance present does not always determine the quantity group. For example, the withdrawal of 30 litres of a liquid from a large tank (> $m^3$) would fall under the quantity group "medium". If in doubt, use the higher quantity group.

Another factor that can affect the exposure level is the size of the surface a chemical is applied to. Wide dispersive uses of chemicals (painting, applying adhesives, etc.) can lead to significantly higher exposure levels than the predicted ones (Tischer 2003 a, b). As a consequence of these observations the EMKG-Expo-Tool considers wide dispersive use situations in the following way: If small amounts of a substance are applied to large surface areas (e.g. >1 $m^2$ in painting or cleaning etc.) no more than 1 litre (cumulative) of the substance per full working day should be used. If the used amount exceeds 1 litre and a large surface (benchmark >1 $m^2$) is treated, a wide dispersive use situation has to be assumed. In that case the next higher exposure range has to be selected.

Exposure potential band

Combining the substance's physical properties and the amount used gives a measure of the exposure potential. For both solids and liquids, all combinations of operational and physical determinants' exposure potential bands could be condensed into four combined bands which are called exposure potential bands. These are defined below in Table R.14-13.

**Table R.14-13:** Exposure potential bands (EP)*

| Solids – EP band | Use band | Dustiness band | Description |
|---|---|---|---|
| 1 | Small | Low or Medium | Grams of low / medium dusty solid |
| 2 | Small | High | Grams of high dustiness solid, kg /Tonnes of low dustiness solid |
| | Medium or Large | Low | |
| 3 | Medium | Medium or High | Kg of medium / high dustiness solid |
| 4 | Large | Medium or High | Tonnes of medium / high dustiness solid |
| **Liquids – EP band** | **Use band** | **Volatility band** | **Description** |
| 1 | Small | Low | Millilitres of low volatility liquid |
| 2 | Small | Medium or High | Millilitres of medium / high volatility liquid, litres / cubic meters of low volatility liquid |
| | Medium or Large | Low | |
| 3 | Large | Medium | Cubic meters of medium volatility liquid, litres of medium / high volatility liquid |
| | Medium | Medium or High | |
| 4 | Large | High | Cubic meters of high volatility liquid |

*The exposure potential increases from EP1 to EP4. In the case of applications with large surfaces involved (e.g. painting, applying adhesives etc.) and more than 1 litre substance/product used per shift, one EP band higher should be selected.

Control strategies

Within the scope of the EMKG-Expo-Tool, the scale of use, volatility and dustiness are used to build a simple model of the exposure potential. In contrast the control strategy is defined in considerable detail with a number of factors that aim at exposure reduction (Table R.14-14). The corresponding approach starts with the following categories:

**Table R.14-14**: Control strategies

| Control Approach | Type | Description |
|---|---|---|
| 1 | General ventilation | Good general ventilation and good work practice |
| 2 | Engineering control | Local exhaust ventilation (e.g. single point extraction, partial enclosure, incomplete containment) and good work practice |
| 3 | Containment | Enclosed, but small breaches may be acceptable. Good work practice. |

These general control solutions are underpinned by a series of Control Guidance Sheets (CGS) which provide practical examples of each control approach for common industrial unit operations

such as weighing and filling. The CGS are essential to demonstrate a safe use and there are a number of key points that the user has to follow to control exposure, e.g. access to the work area, design and equipment, maintenance of equipment, examination and testing of equipment, cleaning and housekeeping, personal protective equipment, training, supervision.

The Control Guidance Sheets at the COSHH Essentials website can be accessed directly through the following link: http://www.coshh-essentials.org.uk/assets/live/g###.pdf and by replacing the ### with the number of the Control Guidance Sheet you want to see; for example 212 for the drum filling scenario using engineering control. The appropriate CGS can be chosen from a list (see Appendix R.14-3) in which the relevant control approach vs. the used amount is displayed. As an example the CGS for "weighing solids" is also depicted in Appendix R.14-3.

The German version of the CGS, "Schutzleitfäden" can be accessed through the following link:

http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/EMKG/Schutzleitfaeden.html

#### R.14.4.9.2 Model output (to be used in the CSA)

Depending on the exposure potential of the substance and the applied control strategy the assessment leads to six possible predicted exposure ranges (see Table R.14-15) for both dust and vapours. They represent exposures differing by one level of magnitude. Each control approach group is divided in four bands, depending on the tonnage/ volume of the substance used and its properties (dustiness and volatility). For both solids and liquids, the highest exposure potential group (Band 4) with lowest control strategy (control approach 1) is considered to be too high to deliver adequate control of the risks. For solid materials, this predicted exposure is greater than 10 $mg/m^3$ (The German technical rule TRGS900 (AGS 2007) prescribes an OEL of 10 $mg/m^3$ for total inhalable dust). Similarly, for liquids, the exposure is considered to be too high to deliver adequate control if it is greater than 500 ppm. This is close to the highest exposure limit for vapours (1000 ppm) set by TRGS900 and caution and careful monitoring of the exposure situation are recommended.

**Table R.14-15:** Predicted exposure ranges

| Solids | | | | |
|---|---|---|---|---|
| **Control approach** | **Predicted exposure level for dust, mg/m³** | | | |
| | **Solids EP Band 1** (g of low / medium dustiness solid) | **Solids EP Band 2** (g of high dusty solid, kg / t of low dustiness solid) | **Solids EP Band 3** (kg of medium/high dustiness solid, | **Solids EP Band 4** (t of medium / high dustiness solid) |
| 1 | 0.01 - 0.1 | 0.1 – 1 | 1 - 10 | >10 * |
| 2 | 0.001 - 0.01 | 0.01 - 0.1 | 0.1 - 1 | 1 - 10 |
| 3 | <0.001 | 0.001 - 0.01 | 0.01 - 0.1 | 0.1 - 1 |
| **Liquids** | | | | |
| **Control approach** | **Predicted exposure level for vapour, ppm** | | | |
| | **Liquids EP Band 1** (ml of low VP liquid) | **Liquids EP Band 2** (ml of medium / high VP liquid, L / m³ of low VP liquid) | **Liquids EP Band 3** (m³ of medium VP liquid, L of medium / high VP liquid) | **Liquids EP Band 4** (m³ of high VP liquid) |
| 1 | <5 | 5 - 50 | 50 - 500 | >500 * |
| 2 | <0.5 | 0.5 – 5 | 5 - 50 | 5 - 500 |
| 3 | <0.05 | 0.05 - 0.5 | 0.5 - 5 | 0.5 - 5 |

*not recommended

The predicted exposure levels are considered to be task-based and the exposure level characterises a specific core model scenario determined by the exposure potential of the handled material and the control approach applied. If the task is carried out during a full shift (8h), the predicted exposure level represents an 8 h time-weighted average. Although simple, the model is able to predict a reasonable exposure range from a small number of parameters. As a general rule the upper level of the predicted exposure range should be used for comparison with the DNEL. If sufficient control of risk cannot be demonstrated, it is possible to introduce RMMs into the calculations by selecting another appropriate control guidance sheet.

Short term exposure

If the activity is carried out for less than 15 minutes a day, the next lower exposure range can be used. This is justified because exposure duration of 15 minutes during a full 8 hour shift gives a TWA exposure of 0.03 times the short-term exposure level (assuming exposure to be zero during the rest of the shift). The upper level of the exposure range can be compared with an acute DNEL.

### R.14.4.9.3 An example of exposure estimation using the EMKG-Expo-Tool

Table R.14-16 shows example estimates and output parameters for the EMKG-Expo-Tool. In order to arrive at a conservative estimate the upper value (bold type) of the exposure range should be used for comparison with the DNEL. The example clearly shows how the assessor may develop his assessment by correctly modifying input parameters. The example substance is a solid dye

mixture (~70%) with dust suppressing agents that is used in textile processing. The following operational conditions and risk management measures are assumed:

**Operational Conditions**

**Tasks:** storage, weighing, mixing
**Amount:**
<1 kg (cleaning up spills, laboratory),
5 - 10 kg per batch (dye kitchen)
**Duration and frequency:**
<15 minutes (cleaning up spills),
6 times a shift for 15 minutes (weighing/mixing)

**Risk Management Measures**

General ventilation (storage, weighing/mixing),
LEV (weighing/mixing),
Gloves, protective clothing

**Table R.14-16:** Output of EMKG-Expo-Tool

| Task | Control strategy | Dustiness | Scale of use | Duration | Predicted exposure range |
|---|---|---|---|---|---|
| Storage (clean up of spills) | General ventilation (CGS101) | medium | small (<1 kg spills) | <15 minutes | 0.001-**0.01** mg/m$^3$ |
| Weighing and mixing in the dye kitchen | General ventilation (CGS100) | medium | medium (5-10 kg/ batch) | >15 minutes | 1-**10** mg/m$^3$ |
| Weighing and mixing in the dye kitchen | General ventilation (CGS100) | medium | medium (5-10 kg/ batch) | <15 minutes | 0.1-**1** mg/m$^3$ |
| Weighing and mixing in the laboratory | General ventilation (CGS100) | medium | small (<1 kg/ batch) | >15 minutes | 0.01-**0.1** mg/m$^3$ |
| Weighing in the dye kitchen | LEV (CGS214) | medium | medium (5-10 kg/ batch) | >15 minutes | 0.1-**1** mg/m$^3$ |
| Mixing in the dye kitchen | LEV (CGS215) | medium | Medium (5-10 kg/ batch) | > 15 minutes | 0.1-**1** mg/m$^3$ |

The predicted exposure range results marked with bold (upper end of the range) are taken for risk characterisation. The RMMs given in the guidance sheet are communicated to DUs in exposure scenarios attached to SDSs.

## R.14.5 Higher Tier exposure assessment

When according to the Tier 1 assessment the level of protection is not adequate, a Tier 2 assessment is necessary. This assessment is generally (much) more detailed and specific than the assessment in Tier 1. The assessment at Tier 2 can be done by any suitable method that is valid and sufficiently accurate. Higher Tier assessments are meant to be carried out by experienced assessors. The assessor must normally have more detailed information on the exposure situation and on the specifications of the model to be able to carry out the assessment successfully.

Several new approaches and tools are under development by industry and consortia of European institutions. Three of these approaches will be indicated here: Stoffenmanager exposure model (Section R.14.5.1), the RISKOFDERM dermal model (Section R.14.5.2) and the Advanced REACH Tool (ART) (Section R.14.5.3) for occupational exposure assessment.

In addition, many algorithms that have been developed for specific purposes may be used for higher tier assessments. Exposure assessment models that have been collected for the exposure assessment of biocides (TNsG) and pesticides (EUROPOEM and others) can be applied for some worker exposure assessments. In the USA, EPA and several institutions cooperating with EPA have developed many tools which may contain useful approaches for higher Tier exposure assessments. The reader is referred to the EPA website for these approaches http://www.epa.gov/oppt/exposure/.

If an exposure assessment on Tier 1 level does not produce an acceptable level of exposure, one possibility, instead of or in addition to higher Tier models, is to carry out exposure measurements in real exposure situations. These might produce exposure levels clearly below DNELs, and if not, the development of exposure scenarios should focus on implementing more effective RMMs.

### R.14.5.1 Stoffenmanager exposure model

The “Stoffenmanager” (Dutch for “substance manager”) tool was originally a web-based risk prioritizing tool for small and medium sized enterprises (www.stoffenmanager.nl). The version 4.0[10] includes a quantitative model for estimating inhalation exposure to vapours, aerosols of low volatility liquids and inhalable dusts (including comminuting activities such as grinding and sawing). The model is also available in English. The web-based tool now has a specific REACH section and a section for exposure calculations in which e.g. full shift time weighted averages can be calculated. An exposure database containing around 1000 measurements with all relevant Stoffenmanager parameters is used to further underpin and validate the model. The database is still growing to allow future further validations and updates of the model. The Dutch Labour Inspectorate accepts Stoffenmanager 4.0 results as an alternative to measurements.

The Stoffenmanager 4.0 exposure model tool is currently somewhere between first Tier and higher Tier models. The rationale of the underlying exposure algorithm is based on work of Cherrie and Schneider (1999) but is adapted in several ways. The model uses process information, physicochemical characteristics, and mass balance to assess exposure situations. It needs more information than Tier 1 tools, but its flexibility is higher and the results are expected to be more accurate (and therefore in many instances probably less conservative). The model is easy to use. Stoffenmanager estimates task based exposure levels in mg/m$^3$. A time-weighted average can be calculated for one or several combined tasks with duration of less than 8 hours. This is however only possible in the ‘exposure calculation’ section.

The following text gives a short evaluation of the Stoffenmanager 4.0 tool.

*Strengths*

- Clear and user friendly structure; easy to understand and use

10 Please note that the newest version of the tool is version 4.5. However, the present corrigendum only addresses alignment with the CLP Regulation and minor editorial/changes and corrections. Thus, the reference to Stoffenmanager in the text are referring to the version 4.

- Based on handling categories that largely resemble the "technical process in which the substance is used" that is required in the short title of the exposure scenarios under REACH.
- Several choices for Operational Conditions and Risk Management Measures enable more specific estimates of exposure compared to simpler models.
- The output is based on statistical analyses of the relation between deterministic scores and around 1000 real exposure measurements.
- Results of assessments can be saved for later use or modification.
- The variation in the model is included in the exposure assessment output, which enables the use of different percentiles of the exposure distribution. The estimated exposure distribution is also visualized in a graph.
- Based on the outcome of the model, several control strategies (with different RMMs) can be selected and the effect of these strategies on the exposure estimate can be calculated.

*Limitations*

- Stoffenmanager 4.0 cannot (yet) be used to assess exposure to 1) gases, 2) fibres, 3) solid objects (= articles in REACH) other than wood or stone, or 4) "hot work techniques" like welding or waste burning.
- Handling categories are not directly linked to use descriptors (PROCs)
- Choice of dustiness category is not always obvious.
- No direct quantitative influence of parameters such as use rate or ventilation rate.
- No probabilistic use of input parameters possible yet.
- Changes in the calibration in the tool over time are not visible to the user
- Some parameters used to determine exposure are difficult to apply in the context of REACH. (e.g. room volumes)

*Ways to compensate for limitations*

- PROCs can be transposed to Stoffenmanager handling categories.
- Use the most conservative option of the dustiness category that is possibly relevant.
- Run the model with several combinations of input parameters, if the conditions are variable, and select a conservative but reasonable outcome from the resulting values, i.e. the most conservative option from the handling categories that are possibly relevant (expert assessor work).

*Applicability*

- The tool cannot be used for gases, fibres, particles from articles and hot work operations.

*Status of validation*

The tool is based on a published scientific conceptual model of exposure (Marquart 2007, Tielemans 2007a). Extensive comparison with measured data sets has been carried and published (Marquart 2007, Tielemans 2007a). Stoffenmanager is regularly validated by comparison with independent measurement data. After validation, where relevant, the calibration is updated and the validity domain is expanded (Schinkel 2009).

#### R.14.5.1.1 Input data

The following parameters are needed as input data for the quantification of exposure with the Stoffenmanager:

- Physical state of the substance (solid or liquid)

- Whether there are activities involving articles (= solid objects) that may cause emission of dust.
- Vapour pressure of liquids (used directly) or dustiness (solid articles, firm granules or flakes, granules or flakes, coarse dust, fine dust, extremely dusty products)
- Type of dust emitted from solid objects (presently only stone or wood)
- Percentage of the substance(s) in the product
- Level of dilution of liquid products (undiluted = 100%)
- Handling category
- Local controls (including local exhaust ventilation (LEV) and containment)
- Distance of the worker from the source (within one meter or not)
- Presence of secondary emission sources:
    - Other workers using the same substance simultaneously
    - A period of drying or hardening after the activity (with prolonged emission of vapours)
- Room volume
- General ventilation
- Emission control measures (such as control rooms)
- Personal protective equipment used
- Information on whether the work area is regularly cleaned
- Information on whether machinery and equipment are regularly inspected and kept in good order.

To calculate time weighted averages, separate assessments for each activity should first be made and then combined using the duration of each activity entered to calculate time weighted averages.

In addition to the required inputs for exposure estimation a number of other inputs are needed. These are data on the product name, information on the relevant R-phrases of the product, the date of the Safety Data Sheet, the name of the supplier as well as the department or work area for which the assessment is being made and the duration and frequency of the task being assessed. Although these data will not influence the quantitative calculations, inputs are required for the software to function.

#### R.14.5.1.2 Output data (to be used in the CSA)

The tool basically predicts a median task-based exposure level. A number of percentiles of the exposure distribution are also calculated for the given input values. The predicted percentiles are based on calibration with substantial measurement series covering exposure to vapours, liquids aerosols and inhalable dust. Depending on how conservative the inputs provided are, a higher or lower percentile should be used as an estimator of the reasonable worst case. If more or less typical values are provided for all inputs, the 90$^{th}$ percentile of the output distribution is recommended for use in risk assessment. If conservative values are used for all inputs, the 75$^{th}$ percentile of the output distribution is recommended for use in risk assessment.

Task based exposures can be combined into shift exposures through time weighting in the ‘exposure calculation’ section.

### R.14.5.2 RISKOFDERM dermal model

The RISKOFDERM dermal model is the result of a European 5$^{th}$ framework programme project focused solely on dermal exposures in industrial and professional settings (Warren 2006). On the basis of measured data, approaches were developed to assess dermal exposure for six different so-called Dermal Exposure Operation units (DEO units). It assesses potential dermal exposure, i.e.

exposure on the skin and on the layers (of clothing or e.g. gloves) covering the skin. It therefore does not take into account any protective effect of clothing or gloves.

An Excel spreadsheet version of and a guidance document for the model can be downloaded from the TNO website[11]. A web-based version, with extended functionalities, is under development.

The basic estimate made by RISKOFDERM is the potential exposure per minute (for hands and/or remainder of the body). Total exposure over a longer period is calculated by entering the duration of the activity leading to exposure.

The following text gives a short evaluation of the tool.

*Strengths*

- Clear and user-friendly structure
- Model takes into account the influence of handling type/process through different algorithms for six Dermal Exposure Operation units (DEO Units)[12]
- The model is task-based
- Potential exposure of the hands and of the body are estimated separately (for some of the DEO Units)
- Several OCs and RMMs can be included
- Duration of exposure is taken into account
- Use rate of product is taken into account
- Algorithms are based on statistical analyses of a large set of measured potential dermal exposure data
- Choice of percentile of the output distribution can be based on the relative conservatism of the inputs
- The model provides warnings for input values outside of the ranges used for building the model
- The model also provides warnings if exposures are estimated that are expected to be unreasonably high compared to the level of contamination that the skin can contain.

*Limitations*

- The basis for the algorithms for handling of powders is relatively limited
- Information that is needed may not always be available to the assessor (e.g. use rate, direction of airflow)
- Only hands or body can be chosen as the exposed area, no further differentiation is possible
- Model does not take into account protective effect of clothing or gloves
- Algorithms for potential exposure of hands or body are not available for all DEO Units. Also, within DEO Units, not all possible situations were covered by the measured data underpinning the model[13]
- The dermal exposure data set supporting the algorithms may be heterogeneous
- The Choice of percentile of the output distribution is not always obvious

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11 http://www.tno.nl/downloads/RISKOFDERM%20potential%20dermal%20exposure%20model%20vs%202.1t.xls

12 In practice the model only provides estimates for the types of activities within DEO units for which sufficient measured data were available. The names of the different modelled situations are therefore slightly different from the names of the original DEO units so as to provide a more specific indication of the modelled situations.

13 There were e.g. no data on substances with a relatively high vapour pressure, so the influence of evaporation from the skin after contamination is not properly taken into account.

- Probabilistic assessments are not possible in the spreadsheet version
- The model does not combine estimates for separate tasks to full shift estimates.

*Ways to compensate for limitations*

- Conservative inputs can be chosen for parameters for which the assessor has limited real information available
- A few "what if" analyses can be done to study the influence of uncertain inputs
- A known or assumed effect of (protective) clothing or gloves can be taken into account separately from the model
- When conservative values are used for all inputs, the 75$^{th}$ percentile of the output distribution can be used as a reasonable worst case estimator; when less conservative input values are used, the use of the 90$^{th}$ percentile of the output distribution is recommended.

*Applicability*

Due to a lack of data on dermal exposure to volatile substances the model is not optimally suitable for very volatile substances (e.g. > 500 Pa vapour pressure). Use with input values outside those found in the measured data sets should also be done very carefully. These boundaries are provided in the Guidance document with the spreadsheet version that can be downloaded from the TNO website.

*Status of validation*

The validity of the model has not been established with independent data. A benchmark study after a first draft version showed that in general the model appeared to be quite reasonable. The validity and adequacy of the model is relatively well-known for situations resembling those measured in the data set that was the basis for the model (Warren 2006).

#### R.14.5.2.1 Input data

The first step in using the RISKOFDERM dermal exposure model is to input the type of exposure process (choice between one of six processes or DEO units). The next step depends on the exposure process input and the following items may be needed:

- type of skin contact
- frequency of skin contact
- type of product handled
- viscosity of the product
- volatility of the product
- dustiness of the product
- use rate of the product
- formation of aerosols
- manual or automated tasks
- direction of application
- tools used
- quality of ventilation
- direction of airflow
- segregation of worker from source
- distance of worker from sources

In all cases, the duration of exposure is also needed. In the web version a choice needs to be made for estimating hand and/or body.

#### R.14.5.2.2 Output data (to be used in the CSA)

The spreadsheet version of the RISKOFDERM dermal model provides exposure estimates for the median exposure level corresponding to the inputs provided and for any chosen percentile. Also, the values are presented for a number of fixed percentiles of the output distribution. Depending on the exposure process only hand exposure, only body exposure or both are estimated.

The web based version provides a distribution of exposure estimates for the input distributions provided. The RISKOFDERM dermal exposure model makes calculations based on equations derived from mixed-model statistical analyses from a relatively large set of measured data.

### R.14.5.3 Advanced REACH Tool (ART)

The ART approach makes use of mechanistically modelled estimates of exposure and any relevant measurements of exposure. The tool provides estimates of the whole distribution of exposure variability and uncertainty, allowing the user to produce a variety of realistic and reasonable worst-case exposure estimates, dependent upon the requirements of the particular risk assessment. The approach facilitates the inclusion of any new data that become available in the future or during the risk assessment process. The tool is suitable for expert assessors.

Since the tool allows the use of analogous exposure data from comparable scenarios, exposure assessments will not automatically require scenario-specific exposure data (Tielemans 2007b). However, the tool will provide an incentive for uniform exposure data collection and facilitate the sharing of exposure data up and down the supply chain. The tool incorporates both a mechanistic model and an empirical part with information from an exposure database. Both parts will be combined using a Bayesian statistical process in order to produce exposure estimates for specific scenarios relevant to the REACH process.

ART is a web-tool that is free to use following registration. Registration can be easily done via the website http://www.advancedreachtool.com.

*Strengths*

- Easy to use well structured web-tool
- The model takes into account several operational conditions and risk management measures throughout the whole exposure pathway from source to worker
- The effect of determinants is based on a combination of published effects and expert judgement
- The model was calibrated with extensive measured data
- It provides the choice of several percentiles of the resulting exposure distribution
- It provides an indication of the uncertainty of the mechanistic model result
- There is the possibility to estimate exposure during a number of consecutive activities
- It combines mechanistic model results with measured data in a Bayesian statistical process

*Limitations*

- High information requirements compared to Tier 1 models
- Expert judgement is often required in the selection of input parameters
- The tool does not predict dermal exposures
- Changes in the data set are not easily detected by the user
- The present version of ART cannot estimate exposure to fumes or gases

- It is difficult to convert the factors driving the exposure estimate in ART into operational conditions and risk management measures to be assessed and communicated under REACH

*Ways to compensate for limitations*

- Defaults for many inputs could be established, e.g. by registrants or consortia in an internal process or (preferably) in a wider stakeholder process
    - Such defaults could be dependent on the industry sector or substance category
    - Defaults could be included in Generic Exposure Scenarios based on ART, which could also include integration of available measured data
- Full shift exposure levels for short term activities can be calculated within the tool.

*Applicability*

ART can be used when exposure needs to be assessed for liquids and solids that are used in processes (either manual or non-manual). It can also be used for liquids and solids that are formed during processes such as fracturing of solid objects, abrasive blasting, impaction on, and handling of contaminated objects. It is, however, not suitable for use in scenarios where substances are formed through reaction processes (e.g. exhaust fumes, rubber fumes) or for scenarios where gases or fibres are used.

*Status of validation*

An evaluation of the tool predictions against an independent set of modelled data has not been published yet.

#### R.14.5.3.1 Input data

The inputs are arranged in sets of 'principal modifying factors' (MF) such as intrinsic emission rates, efficacy of local controls and methods of handling or processing of chemicals. Based on a relatively abstract definition of the MFs, specific inputs (determinants) have been derived. The user of the tool is guided through these inputs.

For calculation of exposure with the mechanistic model the following inputs are needed:

- Duration of activities (each will get a separate assessment) within the shift
- Type of material used (powdered, granular or pelletised material; solid objects; liquids)
- For powdered, granular or pelletised material:
    - Dustiness (measured) or dustiness category
    - Moisture content of the material
- For solid objects:
    - Material of which the solid object is composed
    - Moisture content of the material
- For liquids:
    - Temperature of liquid in process (or relative compared to room temperature)
    - Vapour pressure of the liquid
    - Boiling point of the liquid
    - Viscosity of the liquid
    - Activity coefficient of the substance in the liquid
- For all materials: molar or weight fraction of the substance in the material

- Primary emission source in the breathing zone of the worker (yes/no)
    - If yes, secondary sources outside the breathing zone also need to be assessed.

For both primary and secondary emission sources the following information has to be provided separately:

- Activity class of the activity
    - In some cases, also activity subclasses are defined
    - For some activity classes, further questions are asked, such as:
        - Spray direction (for spraying)
        - Drop height (for dropping of material, e.g. in transfer)
    - For several activity classes a parameter representing the 'scale' of the activity needs to be provided (in classes), e.g. 'use rate' or 'surface area'

For primary sources (both within and outside the breathing zone) the following information on RMM needs to be provided

- Any control measures close to the source with the following choices and sub-options
    - Suppression techniques (only for powdered, granular or pelletised material)
    - Containment without extraction
    - Local exhaust ventilation - three options, each with two to three sub-options
- Measures to limit surface contamination and fugitive emissions
    - Enclosure of process
    - Evidently effective housekeeping
    - General housekeeping
- Conditions and measures of dispersion
    - Working indoors, outdoors or in a spray room
        - For indoors: room size and ventilation rate
        - For outdoors: placement of source relative to buildings and of workers relative to source

For primary sources outside of the breathing zone only the following RMMs need to be evaluated:

- Emission source segregated from the worker (several options)
- Worker separated from the emission source by a personal enclosure (several options)

For secondary sources (outside the breathing zone) the question regarding emission sources segregated from the worker also applies.

In addition, some administrative data on e.g. the name of the substance and the name of the assessment are also required to perform calculations.

#### R.14.5.3.2 Output data (to be used in the CSA)

ART version 1.0 provides the following results:

- **Full-Shift exposure (recommended for REACH evaluations)**: ART calculates an overall distribution for full-shift exposures. In this case, the 90$^{th}$ percentile provides the exposure level, which has a 10% probability of being exceeded by the exposure of a randomly selected worker on a randomly selected day.
- **Long-Term Average exposure**: ART calculates the distribution of workers' long-term average (mean) exposure (e.g. over a period of months). In this case, the 90$^{th}$ percentile

provides the long-term mean exposure level, which has a 10% probability of being exceeded by the long-term exposure of a randomly selected worker.

- The tool allows to use 50$^{th}$, 75$^{th}$, 90$^{th}$, 95$^{th}$ and 99$^{th}$ percentile of the output distribution and 90%, 95% or 99% confidence interval around the chosen percentile (the assessor should have special expertise to handle and interpret the data).

*Version updates*

Further updates will include an exposure database from which analogous data can be derived and with the possibility to assess short-term exposure levels.

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## Appendix R.14-1: Evaporation rate

For the purpose of determining the evaporation rate of a substance, an equation can be used which was derived within the framework of a research project (Weidlich and Gmehling 1986; Gmehling et al., 1989). This project aimed to provide a method of calculating airborne concentrations of substances when emitted from liquid mixtures taking into account the evaporation and the spreading of the substance at the workplace. To calculate the evaporation times of substances, an equation was derived based on the mass transfer at the interface between the liquid and the vapour (two-film-theory). Mass transfer during evaporation occurs until the equilibrium state is achieved. The main influence on evaporation is the transfer through the interface.

For pure substances, the following equation is used:

$$t_{(s)} = \frac{mRT}{M\beta pA} K \qquad (1)$$

Explanation of symbols

| | | | |
|---|---|---|---|
| t: | Time | | [s] |
| m: | mass | | [mg] |
| R: | gas constant: | 8.314 | $[J \cdot K^{-1} \cdot mol^{-1}]$ |
| T: | skin temperature | | [K] |
| M: | molar mass | | [g/mol] |
| $\beta$: | coefficient of mass transfer in the vapour phase [m $h^{-1}$], for calculation: $\beta$ = 8.7 m/h, see below | | |
| p: | vapour pressure of the pure substance | | [Pa] |
| A: | area | | $cm^2$ |
| K: | conversion factor: | | $3.6 \cdot 10^4$ |

The skin temperature is normally 28 – 32°C (ambient temperature: 20 – 22°C). The reduction of the skin temperature and accordingly of the vapour pressure caused by the evaporation process is not considered in the equation. This could be done by choosing a lower mean temperature for the evaporation process. For calculating the evaporation time of the substance in contact with gloves, a temperature of 20 °C is chosen.

The coefficient of mass transfer β is described based on empirical studies:

Explanation of symbols

| | | |
|---|---|---|
| $\beta$ = | $(0.0111 \cdot v^{0.96} \cdot D_g^{0.19}) / (\nu^{0.15} \cdot X^{0.04})$ | |
| $D_g$: | coefficient of diffusion, gas phase | |
| v: | velocity of air | [m/h] |
| ν: | kinematic viscosity of air | [m²/h] |
| X: | Length of the area of evaporation in the direction of the air stream | [m] |

In the equation given above, the main influencing parameter is the velocity of the air (v). At workplaces v is often between 0.3 m/s and 0.6 m/s. Since the hands, from which a substance evaporates, are often in motion, the air velocity might be higher. For a conservative approach, the lower value (0.3 m/s) was chosen.

For different organic solvents, the coefficient of diffusion for the gas phase, $D_g$, is approx. 0.05 $m^2/h$. By using the range 0.03 – 0.06 m²/h for v, $Dg^{0.19}$ ranges between 0.51 and 0.58 are obtained. A literature value was taken for the kinematic viscosity of air ($5.4396 \cdot 10^{-2}$ m²/h). The parameter X, representing the length of the area of evaporation in the direction of the air stream [m] does not significantly influence the outcome due to its low exponent (0.04). For the calculation, a length of 10 cm can be used. Taking into account a rather low velocity of air (0.3 m/s), β is about 8.7 m/h. This value corresponds well with experimental values for similar substances: for ethyl acetate, β amounts to 8 m/h (air velocity 0.31 m/s) and for butyl acetate, a value of 9.2 m/h (air velocity 0.31) was obtained.

In Table R.14-17 calculated evaporation times for different substances are given. The values should be regarded as representative of the order of magnitude, since it is not known to what extent the interaction of the skin with the substance influences the evaporation time. The error caused by this interaction is regarded as higher that caused by the uncertainty in the calculation of β. For different substances (7 substances were investigated) β differs by about ± 5%.

**Table R.14-17**: Calculated evaporation times for T = 20°C (gloves) and T = 30°C (skin)

| Substance | Molar mass | Temperature [°C] | Vapour pressure [Pa] | Time [s] (m = 1 mg) [1)] | Time [s] (m = 5 mg) [2)] |
|---|---|---|---|---|---|
| Ethyl benzene | 106.2 | 20 | 930 | 102 | 511 |
| | | 30 | 1,600 | 61 | 307 |
| n-Propanol | 60.1 | 20 | 1,930 | 87 | 435 |
| | | 30 | 3,600 | 48 | 241 |
| Toluene | 92.1 | 20 | 2,780 | 39 | 197 |
| | | 30 | 4,520 | 25 | 125 |
| Benzene | 78.1 | 20 | 9,970 | 13 | 65 |
| | | 30 | 15,780 | 8 | 42 |
| Cyclohexane | 84.2 | 20 | 10,300 | 12 | 58 |
| | | 30 | 16,200 | 8 | 38 |
| Methyl acetate | 74.1 | 20 | 22,580 | 6 | 30 |
| | | 30 | 35,380 | 4 | 20 |

1) Upper value of EASE estimate: non dispersive use, contact level: intermittent
2) Upper value of EASE estimate: non dispersive use, contact level: extensive, or: wide dispersive use, intermittent

## References

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Weidlich U, Gmehling J (1986). Expositionsabschätzung. Eine Methode mit Hinweisen für die praktische Anwendung., Schriftenreihe Bundeanstalt für Arbeitsschutz und Arbeitsmedizin (BauA), Forschung Fb 488, Wirtschaftsverlag NW, Bremerhaven, Germany.

## Appendix R.14-2: Derivation of short term inhalation exposure (reasonable worst case)

To enable derivation of short term reasonable worst case values from full shift reasonable worst case values in situations with more or less variability several ratios of short term and full shift estimators have been plotted in Figures 1 to 4. All figures are based on calculations using equations from Kumagai and Matsunaga (1994) with corrections for autocorrelation relevant for the relative difference of averaging time also derived from this publication.

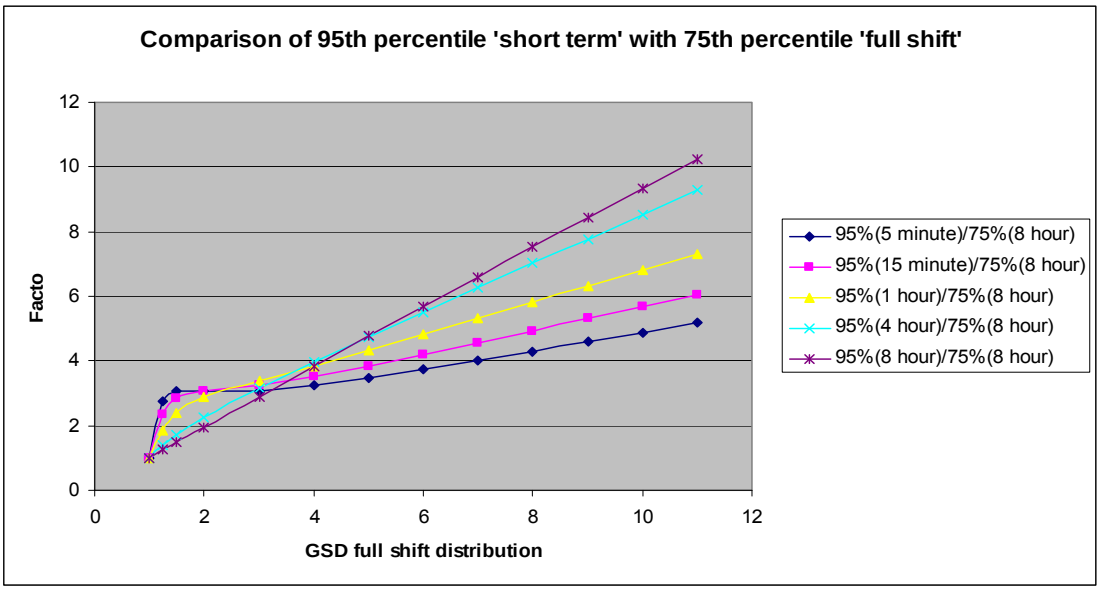



**Figure R.14-1**: Ratios between 95th percentiles of different averaging times and 75th percentiles of full shift values, relative to the GSD of the full shift values

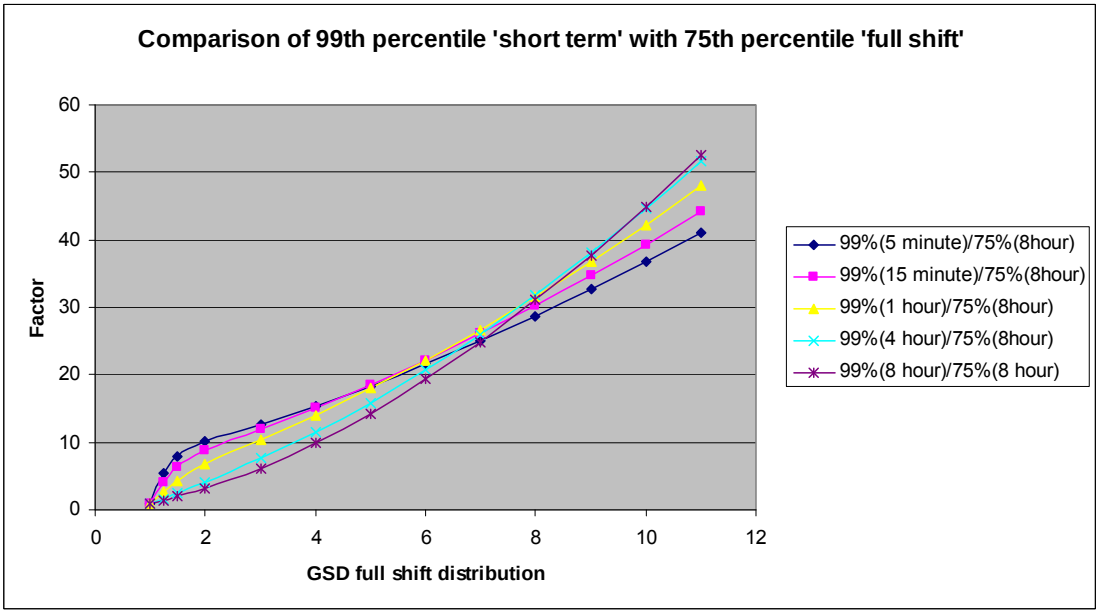



**Figure R. 14-2:** Ratios between 99th percentiles of different averaging times and 75th percentiles of full shift values, relative to the GSD of the full shift values

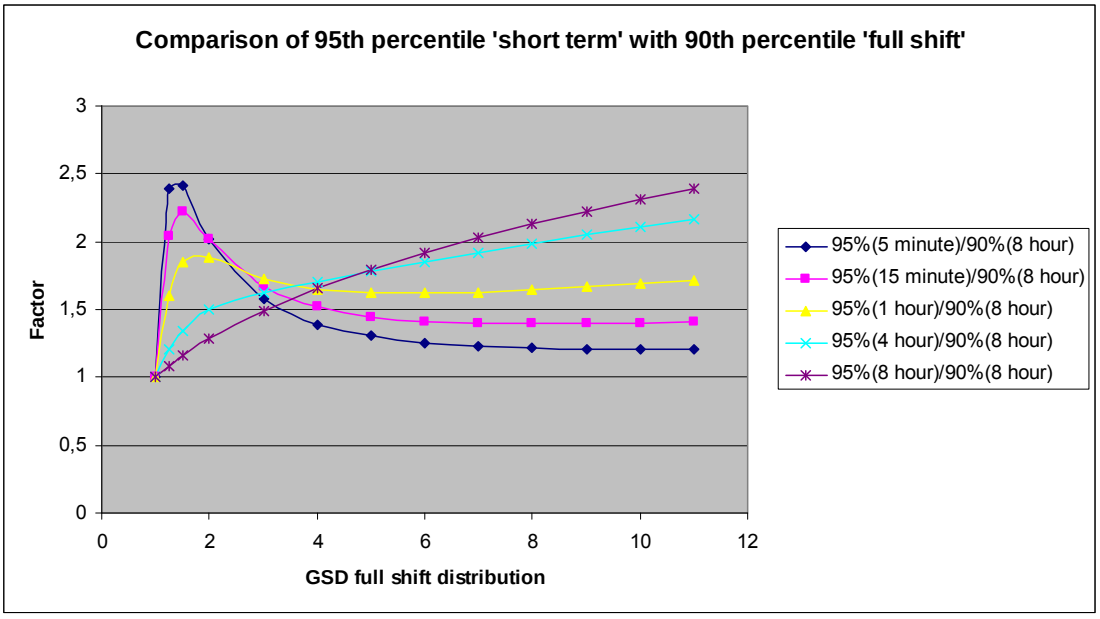



**Figure R.14-3:** Ratios between 95th percentiles of different averaging times and 90th percentiles of full shift values, relative to the GSD of the full shift values

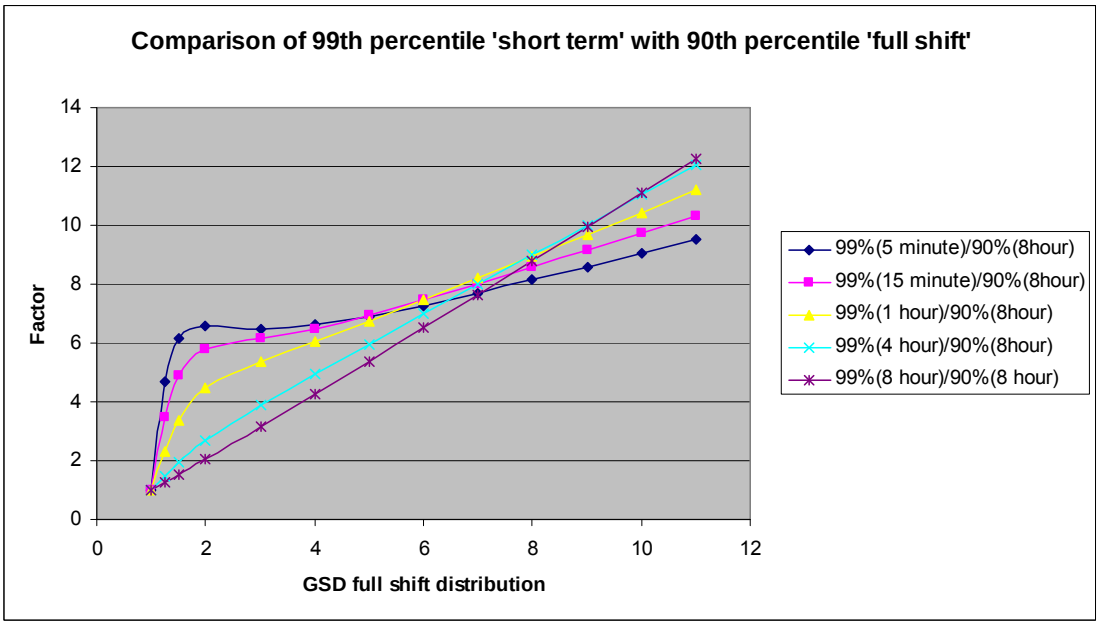



**Figure R.14-4**: Ratios between 99th percentiles of different averaging times and 90th percentiles of full shift values, relative to the GSD of the full shift values

Table R.14-18 can be used to indicate default factors for multiplication of the full shift reasonable worst case (75th or 90th percentile) from data or models, with known GSD of the full shift distribution, to derive a 95th or 99th percentile of short term distributions of ≤15 minutes or 1 hour. The differences in factors for averaging times below 15 minutes are generally small. A short term averaging time of 1 hour is considered to be a relatively long plausible averaging time for short term exposure; if exposure situations have a longer duration they could be directly compared to the full shift DNELs.

For data or models with unknown GSD of the full shift distribution the following values are suggested:

- If limited variability is expected and the GSD of the full shift distribution is expected to be small → use the values estimated for a GSD of 4-6

- except when deriving a short term 95th percentile from a full shift 90th percentile; in that case use a factor of 2 (from a GSD of 2-4)

- If large variability is expected and the GSD of the full shift distribution is expected to be large → use the values for a GSD > 8.

For full shift estimates based on ECETOC TRA it is assumed that these represent the 90th percentile of the exposure distribution. It is also assumed that in general the variability will not be very high. Therefore, it is recommended to multiply a full shift ECETOC TRA estimate by a factor of 2 to estimate the 95th percentile or a factor of 6 to estimate the 99th percentile of the related short term exposure distribution. For full shift estimates with models providing percentiles of the output distribution (e.g. Stoffenmanager) the factor to be used is dependent on the percentile used for the full shift estimate.

The above mentioned method should not be used if it is clear that the short term exposure distribution cannot be considered to be lognormal. If e.g. the full shift exposure is fully caused by a short term exposure during e.g. less than 1 hour and there is no or only negligible exposure during the remainder of the shift, it is recommended to estimate the exposure level (by modeling or measurements) specifically for the short term exposure period and use these estimates directly as an estimator for peak exposure.

**Table R. 14-18: Factor for multiplication of the full shift reasonable worst case estimate to derive short-term reasonable worst case estimate**

| Situation | Full shift estimate = 75th percentile | | | | Full shift estimate = 90th percentile | | | |
|---|---|---|---|---|---|---|---|---|
| | Short term = ≤15 minutes | | Short term = 1 hour | | Short term = ≤15 minutes | | Short term = 1 hour | |
| | Estimator 95th perc. | Estimat or 99th perc. | Estimator 95th perc. | Estimator 99th perc. | Estimator 95th perc. | Estimat or 99th perc. | Estimator 95th perc. | Estimat or 99th perc. |
| Full shift data available | Multiply full shift reasonable worst case by | | | | | | | |
| GSD = 1 - 2 | 3 | 9 | 3 | 7 | 2.2 | 6 | 2 | 4 |
| GSD = 2 – 4 | 3 | 15 | 4 | 15 | 2.0 | 6 | 2 | 6 |
| GSD = 4 – 6 | 4 | 20 | 5 | 20 | 1.5 | 7 | 1.6 | 7 |
| GSD = 6 – 8 | 5 | 30 | 6 | 30 | 1.4 | 8 | 1.7 | 9 |
| GSD > 8 * | 6 | 40 | 7 | 45 | 1.4 | 10 | 1.7 | 10 |

* The value for a GSD of approximately 10 is used for this category

### References

Kumagai S, Matsunaga I. 1994. Approaches for estimating the distribution of short-term exposure concentrations for different averaging times. Annals of Occupational Hygiene 38: 815-825.

## Appendix R.14-3: Control guidance sheet numbering system and an example "weighing of solids"

(Note: The Control Guidance Sheets at the COSHH Essentials website can be accessed directly through the link: http://www.coshh-essentials.org.uk/assets/live/g###.pdf, by replacing the ### with the number of the desired Control Guidance Sheet shown below in the Table; for example 102 for open bulk storage for large amount of solids and with general ventilation).

| | | Amount of solids used | | | Amount of liquids used | | |
|---|---|---|---|---|---|---|---|
| Unit operation | Sheet title | Small | Medium | Large | Small | Medium | Large |
| **Control approach 1: General ventilation** | | | | | | | |
| General task | General ventilation | 100 | 100 | 100 | 100 | 100 | 100 |
| Storage | General storage | 101 | 101 | 101 | 101 | 101 | 101 |
| | Open bulk storage | | | 102 | | | |
| Dust extraction | Removing waste from a dust extraction unit | | 103 | 103 | | | |
| **Control approach 2: Engineering Control** | | | | | | | |
| General task | Local exhaust ventilation | 200 | 200 | 200 | 200 | 200 | 200 |
| | Fume cupboard | 201 | | | 201 | | |
| | Laminar flow booth | | 202 | | | 202 | |
| | Ventilated workbench | 203 | | | 203 | | |
| Storage | General Storage | 101 | 101 | 101 | 101 | 101 | 101 |
| | Removing waste from a dust extraction unit | | 204 | 204 | | | |
| Transfer | Conveyor transfer | | 205 | 205 | | | |
| | Sack filling | | 206 | 207 | | | |
| | Sack emptying | | 208 | | | | |
| | Filling kegs | | 209 | | | | |
| | Charging reactors and mixers from a sack or keg | 210 | 210 | | | | |
| | IBC filling and emptying | | | 211 | | | |
| | Drum filling | | | | | 212 | |

| | | Amount of solids used | | | Amount of liquids used | | |
|---|---|---|---|---|---|---|---|
| Unit operation | Sheet title | Small | Medium | Large | Small | Medium | Large |
| | Drum emptying using a drum pump | | | | | 213 | |
| Weighing | Weighing | 201 | 214 | | 201 | | |
| Mixing | Mixing solids with other solids or liquids | 201 | 215 | 216 | 201 | 217 | 217 |
| Sieving | Sieving | 218 | 218 | | | | |
| Screening | Screening | | | 219 | | | |
| Surface coating | Spray painting (small scale) | | | | 220 | 221 | |
| | Powder coating | | 222 | 222 | | | |
| Lamination | Batch lamination | | | | | 223 | 223 |
| | Continuous lamination | | | | | 224 | 224 |
| Dipping | Pickling bath | | | | | 225 | 226 |
| | Vapour degreasing bath | | | | | 227 | 227 |
| Drying | Tray drying oven | | 228 | | | 228 | |
| Pelletising | Pelletising | | 230 | 230 | | | |
| | Tablet press | | 231 | | | | |
| **Control approach 3: Containment** | | | | | | | |
| General tasks | Containment | 300 | 300 | 300 | 300 | 300 | 300 |
| | Glove box | 301 | | | | | |
| Storage | General storage | 101 | 101 | 101 | 101 | 101 | 101 |
| Dust extraction | Removing waste from a dust extraction unit | | 204 | 302 | | | |
| Transfer | Transferring solids | | 303 | 303 | | | |
| | Sack emptying | | 304 | | | | |

| | | Amount of solids used | | | Amount of liquids used | | |
|---|---|---|---|---|---|---|---|
| Unit operation | Sheet title | Small | Medium | Large | Small | Medium | Large |
| | Drum filling | | | | | 305 | 305 |
| | Drum emptying | | | | | 306 | |
| | Infrequently charging reactors and mixers from a sack or keg | 210 | 210 | | | | |
| | IBC filling and emptying | | | 307 | | | 308 |
| | Tanker filling and emptying | | | 309 | | | 310 |
| | Filling kegs | | 311 | | | | |
| | Transferring liquid by pump | | | | | 312 | 312 |
| | Packet filling | 301 | 313 | 313 | | | |
| | Bottle filling | | | | 301 | 314 | 314 |
| Weighing | Weighing | 301 | 315 | 315 | 301 | 316 | 316 |
| Mixing | Mixing | 301 | 317 | 317 | 301 | 318 | 318 |
| Surface Coating | Robotised spray booth | | | | | 319 | 319 |
| | Automated powder coating | | 320 | 320 | | | |
| Dipping | Vapour degreasing bath | | | | | 321 | 321 |
| Drying | Spray drying | | 322 | 322 | | 322 | 322 |
| Pelletising | Tablet press | | 231 | | | | |

2 HSE

Control approach 2

This guidance sheet is aimed at **employers** to help them comply with the requirements of the Control of Substances Hazardous to Health Regulations 2002 (COSHH) by controlling exposure to chemicals and protecting workers' health.

The sheet is part of the HSE guidance pack *COSHH essentials: easy steps to control chemicals*. It can be used where the guide recommends control approach 2 (engineering control) as the suitable approach for your chemical(s) and task(s).

This sheet provides good practice advice on weighing medium quantities of solids. It describes the key points you need to follow to help reduce exposure to an adequate level.

It is important that **all** the points are followed.

Some chemicals can also be flammable or corrosive. Where they are, your controls must be suitable for those hazards too. Look at the safety data sheet for more information.

Depending on the scale of work, releases into the atmosphere may be regulated within the pollution prevention and control (PPC) framework. You should consult your local authority or the Environment Agency. In Scotland, consult the Scottish Environment Protection Agency (SEPA). They will advise you if PPC legislation applies to your company, and about air cleaning and discharging emissions into the air. Otherwise, minimise emissions into the air.

*Control guidance sheet* **214**

# Weighing solids

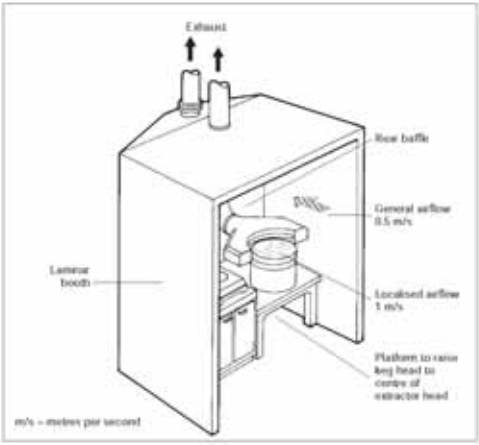
## Engineering control 214

### Access

✓ Restrict access to the working area to authorised staff only.

### Design and equipment

✓ The general airflow into the enclosure should be at least 0.5 metres per second. The airflow towards the hood slots should be at least 1 metre per second.
✓ Enclose the weigh station as much as possible (see illustration).
✓ Make the enclosure deep enough to contain equipment and materials.
✓ Keep the open area as small as possible - while allowing enough room for safe working. Use see-through panels and plastic strips to reduce the open area.
✓ Provide good lighting. It should be suitable for the chemical(s) and task(s), eg dust tight or flameproof.
✗ Avoid using deep kegs or kegs over 25 kg.
✓ Where possible, locate the work area away from doors, windows and walkways to stop draughts interfering with the ventilation and spreading dust.
✓ Provide an air supply to the workroom to replace extracted air.
✓ Provide an easy way of checking the control is working, eg a manometer, pressure gauge or tell-tale.
✓ Discharge extracted air to a safe place away from doors, windows and air inlets.
✓ You can re-circulate clean filtered air into the workroom.




*Control guidance sheet* **214**

### Maintenance

✓ Maintain the equipment as advised by the supplier/installer, in efficient and effective working order.

### Examination and testing

✓ Get information on the design performance of the ventilation equipment from the supplier. Keep this information to compare with future test results.
✓ Visually check the ventilation equipment at least once a week for signs of damage.
✓ Have ventilation equipment examined and tested against its performance standard - generally at least every 14 months (see HSE publication HSG54).
✓ Keep records of all examinations and tests for at least five years.

### Cleaning and housekeeping

✓ Clean work equipment and the work area daily. Clean other equipment and the workroom regularly - once a week is recommended.
✓ Deal with spills immediately.
✓ Store containers in a safe place and dispose of empty containers safely (see CGS 101).
✓ Put lids on containers immediately after use.
✗ Don't clean up with a dry brush or compressed air. Vacuum or wet clean.

### Personal protective equipment (PPE)

✓ Chemicals in **hazard group S** can damage the skin and eyes, or enter the body through the skin and cause harm. See CGS S100 and S101 for more specific advice. Check the safety data sheets to see what personal protective equipment is necessary.
✓ Ask your safety clothing supplier to help you select suitable protective equipment.
✓ Respiratory protective equipment should not be necessary for routine operations. It may be necessary for some cleaning and maintenance activities, eg cleaning up spills.
✓ Keep PPE clean, and replace it at recommended intervals.

### Training

✓ Give your workers information on the harmful nature of the substance.
✓ Provide them with training on: handling chemicals safely; checking controls are working and using them; when and how to use any PPE you provide; and what to do if something goes wrong.

### Supervision

✓ Have a system to check that control measures are in place and being followed.

### Further information

- Safety data sheets
- *Maintenance, examination and testing of local exhaust ventilation* HSG54 (second edition) HSE Books 1998 **ISBN 0 7176 1485 9**
- *An introduction to local exhaust ventilation* HSG37 (second edition) HSE Books 1993 **ISBN 0 7176 1001 2**
- Control guidance sheets 101, 204, S100 and S101

### Employee checklist for making the best use of the controls

☐ **Make sure the ventilation system is switched on and is working.**

☐ **Make sure it is running properly; check the manometer, pressure gauge or tell-tale.**

☐ **Look for signs of damage, wear or poor operation of any equipment used. If you find any problems, tell your supervisor. Do not carry on working if you think there is a problem.**

☐ **Make sure that paper bags and other waste material aren't drawn into the ventilation duct.**

☐ **Make sure that large items do not obstruct the working opening.**

☐ **Wash your hands before and after eating, drinking or using the lavatory.**

☐ **Do not use solvents to clean your skin.**

☐ **Clear up spills immediately. Use vacuum cleaning or wet mopping. Dispose of spills safely.**

☐ **Use, maintain and store any PPE provided in accordance with instructions.**

HSE

COSHH essentials
easy steps to control chemicals
October 2003

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