Guidance on information requirements and chemical safety assessment

Chapter R.14: Occupational Exposure Estimation

December 2009

(version 2 Rev.:0.0)

Guidance for the implementation of REACH

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

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 are aimed 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/reach_en.asp). 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].

1 Corrigendum to 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); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

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.	December 2009
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.	December 2009
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	December 2009
Version 2	The text on other models (Stoffenmanager, Riskofderm, ART) has been updated	December 2009
Version 2	The text on EMKG/ BauA-COSHH) model has been edited	December 2009
Version 2	The text on measurement data has been updated (R 14.4.4 and R14.4.5)	December 2009
Version 2	A new section R14.4.6 on short term exposure data has been introduced	December 2009

Convention for citing the REACH regulation

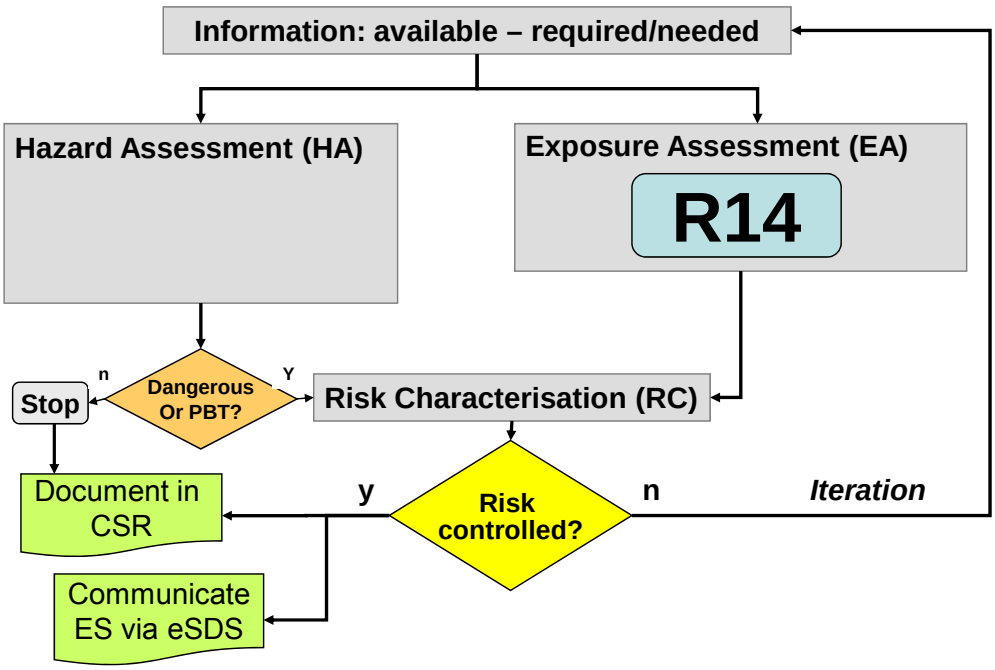
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

The figure below indicates the location of Chapter R.14 within the Guidance Document.



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R.14 OCCUPATIONAL EXPOSURE ASSESSMENT

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 the 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 require also 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 preparation;
- **Industrial use**: Application of the substance, preparation/product in an industrial process;
- **Professional use**: Application of preparations/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 it is 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.14.4.2)
    - Use and selection of measured data (Section R.14.4.3 and Section R.14.4.4)
    - ECECTOC TRA (Section R.14.4.8)
    - Easy-to-use workplace control scheme for hazardous substances (EMKG/ BauA-COSHH) (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), or sometimes even by swallowing (ingestion). Exposure to a particular substance should normally be understood as 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 digestive system, respiratory system and entering the body through the skin. Information on the exposure should therefore clearly indicate whether the exposures under discussion are external or internal.

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

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, needs to be considered, as well as other parameters such as duration and frequency of exposure. Exposure assessment should be planned taking into account both acute and chronic effects and local and systemic effects caused by the substance. Task-based scenarios appear appropriate to 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 by inhalation depends on 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 (nominally 8 hours) is generally used. If the substance has a 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 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 available in the ambient air. Especially exposure to aerosols is difficult to assess properly, since 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 solid aerosol exposure.

Inhalation exposure can be influenced by the concentration of the substance in air, and the duration and frequency of exposure. Inhalation exposure is generally expressed in ppm (parts per million) or amount per air volume inhaled, averaged over the duration of relevant task or shift.

Dermal exposure

For many substances the main route of exposure is by inhalation; however, substances may also 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 or in some cases from exposure to high air concentrations of vapour. Dermal exposure can be influenced by the amount and concentration of the substance, presence of other substances that may facilitate the absorption, the area of exposed skin, the duration and frequency of exposure and personal 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 this.

Contaminated clothing can also be a source of skin exposure particularly to 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

There are no accepted methods for quantifying exposure by ingestion as such. Nevertheless, ingestion (oral) exposure may occur in many situations where one is exposed 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.

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. 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 with relation to the source of the exposure and the exposure determinants:

- where the substance is used? (including description of processes, activities and products);
- the composition of mixtures (preparations)[3] and articles (including approximate percentages);
- how the substance is used? (including description of work activities/tasks leading to exposure, quantities used);
- approximate percentage in process materials and finished products;
- the form in which the substance is handled (e.g. powder, pellets, liquid);
- the nature of exposure, i.e. the Operational Conditions (including 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 in inputs to be made for the Tier 1 tool. For higher Tiers many additional details will be necessary for the exposure estimation (see Sections R.14.4 and R.14.5).

[3] Also referred to as formulations or chemical products

Product related RMMs, e.g. reducing the dustiness by converting a powder into an oil-coated powder, in 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) needs to be applied. The RMMs recommended for DUs should be practical for the DU and proportionate to the anticipated risk. For details the reader is referred to Guidance on Risk management measures and operational conditions R.13, including introduction to the RMM Library.

R.14.4 Exposure estimation with measurements and modelling approaches

R.14.4.1 Introduction

Human 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 the exposure during defined activities under the Operational Conditions and Risk Management Measures relevant for the exposure scenario. Such scenarios should be representative for 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 in a small percentage of cases over the whole spectrum of likely circumstances of use for that particular scenario. It excludes 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 reduction/control measures (RMMs) that are already in place should be taken into account (for details see Guidance R.13 and Part D). Consideration should be given to the possibility that, for parts of the exposure scenarios, risk reduction/control measures (RMMs) which are required or appropriate in 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 need to be compared to external DNELs[4]. This may then reflect short-term or long-term DNELs. For each

[4] Where appropriate, DMELs should be used instead of DNELs.

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, dermal and oral RCR).

Exposure could be a single event, a series of repeated events, or as 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.

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

1. measured data, including the quantification of key exposure determinants;
2. appropriate analogous/surrogate data, including the quantification of key exposure determinants;
3. modelled estimates.

Of course, this 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.

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, of a suitable quality and supported by sufficient information that enables them to be seen as being representative of any particular exposure scenario, will reflect the 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). 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 exists, 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. 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 scenario(s) are also indicated in the table.

Table R.14-1Workplace exposure assessment rating criteria

Data characteristics	**Comments & interpretation**
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 of key exposure determinants.	This form of data is likely to enable a decision whether or not there is safe use. There may be a need for more information, if key activities in the exposure scenario are not covered by measurement data presented. Data confidence is high.
Analogous/surrogate measurement data of a similar quality to the above and which describe exposures that derive either from: • other substances having similar exposure characteristics[5] (e.g. volatility, dustiness), or • other comparable activities considered likely to provide a reliable estimate of exposure for the scenario in question. 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. Data confidence is good and this should positively affect the interpretation of the data.
Predicted exposures derived from suitable models and using input criteria/values that are relevant for the scenario and are derived from generally accepted sources. Actual data of lesser quality, e.g. where data are only available from compliance monitoring or static sampling; where limited information on key exposure determinants are available. Surrogate 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	To reflect the increased uncertainty of data, this might lead to the conclusion that there is safe use only if the exposure level is (significantly) lower than the DNEL. With (conservative) Tier 1 modelled data in the region of the DNEL the safety of use is less certain. The conclusion that there is concern may be appropriate in other cases. The conclusion that there is a need for more information is likely to be appropriate

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

Data characteristics	Comments & interpretation
may be insufficient to suggest representativeness.	in some cases as well. In these cases further iteration, or more data may be required Data confidence remains acceptable, particularly when the exposure assessment is derived from an extensive range of sources. Exposure data derived from compliance monitoring are often biased towards reflecting high-end exposures. This in-built bias should be taken into consideration.
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 when 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. 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 where 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 for Tier 1 exposure scenarios:

- physical state of the substance
- physical state of the product handled
- vapour pressure (for liquids)
- "dustiness" (for solids)
- the level of containment
- presence or absence 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 for the first exposure estimation that focuses on potential exposure, even when it might be used. Exceptions are situations where the work cannot be carried out without PPE, for instance the use of gloves when handling corrosive substances, which cannot be used otherwise without serious health risks, or the use of respirators in asbestos work.

The exposure-reducing effect of PPE is considered as a next step (See Guidance 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, 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 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 define which percentile of the exposure distribution in an Exposure Scenario refers to. The general aim is 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 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 Guidance R.13) to control exposures at 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 amount 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 both respects 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 judging on measured data is called “assessor”, since it may be a person representing manufacturer or importer (M/I), a formulator, a branch organisation, or a single

company. In many cases, measured data will be taken into account. These data may be gathered from

- a database;
- surveys on 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 of the public domain.

The measurement data may be related to the substance as such (which is preferred) or analogous substances. Besides that, the measured data may present the situation as in the scenario or analogical situations. For the purposes of exposure assessment, analogous/surrogate data are, in most cases, data based on similar operations, utilising the same substance, or in less prevalent cases, data based on the same operation, but for similar substances. It is considered that most substances will have analogous/surrogate 'markers', e.g. substances that can be used if data on the assessed substances are not available or insufficient,. Whilst not providing equivalent reliability in terms of their status in the hierarchy of preferred data (Table R.14-1), such information on "markers" provide information which is more valuable than that obtained from modelled estimates.

When using data from analogous/surrogate substances, the M/I must ascertain that the estimation gives the result on the safe side. For example, for solvents, the estimation could be made using a more volatile substance as an analogue. Suppose 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/surrogate and used in the manner described in more detail in Table R. 14-1. However, the estimation of toluene exposure based on xylene exposure cannot be recommended, as toluene is clearly more volatile. The bottom line is here that volatility is a very important parameter for inhalation exposure and that comparability should be justified. Similarly, if an exposure estimate needs to be made for discharging 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.[6]

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 in order to obtain a 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 is not available, assessors still need to have all of the descriptive data in order to use exposure models.

(Table R. 14-1) shows a scheme for evaluating the usefulness and appropriateness of available exposure data and information in order to determine both reasonable worst case and typical exposure values.

[6] 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.

R.14.4.5 Selection 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 the REACH exposure assessment.

M/I 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 measurement 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.

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 covered sufficiently 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 better be described by their own specific Operational Conditions, Risk Management Measures and resulting exposure levels. For manufacturing processes of chemical products a differentiation may e.g. be warranted between general operations, loading and unloading activities and maintenance work.

Where exposure measurements are available, it should be possible to link them to the Operational Conditions and Risk Management Measures 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 and analytical methods.
- 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). Samples should be taken at breathing zone height and in the immediate vicinity of workers. If there is a large quantity of data available pooled and statistically evaluated, 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 for that matter) to see if needed.
- Details that enable the reliability and representativeness of the data have to be assessed. This includes considerations such as:

- Quality assurance information providing evidence that data has been collected and analysed according to recognised protocols and methods. This might include satisfactory performance within appropriate inter-laboratory quality assurance schemes and a description of the sampling strategy.
- When and why it was obtained?
- Do the data cover the use(s) incl. processes, activities, RMMs defined in the exposure scenario?
- What were conditions at the time of the measurement, e.g. normal or abnormal?
- Were the data collected according to defined sampling strategies 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 is it representative of the industry?

Inhalation data

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[7] (see Table R.14-2). It should be noted that data from one company might not be representative of a whole industrial sector.

Table R.14-2 Number of measurements at different risk characterisation levels leading to different confidence levels[8]

		RCR : <1 - 0.5	RCR : <0.5 - 0.1	RCR : <0.1
		N	N	N
Confidence in the exposure data, related to: • specificity of the data • broadness of the measured and assessed situation# • fit between the measured data and the assessed situation	High*	~20-30	12-20	6-12
	Moderate+	~30-50	~20-30	12-20
	Low^	>50	~30-50	~20-30

N= number of samples
RCR = Risk Characterisation Ratio

[7] 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. For practical reasons the following example of estimating how many data are needed to qualify is presented. When other relevant exposure information is available, the number of measurement data can possibly be lowered with a Bayesian statistical exposure evaluation. The true confidence should be determined in the final risk assessment.

[8]Expert judgement

* **High** confidence is likely to be associated with specific ESs where good quality data (actual or analogous) that fit the assessed situation tightly have been used for the estimate
+ **Moderate** confidence is likely to be associated with specific ESs where moderate/low quality data (actual or analogous) with some uncertainty regarding representativeness of the data have been used for the estimate or disperse ESs where good quality data have been used.
^ **Low** confidence is likely to be associated broad ESs where moderate/low quality data (actual or analogous) with substantial uncertainty regarding the representativeness of the data have been used for the estimate.

[#] A broad measured data set or broad exposure situation may include many different specific situations that could e.g. be clustered into subsets with different OC or RMM, such as 'outdoors' versus

'indoors', 'high', 'medium' or 'low' use rate of a product, or 'mobile LEV', 'fixed point extraction LEV' or 'extracting hood'.

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 this risk 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 should be provided, where available. This information is useful for the estimation of uptake through inhalation, because the biological uptake – the potential to cause adverse health effects - may depend on the deposition location in the airways. This deposition location in turn depends on the particle size distribution. The percentage of respirable particles (10 micrometers or less) is especially relevant and also the possible exposure to ultrafine particles (nanoparticles, < 0.1 μm). As a minimum the size selection characteristics of the sampling methods used should be provided, for measured data on dusts. It is vital to know whether inhalable dust (100 micrometers or less), respirable dust or nanoparticles is measured.

Dermal data

Many of the factors which influence other forms of exposure, such as the way the job is done, environmental conditions, and the 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.

Supporting information should include details of work wear worn, differentiating between general work wear and protective clothing and equipment, and personal hygiene. Potential exposure from unclean general work wear (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. The largest single available source is the RISKOFDERM project that has resulted in large number of measurements, presented in reports from the project and partly in several publications. The project also resulted in development of a model for estimating potential dermal exposure (see Section R.14.5.2).

During handling of corrosive substances the use of protective gloves and other equipment, such as face shields, aprons and good work practices are required. As a result, immediate dermal contacts occur 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, not so much 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 the corrosive substance preparation diluting/mixing occurs which results in a substance or preparation without corrosive properties then dermal exposure to this new substance or preparation 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 impression on the relative percentages of external contaminant that are either absorbed or evaporate from the skin.

Dermal exposure measurements have focused almost solely on low volatility substances.

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 probable.

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 decide whether or not a measured result is representative of a day's exposure or a longer period. In some cases taking one sample at the end of the day is appropriate, whilst in other cases a full day pooled 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, it seldom indicates the primary route of exposure or the relative proportion that different exposure routes contribute to total dose.

Biological monitoring information should be seen as equivalent (i.e. as having neither greater nor lesser importance) to other forms of exposure data e.g. airborne contaminants' measurements. Biological monitoring data must 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 chemicals 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. It may therefore be 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 those cases where the monitored biomarker is a metabolite of the substance, either a DNEL needs to be derived for the metabolite, or it should be made clear how the metabolite values are to be compared to the substance's DNEL. For the risk assessment, biological monitoring data should be compared to appropriate external DNELs, or often with biological monitoring, to more logical internal DNELs. In any case the assessment should be done carefully to account for aspects of absorption, desorption, metabolism and excretion in a proper way. For instance, dermal absorption estimates should either be used in the derivation of the external DNEL or in the comparison of an external DNEL (that assumes 100% absorption) with the external exposure levels. The comparison of biomonitoring data with DNELs is further described in Appendix R.8-5.

Uncertainty and statistics

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

- measurement uncertainties (including those arising from the physical sampling process);
- 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 toxicology 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 by using a more conservative estimator (see also Chapter R.19).

Statistics

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 application of occupational hygiene expertise, 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 process 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 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 Operational Conditions and Risk Management Measures, there is ample room for subgroups to exist. For example the Exposure Scenario 'rolling and brushing of paint containing substance X' should be protective for workers from Northern Europe as well as from (generally warmer) Southern Europe, for working indoors as well as outdoors, in all seasons, and for low and high percentage of X in the paint. Workers using paint products with higher concentrations of X, indoors, in Southern Europe during the summer may be the worst case situation. If the exposure estimate is based on a very broad set of data from all over Europe with (probably) different paints used, but subdivision cannot be made due to lack of detailed information, it is recommended to use a relatively high percentile from the total data set, e.g. the 90th percentile. If however there is a very specific data set for workers in Southern Europe using paints with high percentages of X, while the scenario also covers situations with expected lower concentrations, the use of a lower percentile, such as the 75th percentile should be considered. The general rule here is:

- broad data sets that may include (unknown) subgroups with systematically different exposures or well-defined data sets that do not fit the Exposure Scenario very well: use a high percentile, e.g. 90th percentile;
- narrow and specifically defined data sets, accurately fitting the Exposure Scenario or the expected worst case situations within a broader Exposure Scenario: use a lower percentile, e.g. the 75th percentile.

Even within very homogeneous groups there is expected to be some variation within workers' groups in long term exposure (e.g. working life exposure). If the 50th percentile would be close to the DNEL there would be a substantial probability of a percentage of workers having a long term exposure above the DNEL and therefore being at risk. Therefore, the 50th percentile or median of

measured data is not recommended as the estimator for worker exposure in the Chemical Safety Assessment.

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 Operational Conditions and Risk Management Measures (if certain RMM are e.g. only needed for a high exposure subgroup and not for the total exposed population).

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 Short-term sampling data

Exposure to some substances may lead to acute health effects. In order to provide a relevant estimate of exposure the assessor should request short-term sampling 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 short-term exposure. In the risk assessment the comparison should be made with a relevant DNEL, e.g. a short-term DNEL.

The relevant duration of 'short term exposure' and a 'short-term 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 short term and full shift exposure is. A pragmatic choice could be to assume that exposures up to 1 hour are compared to the short term DNEL, while exposures above 1 hour are compared to a full shift DNEL.

The risks of acute effects need to be assessed when a substance is classified for acute effects and 'peak exposures' are likely to occur. For inhalation exposure peak exposure could generally be considered to be the exposure averaged over 15 minutes (Guidance R.8).[9] This corresponds well with the STEL value (short term exposure limit) for 15 minutes exposure duration used in the workers protection legislation (EC 2000).

The aim of assessing short-term exposures may differ from 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 short exposure, exceeding certain values cannot be allowed at all. It might be important to detect the high peak exposures for e.g. respiratory sensitizers. For effects that are transient and not very severe, 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 rather high percentile of the exposure

9 'The $DNEL_{acute}$ is set based on studies involving exposure for short periods (for inhalation normally 15 minutes' peak exposures)'

distribution of short term measurements e.g., the 95th percentile could be suggested as the reasonable worst case estimator of short term exposure for effects that are reversible and not severe.

Short term measurement data, due to their nature, are more variable than corresponding full shift exposure levels in the same situation. Short term exposure values are also related to each other, especially short term values measured just before or just after each other. Based on this knowledge, relations between parameters of short term and full shift exposure distributions have been calculated (Kumagai and Matsunaga 1994). The 95th percentile of 15 minute exposure data is about 2 times the 90th percentile and 4 times the 75th percentile of full shift data collected for the same situation.

Measuring short term exposure can often be aimed at tasks or conditions with expected highest exposure. In that case, similar numbers of measurements are needed as for full shift exposures. However, when moments of high exposure are difficult to predict and short term 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 95th percentile of the short term 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 short term inhalation exposure

This chapter gives guidance how to estimate reasonable worst case short term 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 short term exposure levels is also needed for the risk assessment. It is possible to extrapolate full shift exposure levels or estimates to derive short term exposure estimates (see the above paragraph on short term exposure measurement data). This statistical extrapolation can be used for substances with less severe and generally transient acute effects, but not with severe acute effects, e.g. death after short term exposures.

Guidance R.8 describes the acute toxicity DNEL as follows: "A $DNEL_{acute}$ can generally be defined as a DNEL for effects that occur after exposure for a short period of time (from minutes to a few hours). The potential for short-term high level (i.e. peak) inhalation exposure is of most concern for workers, and hence, the occupational exposure assessment should always consider the possibility for such peak inhalation exposures, as these peaks could potentially be significantly above the typical (daily average) exposure level. If a DNEL for acute inhalation toxicity needs to be established (based on the toxicological profile of the substance concerned), this should be derived only for a specified fraction of the daily exposure duration (usually 15 minutes for workers)."

If a short term DNEL is derived, there is a need for establishing exposure estimates for comparison with this short term DNEL. Similar to the implicit definition in Guidance R.8, 'peaks' in exposure studies have at least an exposure level which is higher than the full shift time-weighted average exposure level and a duration which is substantially shorter than the full shift (*i.e.* short term, Preller 2004). Short term exposure could be pragmatically defined as an exposure with an averaging duration no longer than 1 hour. It is not necessarily 'peak exposure': also low levels over a short period fall within the definition of short term exposure.

The basis for the extrapolation from full shift exposure estimates to short term is the fact that most exposure distributions tend to be (more or less) lognormal and that the GM and GSD of such distributions with different averaging times are related (Kumagai and Matsunaga 1994). Percentiles of lognormal distributions can be calculated from the geometric mean (GM) and geometric standard deviation (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 short term 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 75th to 90th percentile could be used. For short term exposure estimates, due to the acute nature of the effects, probably a relatively high percentile would be needed.

Short term 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 short term 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 with which the full shift reasonable worst case should be multiplied for estimating a short term reasonable worst case value are presented.

Table R.14-3 Multiplying factors to generate short term reasonable worst case value from full shift values

Situation	**Full shift reasonable worst case = 75th percentile**		**Full shift reasonable worst case = 90th percentile**	
Short term (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	1.4	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 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 is dependent on the percentile used for the full shift estimate.

The above mentioned method should not be used if the short term exposure distribution is not lognormal, as often is the case in industrial exposures. If e.g. the full shift exposure is due to a exposure e.g. less than 1 hour and there is only negligible exposure during the remainder of the shift, it is recommended to estimate the exposure level (by modeling or measurements) for the short term exposure period specifically and use those estimates directly as estimator for peak exposure. Further guidance on assessing short term inhalation exposure is presented in Appendix R14.2.

R.14.4.6.2 Short term 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 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 possible 'peak internal dose'[10] 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 those cases internal peak doses will hardly occur.

Most existing dermal exposure measuring methods, with 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 on skin exposure assessment and good knowledge of the studied work.

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 a pragmatic assumption is that any short term dermal exposure estimate within a long exposure period will not be higher (and will probably be lower) than the long term dermal exposure level for that period. Risk characterization for acute systemic dermal exposure is therefore preferably done with the same exposure values as for repeated systemic dermal exposure. It is to be expected that DNELs for systemic effects as a result of acute dermal exposure would be higher than DNELs for repeated dermal exposure and systemic effects. Safe use for repeated dermal exposure would therefore automatically imply safe use for acute dermal exposure. This also implies that deriving a DNEL for systemic effects due to acute dermal exposure will generally not be useful, based on exposure considerations.

The exposure estimation for local effects on the skin uses other units (µg/cm^2) and is more driven 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 with a maximum percentage of substance in the product should therefore be used as the basis for estimating acute local skin effects.

[10] 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 similar and are defined as a clearly higher exposure than the full shift average occurring over short periods, e.g. from minutes up to an hour.

R.14.4.7 Use of exposure estimation tools

The currently available tools for occupational exposure estimation are, in general, modelling approaches to separate workplace situations with respect to substances, with critical risk levels from which it is possible to indicate safe use (safe exposure level). Therefore, the appropriate tools have to be sufficiently conservative to serve as a first filter stage (Tier 1).

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 Easy-to-use workplace control scheme for hazardous substances (EMKG) is described. In Section R.14.5 higher level assessment tools are presented.

For none of the models, a validation against an independent data set has been carried out so far. However, limited comparison of available measured data with the predicted exposure so far shows a reasonable correlation between measured and predicted exposure. Nevertheless, there is also 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).

Also, the tools use activity/process categories as one of the input parameters largely influencing the exposure prediction. Whether the user of a tool chooses the most appropriate activity/process category for a given activity at company level is outside the possibility of any validation.

Registrants need to be aware that exposure prediction based on the tools described in this guidance cannot be considered as “validated”. Comparison with measured data or using more than one model prediction in parallel reduces the uncertainty in risk characterisation. As a general advice, if (especially for solids) the risk characterisation ratio is close to 1 (e.g. 0.7), confirmation of exposure prediction with a second model or measured data is recommended. All REACH facilitators need to be aware of the potential weaknesses of the exposure calculation tools, especially when they are introduced to plug-in IT tools.

R.14.4.8 ECETOC TRA (Targeted Risk Assessment) tool for occupational exposure

This section describes the methods employed in the determination of exposure for the worker aspects of the ECETOC Targeted Risk Assessment [1]. ECETOC developed the approach to assess the health and environmental risks from the supply and use of chemicals. The features of the overall approach are that the assessment is Tiered, with substances that are less hazardous or with less potential exposure, requiring a simpler assessment to demonstrate low risk, than those that have significant hazardous properties and/or have more widespread exposures to man or the environment. This section describes the methodologies developed to estimate inhalation and dermal worker exposures. The ECETOC TRA assessment tools are made available as three individual assessment tools for worker, consumer or environmental assessment. Alternatively, the three tools are provided in an integrated version which allows the user to perform the assessments 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 do 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 but introduces a more precise, structured and simplified approach in order to make it then amenable to a more rapid approach of assessment and to a larger user community. The additional advantage is consistency, both between assessments and also with known and accepted approaches for assessing exposures.

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 minimal risk for a specific scenario of use, eliminates the subsequent necessity (or value) 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 a 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 means of selecting exposure control (Risk Management Measures) or use factors. This process delivers as an output 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 tool (version July 2009).

Strengths

- Clear structure
- The process categories, (PROCs, as presented in Guidance R12, Appendix R 12-3) are used as basis for assessment
- Duration of process/activity/operation unit is taken into account
- Exposure scenarios based on EASE and expert input from industry stakeholders
- Effectiveness of local exhaust ventilation depends on process
- Differences between industrial and professional situations are taken into account in inhalation exposure
- Percentage of substance in preparation is taken into account in inhalation exposure
- Effect of respiratory protective equipment (RPE) is taken into account in inhalation exposure
- Possibility to calculate several scenarios at once

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[11]
- Influence of 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 preparation used is not taken into account for dermal exposure (Ecetoc 2009)
- Duration of exposure is not taken into account for dermal exposure

[11] In many cases this choice is clear, but there are some situations where 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'.

- Personal protective equipment for dermal exposure is not included
- The type of RPE providing a certain level of reduction are not specified in the tool
- Compared to measured data (RISKOFDERM project) the dermal exposure for situations with local exhaust ventilation is underestimated.
- The efficacy of LEV in ECETOC dermal exposure assessment needs more justifications, especially when analysing the available comparisons with measured data.

Ways to compensate for limitations

- Use the most similar PROC for processes not included in ECETOC TRA Worker
- Assume that small amounts are related to short durations of use
- Assume professional use if it is unclear whether a use fits professional or industrial
- Recalculate the dermal exposure level for substances used in preparations concentration less than 100%) outside of 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
- For guidance on the type of RPE leading to the required reduction in exposure the tool refers to COSHH Essentials sheets
- 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)
- The approach using the specific worker tool (and also the integrated tool) is simple. The worker tool version presents almost all assumed influences of determinants also in separate sheets.

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)
- Physical state of the substance (solid or not)
- 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 preparation
- Concentration range of the substance in the preparation (in classes; only if used in a preparation).

Next to these inputs that are needed to calculate exposures some values need to be entered for substance name, CAS number and short scenario name, because the software requires these.

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[12] (tendency of a substance to become airborne from a heterogeneous system) as defined in an availability banding for an initial assessment. 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 - R14-6 presents the categories used by ECETOC TRA.

Table R.14-4 General fugacity table

Vapour pressure (kPa)	Dustiness	Fugacity
>=0.01- <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	
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, then 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.

[12] The term volatility shall be used in the rest of the description as a proxy for 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 Guidance R12, Appendix R 12-3) as basic starting point for the exposure estimation. All PROCs that are included in the tool receive a quantitative dermal exposure estimate.

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 were:

- Operational conditions
  - Industrial or professional activity
  - Activity taking place indoors or outdoors
  - Duration of the activity
  - Percentage of substance used (if used in a preparation)
- 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. EASE is known to over-predict exposures in some instances. An additional work comparing the output of the above exercise with known values of exposure for a variety of current workplace activities also showed over-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 no personal protection was in use and that dermal absorption/permeation is 100%.

Impact of working outdoors

A default reduction of the basic estimate for working outdoors is calculated by multiplying the basic estimate with a factor of 0.3. 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 on the basic estimate (which assumed that an activity is done full shift). Those 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 with a factor of 0.2, meaning that the exposure is lowered by a factor of 5.

Table R.14-7 Modifiers for duration of activity

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

Impact of percentage of substance used in a preparation

Instead of a simple, but possibly not sufficiently conservative, direct multiplication of the basic estimate with the fraction of substance in the preparation used, ECETOC TRA worker uses a different multiplication factor for bands of concentrations in preparations. 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/EE 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)** Medium fugacity	**Exposure Estimate (Units ppm)**
Exposure scenario (Roller painting) Process Category 10 - Roller application or brushing Public Domain (Professional) activity Initial Exposure Estimate	 100
Exposure modifiers The activity takes place **Indoors** **Ventilation is present** with an assumed **efficiency of 80%** The maximum duration of the activity is **1 - 4 hours** **Respiratory Protection with a minimum efficiency of 90% is used** Is this substance part of a preparation? Yes at 5 – 25% w/w Assessment factor applied is 0,6	 20 12 1,2 0,72
The Inhalative 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)
are estimated at	**1,3714 mg/kg/day**

R.14.4.9 Easy-to-use workplace control scheme for hazardous substances (EMKG/ BauA-COSHH)

The exposure predictive model of the German "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. The Easy-to-use control scheme of BAuA (the acronym EMKG stands for: "Einfaches Maßnahmenkonzept Gefahrstoffe") should be seen as an approach for filtering the rather non-risky workplace situations from those requiring detailed attention (BauA 2006). The exposure assessment part is based on the banding approach of the COSHH Essentials originally developed by HSE (HSE 1999). The tool functions only for inhalation exposure. The English version of the tool is on the website of BauA (www.baua.de), http://www.reach-helpdesk.de/en/Exposure/Exposure.html.

This exposure predictive model is based on three input parameters: volatility or dustiness, amount of substance used, and control approach. 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 scale of use/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. 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 and filling.

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

Strengths

- Very clear and user friendly structure
- The output has been sound for a number of ES
- Provides control strategies for a range of common tasks, e.g. mixing, filling etc.
- Control guidance sheets are available on the Internet.

Limitations

- The estimates are generic in nature and therefore uncertain to some extent
- It is not possible to use the assessed exposure ranges as a basis for further iterations e.g. considering the duration of exposure (only the influence of short term exposure, i.e. < 15 min/day, is considered)
- Validation of the concept is limited
- Not suited for gases (handled or released)
- Should not be used for tasks where fumes are generated or where dusts are formed through abrasive techniques
- Not suited for CMR substances.

Ways to compensate limitations

As the model estimates are uncertain to some extent, the concept acts on the following conservative assumptions:

- 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.

Both COSHH Essentials and the Easy-to-use control scheme "EMKG" are available as web based tools. The exposure assessment parts are not visible to the user. The text below on EMKG provides guidance on how to select the correct model parameters and how to derive an exposure level based on a limited number of decision tables.

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)
- implemented RMMs (control strategy)

- exposure period (<15 min or ≥ 15 min)

For many situations these generic parameters are sufficient to check, whether the measures of the chosen control approach are appropriate (DNEL > upper value of the exposure range). Each of the determinants is arranged in discrete bands. These bands are generic in nature and not sector specific. Nevertheless, there is a strong link to the ES concept of describing the safe use, since for many standard activities Control Guidance Sheets (CGSs) were developed. These CGSs describe good control practice for the specific set of circumstances chosen (e.g. mixing and loading small quantities or mixing and loading large quantities).

R.14.4.9.2 Output data for the CSA

The output from the tool - predicted exposure levels - is used for inhalation exposure assessment. If sufficient control of risk cannot be demonstrated, it is possible to introduce RMMs in the calculations simply by selecting another appropriate control guidance sheet

Exposure potential (dustiness and volatility)

The factors that can lead to the generation of dust and vapour can be subdivided into two general categories, those related to inherent physical properties of the material and those related to how the substance is handled.

Dustiness
For solids, the materials dustiness is the principal physical property that needs to be considered. The user has to determine the dustiness subjectively on a phenomenological basis. In total there are three dustiness bands defined as presented in **Error! Reference source not found.**-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 down 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 form 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 the 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 (**Error! Reference source not found.**-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

For mixtures, 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. Therefore the most volatile component determines the model input on volatility.

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 to be the most important factor, since it impacts on how the material is packaged, transported and used (**Error! Reference source not found.**-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 significant higher exposure levels than the predicted ones [6]. As a consequence of these observations the EMKG takes into account wide dispersive use situations in the following way: if liquid hazardous substances are used on large surface areas (for example when painting or cleaning, e.g. >1 m^2) no more than **1 litre** of the substance **per full working day** should be used in order to qualify for the quantity group „low“; if the used amount exceeds 1 litre **and** a large surface is treated, the quantity group “medium” has to be chosen instead.

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 to four combined bands which are called exposure potential bands. These are defined below in **Error! Reference source not found.**-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 dusty solid, Kg /Tonnes of low dusty solid
	Medium or Large	Low	
3	Medium	Medium or High	Kg of medium / high dusty solid
4	Large	Medium or High	Tonnes of medium / high dusty 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 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 taken.

Control strategies

Within the scope of the EMKG, the scale of use, volatility and dustiness are used to build a simple model of the exposure potential. 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 extract, partial enclosure, not complete 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 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 website of COSHH Essentials 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 **Error! Reference source not found.**-3) in which the relevant control approach vs. the used amount are displayed. As an example the CGS for "weighing solids" is also depicted in **Error! Reference source not found.**-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.14.4.9.3 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 altogether six possible predicted exposure ranges**Error! Reference source not found.**-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 their 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 considered too high to deliver adequate control 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	**Predicted exposure level for dust, mg/m^3**

approach	Solids EP Band 1 (g of low / medium dusty solid)	Solids EP Band 2 (g of high dusty solid, kg / t of low dusty solid)	Solids EP Band 3 (kg of medium/high dusty solid,	Solids EP Band 4 (t of medium / high dusty 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 applied control approach. 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.

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 the TWA exposure of 0.03 of 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.14.4.9.4 Status of validation

The exposure predictive model of COSHH Essentials was validated by comparison of information presented in **Error! Reference source not found.**-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 assessment.

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

R.14.5 Higher Tier exposure assessment

When according to the Tier 1 assessment, conducted for a specific scenario on the basis of the measured data and considering implemented RMMs, the level of protection is not adequate, a higher Tier assessment is necessary. This assessment is generally (much) more detailed and specific than the assessment in Tier 1. The assessment at higher Tiers can be done by any suitable method that is valid and sufficiently accurate.

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 to proceed is to carry out exposure measurements in real exposure situations. They might produce exposure levels clearly below DNELs, and if not, the development of exposure scenarios should focus on implementing more effective RMMs (see Section R14.4.3-5).

R.14.5.1 Stoffenmanager exposure model

The "Stoffenmanager" (Dutch for "substance manager") tool originally is a web-based risk prioritizing tool for small and medium sized enterprises (www.stoffenmanager.nl). It has thousands of registered users. The newest version (version 4.0) 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, which faster leads to an exposure estimate useful under REACH. It also has a section for exposure calculations in which e.g. full shift time weighted averages can be calculated. Data on products, substances and assessments entered within one of the sections are also available in the other sections. 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 in 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 however is only possible in the 'exposure calculation' section.

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

Strengths

- Specific REACH and exposure calculation sections.
- Based on a published and partly validated scientific conceptual model of exposure (Marquart 2007, Tielemans 2007a).
- Clear and user friendly structure; easy to understand and use for non-expert users.
- 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.
- 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).
- 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.

Weaknesses

- 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 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.

Ways to compensate weaknesses

- PROCs can be transposed to handling categories also providing defaults for some other Stoffenmanager parameters that are actually included in some PROCs (e.g. containment, which is included in PROCs 1, 2 and 3).
- 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 of the handling categories that are possibly relevant.

Applicability

To facilitate the choice of percentile to be used for estimating reasonable worst case exposure levels in the risk characterization, a consistent choice of input options is recommended. Typical input values and the 90th percentile of the estimated exposure distribution, or reasonable worst case input values and the 75th percentile of the estimated exposure distribution should be used. Typical input values and the median of the estimated exposure distribution provide an estimate of the average exposure in the assessed scenario (see also the short discussion in Section R.14.5.1).

Both the 'exposure calculation' section and the REACH section of Stoffenmanager 4.0 allow quantification of exposure without the need to fully use all functionalities not relevant for exposure estimations. The advantage of the 'exposure calculation' section is its ability to calculate time weighted averages.

The user needs to register for Stoffenmanager before use. Registration is free and is easily done via the website.

R.14.5.1.1 Input data

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

- 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 to 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
- Immission control measures (such as control rooms)
- Personal protective equipment used
- Is the work area regularly cleaned
- Are machinery and equipment regularly inspected and kept in good order.

For calculating time weighted averages first separate assessments per involved activity should be made. The assessments to be combined can subsequently be selected and the duration of each activity entered to calculate time weighted averages.

Next to these necessary inputs for exposure estimation a number of other inputs need to be entered. These are data on the product name, information on the relevant R-phrase(s) 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 made and the duration and frequency of the task. Although these data will not influence the quantitative calculations, inputs are required for the software to function. Any (hypothetical) input can be used to allow the model to do calculations.

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, liquid aerosols and inhalable dust. Depending on the conservative nature of the inputs provided 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 90th percentile of the output distribution is recommended for use in risk assessment. If conservative values are used for all inputs, the 75th 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 5th framework program project focused solely on dermal exposures in industrial and professional settings. On the basis of measured data approaches have been developed to assess dermal exposure for six different so-called Dermal Exposure Operation units (DEO Units). It assesses potential dermal exposure, i.e. the exposure on the skin and on the layers (clothing or e.g. gloves) covering the skin. It does therefore not take into account any protective effect of clothing or gloves.

An Excel spreadsheet version and a guidance document for the model can be downloaded from the TNO website (Warren 2006).[13] The 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)[14]

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

- The model is task based
- Potential exposure of the hands and of the body are estimated separately (for some of the DEO Units)
- Several Operational Conditions and Risk Management Measures 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 relatively 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.

Weaknesses

- 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)
- Model does not take into account protective effect of clothing or gloves
- Not for all DEO Units algorithms for potential exposure of hands or body are available; also, within DEO Units, not all possibly different situations were covered by the measured data underneath the model[15]
- Choice of percentile of the output distribution is not always obvious
- 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 weaknesses

- 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 75th 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 90th percentile of the output distribution is recommended.

If one wants to take into account the effect of clothing or (protective) gloves, you will have to estimate the actual dermal exposures based on the potential dermal exposures given by the model and knowledge or estimates of the protective effect of the clothing and/or gloves.

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[14] 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 therefore are slightly different from the names of the original DEO units to provide a more specific indication of the modelled situations.

[15] 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.

A full shift estimate can be made by combining the results of separate estimates for different tasks. This is not necessarily a straight forward summing of estimates per task. Skin contamination may be removed from the skin between tasks, either on purpose (e.g. by hand washing) or because of incidental transfer to other surfaces. It is also expected that the processes of contamination and decontamination of the skin will reach equilibrium at a certain level of contamination. Higher and unrealistic estimates can easily be made by simple summation of task-based values and a probabilistic aggregation of exposure (available in the web-based version) may be preferable. If safe use cannot be shown with original input values, the model can rerun by changing input values towards better control of exposure.

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.

R.14.5.2.1 Input data

The RISKOFDERM dermal exposure model first needs input the type of exposure process (choice between one of six processes or DEO units). Afterwards, depending on the exposure process input on the following items can 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 fitting to the inputs provided and for any chosen percentile. Also, for a number of fixed percentiles of the output distribution the values are presented. 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.

Calculations

The RISKOFDERM dermal exposure model does calculations based on equations derived from mixed-model statistical analyses from a relatively large set of measured data. The results are for the full product used, so a correction for fraction of substance in a product may be needed.

R.14.5.3 Advanced REACH Tool (ART)

The need for a higher Tier tool was expressed at 'The Future of EASE workshop' (Northage, 2005). The approach as proposed makes full use of mechanistically modelled estimates of exposure and any relevant measurements of exposure. The approach will provide 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.
Since the tool will allow the use of analogous exposure data from relatively 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 down and up the supply chain.

The new framework incorporates both a mechanistic model (including a Monte Carlo module) and an empirical part with information from an exposure database. Both parts are to be combined using a Bayesian statistical process in order to produce exposure estimates for specific scenarios relevant to the REACH process.

Strengths

- The model is based on a conceptual mechanistic source-receptor model
- It differentiates effect of energy transfer and scale of emission from the source
- The model takes into account several operational conditions and risk management measures throughout the whole exposure pathway from source to worker
- Effect of determinants is based on a combination of published effects and expert judgement
- It is easy to use well structured web-tool
- The model was calibrated with extensive measured data
- Provides the choice of several percentiles of the resulting exposure distribution
- Provides an indication of the uncertainty of the mechanistic model result
- Possibility to estimate exposure during a number of consecutive activities is provided
- Combines mechanistic model result with measured data in a Bayesian statistical process

Weaknesses

- High information requirements compared to Tier 1 models
- The present version of ART cannot estimate exposure to fumes or to gases
- The model is developed for full shift exposure levels. It does not automatically calculate a full shift exposure for situations where exposure tasks cover only part of the full shift and there is no exposure during the remainder of the shift. However, a warning is given in case the total duration of the estimated activities is less than 8 hours.

Ways to compensate weaknesses

- 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 of substance category
    - Defaults could be included in Generic Exposure Scenarios based on ART, which could also include integration of available measured data
- To calculate full shift exposure levels based on short term exposure activities the user can enter information for a 'no exposure task' with inputs leading to minimum exposure levels for that task

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 utilised 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 to be used in scenarios where substances are formed through reaction processes (e.g. exhaust fumes, rubber fumes). The present version (September 2009, beta version) is also not appropriate for scenarios where gases or fibres are used.

ART is most useful for assessing situations where exposure is determined to a relatively large extent by Operational Conditions and Risk Management Measures that are outside of the scope of other models (e.g. automation, remote control, separation, influence of specific types of local exhaust ventilation (LEV), fugitive emissions) and when there are measured data available that can support exposure assessment.
ART is a web-tool that is free to use following registration. Registration can be easily done via the website http://www.advancedreachtool.com.

R.14.5.3.1 Input data

Conceptually, the inputs are arranged in sets of so-called '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 pellitised material:
    - Dustiness (measured) or dustiness category
    - Moisture content of the material (2 classes)
- For solid objects:
    - Material of the solid object
    - Moisture content of the material (2 classes)
- 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 the primary emission source is in the breathing zone, the possibility of secondary sources outside the breathing zone also needs to be assessed.

For both primary and secondary emission sources (separately) the following information have to be provided:

- Activity class of the activity (several activity classes, depending on the type of material used)
  - In some cases, also activities' 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 of 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 palletised material)
  - Containment without extraction
  - Local exhaust ventilation - three options, each with two to three sub-options are available
- 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 worker relative to source

For primary sources outside of the breathing zone only the following risk management measures 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 of the breathing zone) the question regarding emission sources segregated from the worker also applies

In addition to the above mentioned technical parameters that are required to perform calculations, some administrative data on e.g. the name of the substance and the name of the assessment also is requested. A comphrehensive report of the beta version of the tool is available (Warren et al. 2009).

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

The currently available beta version provides a choice of the following results:

- Mechanistic model and Bayesian update results
  - Full shift or long term result, where the long term result takes into account typical within and between workers' groups variation
  - 50^{th}, 75^{th}, 90^{th}, 95^{th} and 99^{th} percentile of the output distribution
  - 90%, 95% or 99% confidence interval around the chosen percentile

Version updates

Following the release of the beta version, a full version 1.0 will be published in 2010, with a larger applicability domain and more functionality. Further updates will include an exposure database from which analogous data can be derived and with the possibility to assess short-term exposure levels.

R.14.6 REFERENCES

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APPENDICES

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 was aimed at 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, EASE estimate		[mg]
R:	gas constant:	8.314	[J · K^{-1} · mol^{-1}]
T:	skin temperature		[K]
M:	molar mass		[g/mol]
β:	coefficient of mass transfer in the vapour phase [m h^{-1}], for calculation: β = 8.7 m/h, see below		
p:	vapour pressure of the pure substance		[Pa]
A:	area, EASE:		1 cm^2
K:	conversion factor:		3.6 · 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

β =	(0.0111 · v$^{0.96}$ · $D_g^{0.19}$) / ($\nu^{0.15}$ · X$^{0.04}$)	
D_g :	coefficient of diffusion, gas phase	
v:	velocity of air	[m/h]
ν:	kinematic viscosity of air	[m^2/h]
X:	Length of the area of evaporation in the direction of the air stream	[m]

In the above given equation, 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, D_g is approx. 0.05 m^2/h. Using the range 0.03 – 0.06 m^2/h, $Dg^{0.19}$ ranges between 0.51 and 0.58. A literature value was taken for the kinematic viscosity of air ($5.4396 \cdot 10^{-2}$ m^2/h). The parameter X, represents the length of the area of evaporation in the direction of the air stream [m] does not influence the outcome a lot because of 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 Error! Reference source not found.-16 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 in how far the interaction of the skin with the substance influences the evaporation time. The error caused by this interaction is regarded to be higher than the one caused by the uncertainty of the calculation of β. For different substances (7 substances were investigated) β differs about ±5%.

Table R.14-16 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

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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.

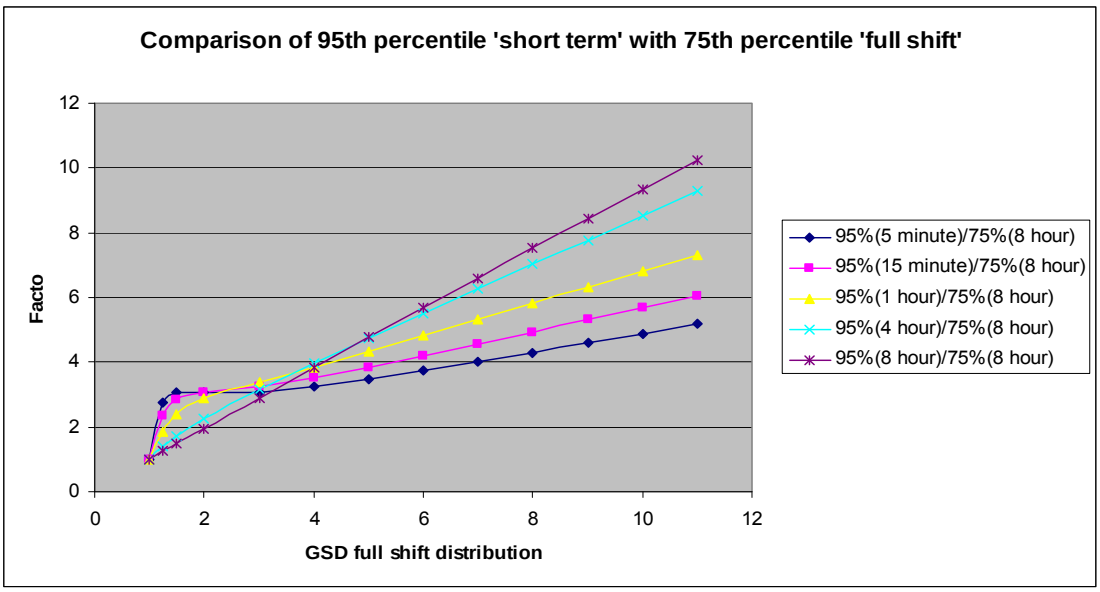


Figure R.14-1 Ratios between 95th percentiles of different averaging times and 75th percentiles of full shift values, relative to the GSD of the full shift values

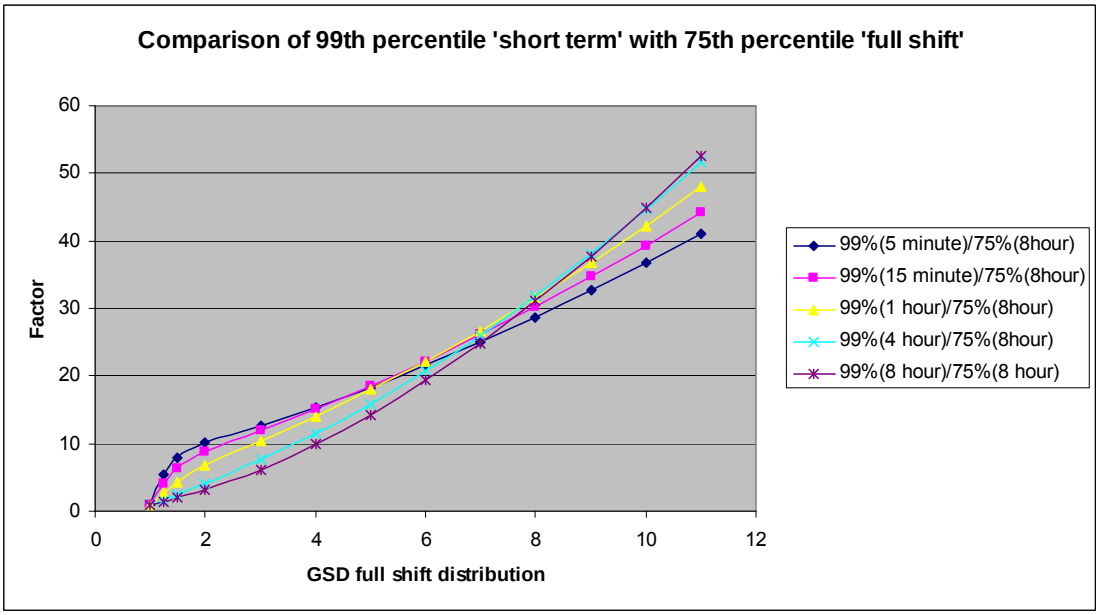


Figure R. 14-2 Ratios between 99th percentiles of different averaging times and 75th percentiles of full shift values, relative to the GSD of the full shift values

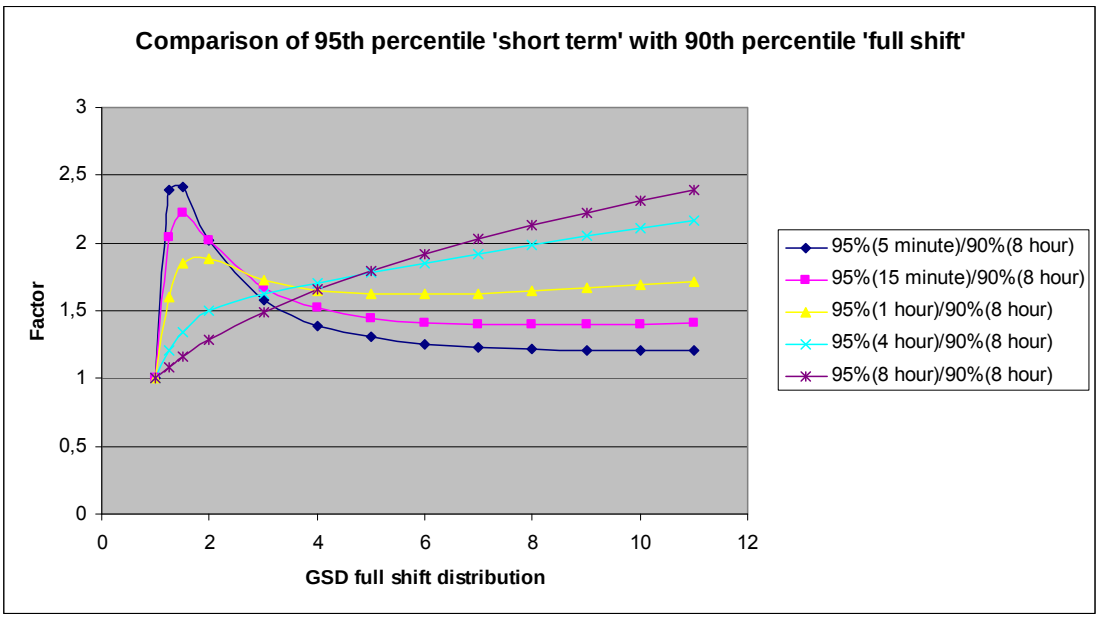


Figure R.14-3 Ratios between 95th percentiles of different averaging times and 90th percentiles of full shift values, relative to the GSD of the full shift values

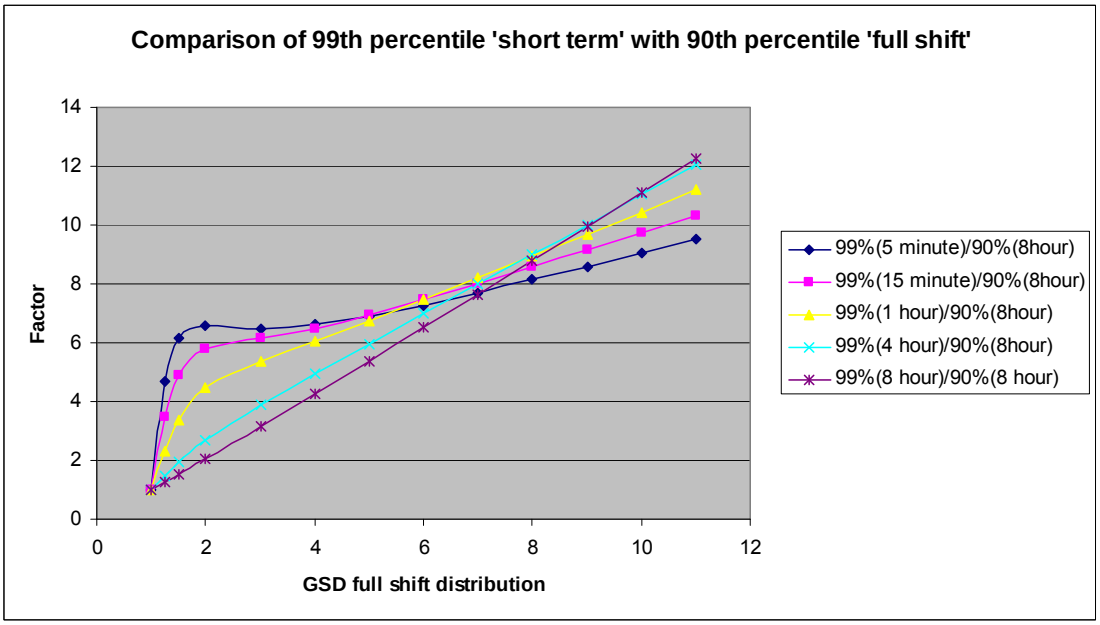


Figure R.14-4 Ratios between 99th percentiles of different averaging times and 90th percentiles of full shift values, relative to the GSD of the full shift values

Table R.14-17 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; use in that case 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) for the short term exposure period specifically and use those estimates directly as an estimator for peak exposure.

Table R.14-17 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.	Estimator 99th perc.	Estimator 95th perc.	Estimator 99th perc.	Estimator 95th perc.	Estimator 99th perc.	Estimator 95th perc.	Estimator 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

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

(Note: The Control Guidance Sheets at the website of COSHH Essentials 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 the 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			

		Amount of solids used			Amount of liquids used		
Unit operation	**Sheet title**	**Small**	**Medium**	**Large**	**Small**	**Medium**	**Large**
	Drum filling					212	
	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			

		Amount of solids used			Amount of liquids used		
Unit operation	**Sheet title**	**Small**	**Medium**	**Large**	**Small**	**Medium**	**Large**
	Sack emptying		304				
	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.

Weighing solids

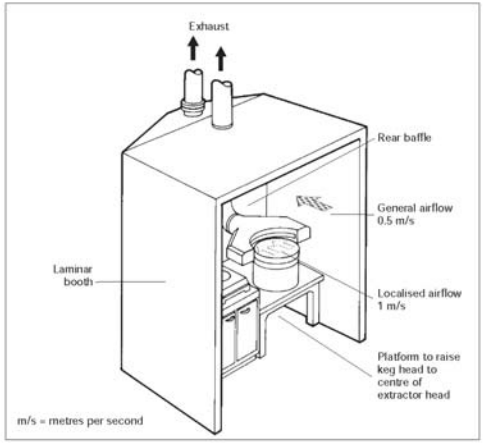
Engineering control 214

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.



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.**

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