# Guidance on information requirements and chemical safety assessment

## Chapter R.15: Consumer exposure estimation


**November 2009**
**(version 2 Rev.:2.0)**

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 1.1 | Footnotes added | July 2008 |
| Version 2 | The information on exposure models in Part D of IR&CSA has been integrated into Chapter 15.4. | November 2009 |
| Version 2 | The Chapter R.15.4 on the ECETOC TRA consumer tool for exposure estimation at Tier 1 has undergone a major revision and updating, with the inclusion of the new version of ECETOC TRA consumer model. | November 2009 |
| Version 2 | The order of chapters on i) the agreed standard algorithms for calculation of consumer exposure (presently R.15.3) and ii) on the ECETOC TRA consumer tool for exposure estimation at tier 1 (R.15.4) has been switched to a reversed order. | November 2009 |
| Version 2 | All presentations on higher tiers have been moved into one chapter R.15.6 and an additional Appendix R.15-4 | November 2009 |
| Version 2 | A new chapter R.15.6 on risk characterisation has been introduced, and all relevant texts from other parts have been moved there. | November 2009 |
| Version 2 | The introduction has been updated | November 2009 |
| Version 2 | The chapter on RMMs (earlier R.15.3.2.1) has been shortened, moved to Chapter R.15.2.7 and duplicate information with R.13 has been deleted. | November 2009 |
| Version 2 | Appendix R.15-1 on consumer preparation and article categories that can be assessed with the ECETOC TRA has been introduced | November 2009 |
| Version 2 | Text on JRC GExFRAME model and EIS-Chemrisks-toolbox in Chapter R.15.5.3 and Appendix R.15.3, including Table R.15-7, has been updated. | November 2009 |
| Version 2 | The default units for the algorithms in R.15.3 have been updated to be consistent with the other guidance (Chapter R.8) and modelling tools | November 2009 |

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| Version 2 | Minor technical and language corrections | November 2009 |

**Guidance for implementing the updates**

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

A registrant having already finalised the consumer exposure estimation based on Chapter R.15 as published in May 2008 may wish to take the following advice into account:

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

  If both questions can be answered with "no", it is unlikely that the adaptation of the already existing Chemical Safety Report to this guidance update is of high priority.

**Convention for citing the REACH regulation**

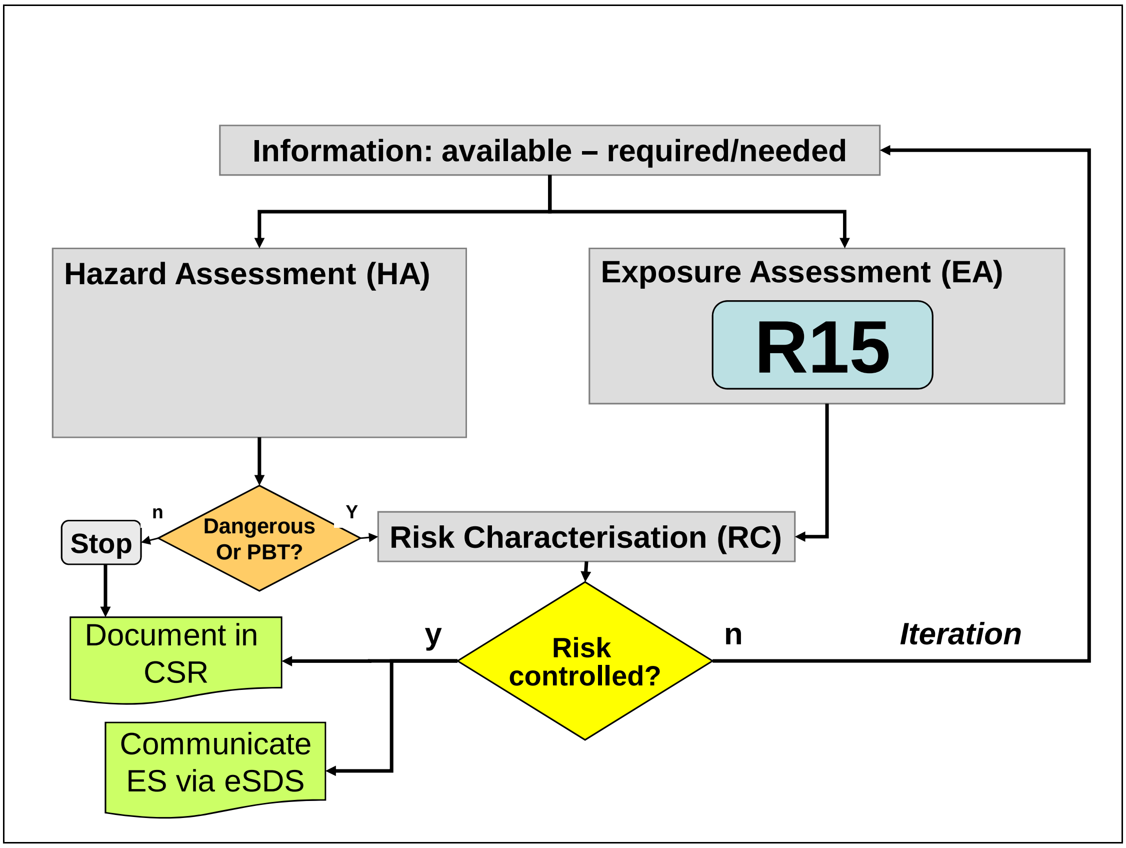
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

**Table of Terms and Abbreviations**

See Chapter R.20

## Pathfinder

The figure below indicates the location of Chapter R.15 within the risk assessment process.



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# R.15 CONSUMER EXPOSURE ESTIMATION

## R.15.1 Introduction

### R.15.1.1 Aim

The aim of this chapter is to describe an efficient, step-wise and iterative procedure for the estimation of consumer exposure to substances on their own, in preparations or in articles. Substances on their own or in preparations that are used by consumers are called consumer products in line with Chapter R.12.

This chapter provides advice on how to assess consumer exposure to chemicals. It consists of the following sections:

- Workflow for consumer exposure assessment (Section R.15.1.2)
- General considerations related to assessment of consumer exposure (Section R.15.2)
- Calculation of consumer exposure at Tier 1 level (Section R.15.3)
- Tools for supporting exposure scenario building at Tier 1 level (Section R.15.4 and Section R.15.5),
- Higher tier models and measured data (Section R.15.6),
- Risk characterisation (Section R.15.7),
- Overview on information sources and available tools (Section R.15.6 and Appendices R.15-3, R.15-4 and R.15-5

Exposure estimation is carried out for the conditions of consumer uses of substances as defined in the relevant exposure scenarios (see Guidance D). The development of exposure scenarios is an iterative process, thus exposure estimation may be needed at different stages of the development of an exposure scenario. Guidance on exposure scenario development for consumers is provided in Guidance D. Guidance on risk management measures relevant for consumer uses is contained in Chapter R.13. Chapter R.12 provides guidance on how to describe consumer uses of substances based on a standardised use descriptor system.

### R.15.1.2 Workflow for consumer exposure estimation

The workflow for consumer exposure estimation is a part of the development of exposure scenarios. The workflow in Guidance D includes several steps where exposure estimation takes place. This chapter provides more detailed guidance to exposure estimation, including iterating and refining the exposure estimates.

Consumer exposure estimation can be performed by a tiered assessment, beginning with a screening estimation (Tier 1). If the result of the screening is that exposure is below the accepted thresholds (DNEL= derived no effect level or other threshold), then there is "no concern" and the risks of the product can be considered to be controlled. If this is not the case, the exposure estimation has to be refined in the iterations of the chemical safety assessment until the risk characterization shows that risks are sufficiently controlled. This can be done e.g. by improving the Tier 1 assumptions, using measured data, going to higher tier exposure estimation models or by introducing risk management measures.

Exposure assessment usually includes the following steps.

- Map the consumer uses of the substance and compile information on the conditions of uses (including operational conditions and risk management measures (RMMs))
- Choose the appropriate product category for a Tier 1 estimate where available (See Appendix R.15-1)
- Carry out a Tier 1 exposure estimation
- Document the assumptions and the advice in initial exposure scenario (ES)
- Invite feedback on initial ES from representative downstream users (DUs)
- If needed, refine the exposure scenario as appropriate and carry out a new Tier 1 exposure assessment and risk characterisation (in the boundaries of the Tier 1 tool).
- Conclude on final exposure scenario or
- Carry out further exposure assessment based on measured data on exposure or higher Tier modelling (if needed)

It is, however, also possible to skip the Tier 1 model, if more detailed information on the conditions of use is readily available to facilitate a more refined higher tier assessment, or where it is already known upfront that it will be impossible to demonstrate the control of risk at Tier 1 level.

## R.15.2 General exposure considerations related to consumers

The consumer, i.e. a member of the general public who may be of any age, either sex, and in any stage of health, may be exposed to a substance by using consumer products or articles. A *consumer product or article* is in general considered to be a product that can be purchased from retail outlets by members of the general public. Consumer exposure estimation deals with the final step of the supply chain. The formulator of the consumer product is the last downstream user, having the responsibility for the particular product under the overall conditions of use defined by the manufacturer. Considering consumer exposure is important because the possible means of controlling the exposure are very limited and cannot normally be monitored, or enforced beyond the point of sale of the products.

Consumer exposure estimation is often difficult due to limited data availability. It should normally address the consumer uses of a substance, a preparation or an article that contains the substance. The formulator of consumer products can use available information from his supply chain. This refers mainly to the information (e.g. concentrations of ingredients) which the formulator receives from his suppliers. The formulator has most of the knowledge related to the consumer uses of his products. Therefore, manufacturers/importers (M/I) of substances and formulators may have different levels of information about exposure resulting from consumer uses of products.

A M/I of substances may initially use a broad or general exposure scenario, and the consumer product manufacturer who formulates the substance into a preparation or an article will have specific information related to the formulation and end use of his product. By communication between M/I's and DUs the initial exposure assumptions that underpin the initial exposure scenario may be developed to become part of the final exposure scenario as described in Guidance D.

### R.15.2.1 Scope of the consumer exposure estimation

The estimation of consumer exposure deals with consumer products and articles that can be purchased from retail outlets by members of the general public. Examples of human exposures to substances arising from the use of consumer products and articles include:

- exposure to solvents from the use of glues/adhesives;
- exposure to textile finishing chemicals or dyes in clothes;

- exposure to substances released from articles e.g. from use of baby bottles in child care.

Additionally, for the purpose of this guidance, other exposures of the consumers are included under "consumer exposure" despite the fact that the exposure does not arise from the use of consumer products or articles, but as a result of being near where a substance is being used or has been used. These additional exposures capture any other human exposure, which are neither considered as occupational nor as indirect exposure via the environment. Examples include:

- exposure to substances at home after use of decorating or cleaning products by professionals;
- exposure to substances in indoor air (residential air: e.g. household, schools, nurseries) including the fraction adsorbed on dust particles arising from building materials;
- exposure to substances in public areas (e.g. swimming pools, recreational areas).

The registrant should consider to address combined risks from different uses of his substance in chapter 10 of the CSR. He is, however, not obliged to carry out a risk characterisation related to uses of the substance not covered in his own registration.

In REACH guidance indirect exposure of humans via the environment is defined as the exposure of humans via consumption of food and drinking water, inhalation of air and ingestion of soil which in turn are directly influenced by the releases of the substance into the environmental compartments air, water and soil. This is not included in consumer exposure assessment in REACH but should be reported in the 'man via the environment' section in the chemical safety report and is further detailed in Chapter R.16.

Exposure levels must be estimated for long-term (repeated or continuous) exposure, and in some cases also for acute exposure (single event, peak exposure), depending on the properties of the substance and the nature of the use, as indicated in the exposure scenario (see also Section R. 15.2.5).

The way in which consumers are exposed to substances can generally be characterised by

1. the different routes of exposure, separately or in combination
2. identifying the different phases of activity in handling the consumer product or article
3. acute vs. repeated exposure

### R.15.2.2 Reasonable worst-case situations

The consumer exposure estimation should normally address the intended uses of the products that contain the substances under investigation. However, since consumers may not accurately follow instructions for use of products, an estimation of other reasonably foreseeable uses should be made.

For example, consumers may over-dose (e.g. of dishwasher detergent in relation to the doses recommended on the product) or fail to take recommended actions that are designed to minimize the potential for contamination (e.g. they may leave containers open after having used the product which can give rise to potential inhalation exposure to substances). Consideration of deliberate abuse is not part of the exposure estimation process. However, the difference between 'other foreseeable uses' and abuse can in certain cases be small. In these situations the assessor should provide clear argumentation why a certain exposure situation is included or excluded in the estimation.

If a substance is used in a consumer product or article that has different types of application (e.g. brush painting and spraying), different exposure scenario options exist:

1) Exposure scenarios can be developed for each use if the operational conditions and risk management measures are different for each use.

2) Alternatively, the exposure estimation for the two different consumer uses can be used to establish the highest exposure, and use this as the worst-case situation to be covered in the exposure scenario. A pre-requisite for combining uses is that the recommended operational conditions and RMMs can ensure control of risks for all these uses.

3) Exposure due to the use of a consumer product or article can occur via different pathways, e.g. both via inhalation and dermal contact. In such cases, combined exposure is calculated to estimate the total exposure (see also Section R.15.2.6).

4) If the same substance (for a single registration) occurs in different consumer products or articles that could reasonably be expected to be used jointly and frequently by an average consumer, it is advised to also calculate the combined risk, in order to prevent underestimation of risk (see Section R.15.6).

Certain sub-populations may be exposed differently than others. If for instance exposure of young children is anticipated, their crawling behaviour and hand to mouth contact may bring them into contact with residues of products on the floor. In addition the children's small ratio of body size to surface area, compared to that of adults, may have a crucial effect on the exposure estimates. Therefore it has to be ensured that exposure scenarios chosen take into consideration exposure pathways for relevant consumer sub-populations, and the corresponding values for exposure determinants such as body weight and skin surface area should then be used in the estimation. Several tools and information sources are available for this (see Section R.15.6 and Appendices R.15-2, R.15-3 and R.15-4.

The identification of all possible consumer uses for the product is also very important. In addition to the every-day use of household detergents and car maintenance chemicals, many consumers also use various products meant for professional use, such as do-it-yourself products and construction materials, e.g. as a hobby or when building or renovating a home. Sometimes this type of consumer use resembles professional use. The M/I of do-it-yourself products and construction products sold at retailers should ascertain that also consumer use is assessed and safe consumer use can be assured. Environmental exposure assessment has to identify release scenarios from consumer use (see Guidance Chapter R.16).

When using any equations or computer models, particularly if default or "reasonable worst-case" values are used, it is essential to check the input parameters of Tier 1. For example, it might be reasonable to assume that 100% of a substance in a consumer product or article could be ingested by a child in a single event. If available information indicates that for instance, only 10% is ingested, the input parameters could be adjusted if more appropriate and justified. Refining the parameters may not be necessary if the judgement is already that consumer exposure is of "no concern". Also, care should be taken to avoid under-estimating exposure.

### R.15.2.3 Routes of exposure

In this chapter, the evaluation of exposure for consumers refers to external exposure. External exposure is characterised by the amount of a substance that can be absorbed after inhalation, dermal contact or oral intake. The aim of this evaluation is to generate information that can be compared to DNELs, which are also expressed as external exposure values. Consumer exposure estimation will need to consider three separate exposure routes:

- inhalation exposure

- dermal exposure
- oral exposure

Inhalation exposure

Inhalation exposure may occur in the case of substances reaching the breathing zone of consumers either during the actual use of the consumer product or article (e.g. as the result of vaporizing solutions or aerosol forming preparations) or as a result of volatilisation after the product has been used (e.g. evaporation of solvents from paints) or due to emissions from articles. Exposure by inhalation is expressed as the concentration of the substance in the breathing zone atmosphere, and is normally presented as an average concentration over a reference time period (e.g. per day). If exposure is of intermittent short duration there may also be interest in exposure over shorter periods (e.g. per event). The assessment can also be based on exposure during specific tasks, which may be carried out over varying time periods. Some consumer products are used as sprays in the form of aerosols. In this case the exposure to the substance is related to the droplets (e.g. particle size) which need to be considered specifically in a higher tier exposure model.

Inhalation exposure is expressed in terms of external exposure, i.e. $mg/m^3$.

Dermal exposure

Dermal exposure is an estimate of the amount of substance contacting the exposed surfaces of the skin. It is the sum of the exposure estimates for the various parts of the exposed body surface. Dermal exposure can occur from splashes on the skin, from direct hand or body contact with the consumer product or article, from deposition on exposed skin of particles or aerosols from an airborne substance or from skin contact with residues of the substance after product use, e.g. residues on clothing after laundering or dry cleaning. For heavy use of consumer products the substances penetrating the clothing may represent an important exposure situation. The amount and concentration of the substance, the area of skin exposed and the duration and frequency of exposure can influence the actual dermal exposure to a substance. Dermal exposure is expressed in terms of the amount of substance per unit surface area of the skin exposed ($mg/cm^2$) or as external dose (mg/kg body weight/day).

Oral exposure

Substances occurring in preparations or articles (see Chapter R.17) that can be ingested can cause oral exposure. A common example is the exposure from the use of household products. Oral exposure may also occur as a consequence of migration due to sucking, chewing or licking of toys, children's books or textiles. This is of particular relevance to children due to their hand to mouth and/or mouthing behaviour.

In some cases, occasional and foreseeable oral exposures to chemicals (e.g. detergents, glues, monomer residues and softeners in plastic and PVC-products) may need to be considered. A specific example of oral exposure is the uptake of dust and soil by children, provided that the loading of soil with substances is related to the use of consumer products or articles, especially due to releases of substances from articles e.g. textiles, or building materials. The exposure to products and chemicals that are hardly ever accessible to children should not be considered.

In case of risk of serious accidents caused by strong acids and alkaline chemicals or strong oxidants and other chemicals of high acute toxicity, this could be described in the risk assessment report as part of the instructions for dealing with human health hazards due to physico-chemical properties

(Chapter R.9). This statement is also relevant for dermal and inhalation exposure – e.g. to aerosol-based oven cleaners.

Migration characteristics of the substance in the matrix, solubility and amounts typically used are important determinants to be considered. These parameters, together with concentration and contact parameters, are used to quantify the respective exposures.

Oral exposure is expressed as the amount of substance ingested per kg body weight, and is normally presented as an average daily external dose (mg/ kg body weight/day).

Other routes of exposure

Besides the three major routes of exposure mentioned above, in special cases other routes of exposure must be considered, e.g. eyes (splashing) or in rare cases, intradermal routes. Intradermal exposure occurs when the integrity of the skin is disrupted by the use of consumer products or articles (e.g. by earrings or piercings). In these cases, the exposure is expressed as the total amount of the migrating substance and normally presented as an average daily dose.

### R.15.2.4 Phases of activity, including post-application

Consumer exposure can be characterised by looking at the different phases of activity in which the products are actually used. There are up to four phases of activity that are relevant to consumer exposure:

1. preparatory activity, which includes tasks like handling and dilution of concentrates solid or liquid;
2. application of product by the consumer user, including handling of articles during their service life;
3. post-use or post-application leading to exposure of the user (e.g. exposure to paints, cleaners etc. after use). It is possible that due to chemical reaction the exposure at this stage may be due to the substance in a different physical state, or exposure to a different substance, e.g. reaction products of the substance.
4. removal/cleaning leading to exposure of the user. This includes activities such as emptying and cleaning equipment, stripping coatings, etc.

Each phase of activity may require separate exposure estimation, given that the first reflects exposure to a concentrate, the second to a diluted solution, the third to a vapour or semi-dry residue and the fourth to "waste material" and different individuals may carry out the tasks. In addition to this, secondary exposure may occur at any stage to people that are not engaged in the activities, but happen to be exposed as well ('bystanders'). In practice however, the resulting exposure scenario for the different products should include some or all of these phases. The exposure scenario could focus on the phase with the highest risk associated with it, provided that the recommended operational conditions or risk management measures also are relevant and practicable for the other phases of activity.

### R.15.2.5 Acute versus chronic exposure

There is a large variety of consumer products and articles, exposure to which both during and after application should be taken into account. Due to the wide variety of exposure situations, exposure duration to substances in products can vary from very short events (seconds) to a maximum of 24h per day, every day a year. This should be addressed in the consumer exposure estimation in order to match the relevant exposure duration and frequency with the corresponding DNELs.

Consumer exposure can be due to single/rare use or repeated/regular uses of substances. A single use of a consumer product or article can lead to short-term exposure, e.g. the use of a spray product, where a peak exposure of a relatively short duration is expected. In some cases it can also lead to long-term exposure if the substance is released from the product or article over a longer time period after use (e.g. slow evaporation of substances from a new carpet). Thus, depending on the type of substance, the consumer product or article type and properties, and the use frequency and duration, exposure can be characterised as either a single, short-term (minutes to few hours) exposure or chronic exposure (either intermittent or continuous). However, in practice, daily, weekly and monthly consumer exposures can be considered as repeated exposures and assessed against a chronic DNEL. This is due to the following considerations:

- It would require substantial data about consumer behaviour to justify that the vast majority of consumers (say 90%) use a product so rarely and for such short time that assessment against an acute DNEL only would be justified.
- The establishment of an acute DNEL is cumbersome and resource intensive. Usually it can be assumed that effects occurring after single short term exposure are prevented if the long-term DNEL is not exceeded (Chapter R.8).

It is to be noted that for products used infrequently, use frequency should not be used to average out exposure over a longer time period. In the first instance, exposure should be calculated for the actual duration of an event (event exposure), and then expressed as that concentration per day.

If the derived risk characterisation ratio (RCR) is lower than 1, the conclusion of the assessment is that there is no relevant risk even from the acute exposure. If the derived RCR is above 1, the assessment may be refined by using available data on event exposure, frequency, duration of exposure and other information to refine the exposure $estimate_e$. Only in situation where a substance is classified for its acute systemic toxicity, the derivation of an acute DNEL and the assessment of peak exposure would be required (see Chapter R.8).

**Example R.15-1 Generic exposure assessment for a solvent**

**Generic exposure assessment for a solvent in multipurpose cleaner**

A solvent (vapour pressure 2000 Pa; chronic DNEL 1200 mg/m$^3$; no classification for acute systemic toxicity) is contained in a cleaner at 50%. 0.25 kg of product is assumed to be used for cleaning work in a 20 m$^3$ room for about 0.3 hours.

Based on the consumer TRA tool, an event exposure of 6250 mg/m$^3$ is calculated. Compared to the chronic DNEL the RCR is about 5.

In order to refine the assessment one would not assess the exposure of 0.3 hours against an acute DNEL because: The acute DNEL is not available, and on top of that, a registrant would be hardly able to exclude that the same person cleans a series of rooms at the same or the following days. Thus other refinement options would be explored:

- limit the concentration in the product to 10% and/or
- assume a minimal air exchange in the room of 0.6 per hour and/or
- make assumptions on the actual exposure time over a day and calculate a time-weighted average exposure over one day. Assume for example 10 cleaning events per day, each 0.3 hours. Thus the total exposure time over the day may be a bit more than 3 hours. Please note: Different than for workers, data on time dependent exposure over the day is not always available for consumer situations, and thus this refinement option may be of limited applicability.

### R.15.2.6 Combined uptake

If a consumer is exposed to a substance in a particular consumer product or article via different routes, the contribution of each route to the total risk due to exposure should be added up. Normally the summation is done for each time scale separately (acute and long-term). The risk characterisation ratios for the different routes will be combined and evaluated to identify the most appropriate methods to control of risks.

### R.15.2.7 Compilation of information on operational conditions and risk management

General information on the use of a consumer product or article is needed to identify the relevant exposure pathways. Internal sales and marketing knowledge is expected to be the starting point for industry. Information gathering can be expanded to public databases and exposure factors collections.

Direct exposure from product use will be the main source of consumer exposure to a chemical present in that product. Characterisation of the direct consumer exposure requires knowledge of the nature of the used products and of the circumstances of their intended and reasonably foreseeable use. Consumer exposure is related to the amount of substances in consumer products or articles. Therefore, the amount of the products used per event, the quantity of chemical in the product and the frequency and duration of the event are essential information needed to estimate consumer exposure.

Release and subsequent exposure also takes place from articles or reacted/dried preparations. Such emissions may be driven by water or saliva contact, skin contact, elevated temperature (e.g. car interior), mechanical abrasion or by slow emission from the article matrix over service life (see Chapter R.17).

The exposure routes are related to the type of use and to substance properties. For example, inhalation may play a role for volatile substances but also for dust-forming conditions of use or conditions promoting mobility of a substance as such, in preparation or article. Low volatile substances can be released by mechanical abrasion (rubbing off), via leaching (e.g. during mouthing) or by migration (e.g. due to elevated temperature or interaction between substance and polymer-matrix) with subsequent release. The Tier 1 calculations for the different exposure routes are given in Section R.15.3.

Effective risk management measures for consumers are usually product-integrated measures (see Chapter R.13). For quantitative exposure estimation only those RMMs which can be controlled by the manufacturer of the product should be applied. This means that RMMs may be implemented by changing operational conditions or product composition, e.g., maximum concentration used in the product, change of the product form (pellets or granules instead of powder) or maximum amount of product used (package size).

The use of consumer instructions as RMMs cannot be expected to be highly effective, unless consumer behavioural data provide evidence that a sufficient degree of compliance can be assumed. The adherence to instructions is fundamentally different for consumers than in occupational settings where the employer has the duty to assure good operational conditions and use of RMMs. Consumer RMMs based on instructions should be introduced only when the use of such RMMs can be shown to effective and well adhered to by consumers.

There are limited circumstances for consideration of personal protective equipment (PPE) in consumer exposure, because people will not necessarily use PPE even though recommended by the manufacturer. Even when PPE is provided with the product (e.g., gloves with a hair dye), it cannot be ensured that consumers will use it. The exposure estimation needs to consider the reasonable worst-case situation which indicates no use of gloves or other PPE. As an element of good practice and personal hygiene, the advice to use household gloves or other skin protection should be part of consumer instructions (e.g. for products that are irritating/corrosive to the skin, such as strongly acidic, alkaline or oxidising household detergents). Further information on consumer RMMs can be found in Chapter R.13 and the RMM library (available via http://www.cefic.org).

## R.15.3 Calculation of exposure

This section details the Tier 1 equations for consumer exposure estimation. The assessor may start the assessment by using Tier 1 tools that implement the algorithms presented in this section. These tools are discussed in Section R.15.4 (Ecetoc TRA) and Section R.15.5 (ConsExpo Tier 1). Tier 1 tools are easy to use because they require information on very few parameters and apply conservative default values to them, thus limiting the amount of work needed for a first assessment. Alternatively, the assessor can directly use the algorithms of Section R.15.3, and if needed, change the default values of the relevant parameters.[2] At first, release and subsequent removal of the chemical are treated by the worst-case assumptions that the release of substances is instantaneous and that there is no removal. This may suffice for simple screening purposes. These assumptions can be overridden if better information is available. Apart from the two tools mentioned above, various other tools are available (see Appendix R.15.4) or may become available in near future. It is

[2] The assessor should pay attention to the importance of correct units in the calculations when using the algorithms.

foreseen that all exposure assessment tools shall be further developed according to the needs detected in REACH exposure assessments.

Consumer exposure estimation will need to consider three exposure routes: inhalation, dermal and oral routes, each exposure calculated separately. An exposure scenario can be derived using a tiered approach to exposure estimation. Initially a first Tier exposure estimate can be used to derive a "worst case", but not unrealistic, approach. Subsequent higher tier estimates can be used to further characterise the exposure.

**Inhalation**: Tier 1 assessment assumes that all substance is released as a gas, vapour or airborne particulate into a standard room. This may be due to direct release or by evaporation from a liquid or a solid matrix (See below Section R.15.3.1).

**Dermal,** two options:

- A: The substance is contained in a preparation. This option is applicable when, for example, hands are put into a solution containing the substance under evaluation, or splashes occur (painting) (Section R.15.3.2.1).
- B: Substance migrating from an article; applicable, for example, when residual dyes in clothing are in contact with skin and migrate from the clothing (Section R.15.3.2.2).

**Oral,** two options:

- A: Substance in a product unintentionally swallowed during normal use (Section R.15.3.3).
- B: Substance migrating from an article; applicable for example when a substance migrates from a pen, cutlery or textile (Chapter R.17)

### R.15.3.1 Inhalation exposure

A substance may be released into a room as a gas, vapour or airborne particulate (e.g. a carrier/solvent in a cosmetic formulation, a powder detergent, dust), or by evaporation from liquid or solid matrices. In the last case, the Equation R.15-1 represents a worst-case situation by assuming that the substance is directly available as a gas or vapour. The equation applies to both volatile substances and airborne particulates. For inhalation exposure, the concentration of the substance in the room air (e.g. $mg/m^3$) must be estimated. The event duration is assumed to be 24 hours in the worst case. For a Tier 1 evaluation, it is assumed that 100% of the substance in the consumer product[3] will be released at once into the room and there is no ventilation. The two essential parameters used are:

- Amount of product used
- Fraction of substance in the product (concentration)

The concentration in air after using an amount $Q_{prod}$ of the product becomes:

[3] This assumption may need to be modified for identifying a reasonable worst case for substances in articles.

$$C_{inh} = \frac{Q_{prod} \cdot Fc_{prod}}{V_{room}} .1000 \qquad \textbf{(Equation R.15-1)}$$

When the inhalable and/or respirable fraction is known, it should be taken into account. The non-respirable fraction can be swallowed and oral exposure may also need to be considered (see Equation R.15-10 and Equation R.15-11, below). For the purpose of calculating overall systemic exposure via different exposure pathways, see Section R.15.2.6.

The air concentration $C_{inh}$ results in an inhalatory dose $D_{inh}$ of:

$$D_{inh} = \frac{F_{resp} \cdot C_{inh} \cdot IH_{air} \cdot T_{contact}}{BW} \cdot n \qquad \textbf{(Equation R.15-2)}$$

**Table R.15-1 Explanation of symbols for inhalation exposure**

| Input parameter | Description | unit |
|---|---|---|
| $Q_{prod}$ | Amount of product used | [g] |
| $Fc_{prod}$ | Weight fraction of substance in product | $[g \cdot g_{prod}^{-1}]$ |
| $V_{room}$ | Room size (default 20 $m^3$) | $[m^3]$ |
| $F_{resp}$ | Respirable fraction of inhaled substance (default 1) | [-] |
| $IH_{air}$ | Ventilation rate of person | $[m^3 \cdot d^{-1}]$ |
| $T_{contact}$ | Duration of contact per event (default 1 day) | [d] |
| BW | Body weight | [kg] |
| n | Mean number of events per day | $[d^{-1}]$ |
| **Output parameter** | **Description** | **Unit** |
| $C_{inh}$ | Concentration of substance in air of room | $[mg \cdot m^{-3}]$ |
| $D_{inh}$ | Inhalatory dose (intake) of substance per day and body weight | $[mg \cdot kg_{bw}^{-1} \cdot d^{-1}]$ |

It should be noted that for Tier 1 assessment for short-term local exposure, the value for $V_{room}$ could be reduced (e.g. to 2 $m^3$) to represent the volume of air immediately surrounding the user ('breathing zone'). If this is not sufficient, higher tier models may be more appropriate. Inhalation exposure can occur to a substance that is released relatively slowly from a solid or liquid matrix (e.g. solvent in paint, plasticizer or monomer in a polymer, fragrance in furniture polish). In these cases, a simple Tier 1 screening model will usually overestimate exposure. Improved estimation models are further described in Section R.15.6.

The calculated external exposure will usually be compared to a DNEL long-term (leading to $D_{inh}$) or, in cases of peak exposure, to a DNEL acute (leading to $C_{inh}$, see Guidance B. and Chapter R.8 for information on calculating and choosing the relevant DNEL).

### R.15.3.2 Dermal exposure

Dermal exposure in case of local effects is expressed as mg/cm$^2$ skin, calculated based on deposited amount per cm$^2$ times the actually exposed body area. This is called the dermal load. Dermal exposure in case of systemic effects is expressed as external dose in mg per kg body weight per day (see Chapter R.8).

#### R.15.3.2.1 Dermal scenario A: Instant application of a substance contained in a preparation

The instant application model assumes that all of the substance in the product is directly applied to the skin (e.g. a drop of liquid soap used to wash the hands). The model is used as a first Tier worst case approach or if details on how the skin is exposed to the compound are not known. If more precise information is available, the amount of product can be changed to reflect the actual use. The exposure expressed as dermal load $L_{der}$ is calculated as the amount of product per surface area of skin or as external dose in mg/kg of bodyweight. The essential parameters used for this model are:

- Weight fraction compound: the fraction of the compound in the total product
- Amount of product: the amount of total product applied to the skin
- The surface area of the exposed skin

The dermal load is calculated as

$$L_{der} = \frac{Q_{prod} \cdot Fc_{prod}}{A_{skin}} \mathbf{.\ 1000} \qquad \textbf{(Equation R.15-3)}$$

and the external dose $D_{der}$ as

$$D_{der} = \frac{Q_{prod} \cdot FC_{prod} \cdot n}{BW} \mathbf{.\ 1000} \qquad \textbf{(Equation R.15-4)}$$

In cases where the substance is contained in a liquid into which certain parts of the body are dipped, the equation is not based on the mass of the substance applied to a certain area of skin, but on the concentration of the substance in the preparation that is in contact with the skin. First, the concentration $C_{der}$ of a substance in contact with skin is calculated. Depending on how the parameters are provided, three analogous calculations are used:

$$C_{der} = = \frac{C_{prod} \cdot 1000}{D} = \frac{RHO_{prod} \cdot Fc_{prod} \cdot 1000}{D} = \frac{Q_{prod} \cdot Fc_{prod} \cdot 1000}{V_{prod} \cdot D} \qquad \textbf{(Equation R.15-5)}$$

The total dermal load $L_{der}$ is then calculated by

$$L_{der} = C_{der} \cdot TH_{der} \qquad \textbf{(Equation R.15-6)}$$

The dermal dose is then derived as:

$$D_{der} = \frac{L_{der} \cdot A_{skin} \cdot n}{BW} \qquad \textbf{(Equation R.15-7)}$$

**Table R.15-2 Explanation of symbols for dermal scenario A**

| Input | Description | Unit |
|---|---|---|
| $C_{prod}$ | Concentration of substance in product before dilution | $[g \cdot cm^{-3}]$ |
| D | Dilution factor (If not diluted, D =1) | [-] |
| $RHO_{prod}$ | Density of product before dilution | $[g \cdot cm^{-3}]]$ |
| $Q_{prod}$ | Amount of product used | [g] |
| $Fc_{prod}$ | Weight fraction of substance in product before dilution | [-] |
| $V_{prod}$ | Volume of product used before dilution | $[cm^3]$ |
| $V_{appl}$ | Volume of diluted product actually contacting the skin | $[cm^3]$ |
| $TH_{der}$ | Thickness of product layer on skin (default 0.01 cm) | [cm] |
| $A_{skin}$ | Surface area of the exposed skin | $[cm^2]$ |
| BW | Body weight | [kg] |
| n | Mean number of events per day | $[d^{-1}]$ |
| **Output** | **Description** | **Unit** |
| $C_{der}$ | Dermal concentration of substance on skin | $[mg \cdot cm^{-3}]$ |
| $L_{der}$ | Amount of substance on skin area per event | $[mg.cm^{-2}]$ |
| $D_{der}$ | Amount of substance (external dose) that can potentially be taken up (account later for actual dermal absorption) per body weight | $[mg \cdot kg_{bw}^{-1} \cdot d^{-1}]$ |
| **Further applications** | **Description (see the text below)** | |
| $V^*_{appl}$ | Volume of diluted product actually remaining on the skin | $[cm^3]$ |
| $Fc_{der}$ | Fraction of the applied product remaining on the skin | [-] |

The above dermal equations apply also to:

- a non-volatile substance in a medium used without further dilution. In this case the dilution factor ($D$) is set to 1;
- a non-volatile substance contained in an undiluted medium removed from the skin by, for example, wiping or rinsing and drying (e.g., liquid soap). Recalculate the $V^*_{appl}$ "real" volume of application based on volume of application ($V_{appl}$) as $V^*_{appl}=V_{appl} \cdot Fc_{der}$; where $Fc_{der}$ is the fraction of the product remaining on the skin;
- a non-volatile substance in a volatile medium. The concentration $C_{der}$ (Equation R.15-5) is only valid at the very beginning of exposure. However, this concentration can still be used to calculate $L_{der}$ (Equation R.15-8), because the substance is non-volatile.

**Example R.15-2 Calculating dermal exposure to a substance in a solution**

**The identified use is a waterborne "Washing and cleaning products"**

In this example, the undiluted cleaning product is a surfactant-water mixture, where the weight fraction of the surfactant ($Fc_{prod}$ in Equation R.15-5) is 0.1 (=10%). It is assumed that the density of the product can be set to 1 (RHO = 1 in Equation R.15-5) and thus the concentration of the substance in the undiluted product is 0.1 g/cm$^3$ or 100 g/L ($Cprod$ = 0.1 in Equation R.15-5.).

Exposure is calculated for the situation that the hands are dipped into the diluted product. The concentration of the substance after dilution (dilution factor D = 40) is 0.0025 g/cm$^3$. The dermal concentration of substance on skin ($C_{der}$) is 2.5 mg/cm3.

Equation R.15-6 is applied to derive the dermal load to skin ($L_{der}$) by multiplication $C_{der}$ with the thickness of layer ($TH_{der}$). The thickness of the layer in direct exchange with the skin is assumed to be 0.01 cm by default (see Table R.15-2).

$$L_{der} = C_{der} \cdot TH_{der} = 2{,}5 \text{ mg/cm}^3 * 0.01 \text{ cm} = 0.025 \text{ mg/cm}^2.$$

In Tier 1 scenario, default parameters leading to worst-case assessment are applied. Accordingly, the body surface areas of males is assumed, but the body weight of women (60 kg, Appendix R.15-5) is applied. Table R.15-13 in Appendix R.15-5 gives as the area of contact $A_{skin}$: hands (fronts and backs) for males 840 cm².

Using the Equation R.15-7, the external dermal dose (in mg per kg body weight can be calculated.

$$D_{der} = \frac{L_{der} \cdot A_{skin} \cdot n}{BW} = 0.025 \text{ mg/cm}^2 * 840 \text{ cm}^2 * 1/60 \text{ kg} = 0.35 \text{ mg/kg bw},$$

RMMs are not considered in the quantitative exposure estimation because consumer compliance to the advice 'wear gloves while cleaning' cannot be ascertained. However, it is considered good advice if this was added as a labelling instruction for consumer use. In Tier 1 assessments, exposure times are not taken into account.

### R.15.3.2.2 Dermal scenario B: a non-volatile substance migrating from an article

The exposure calculation will involve estimating the amount of substance which will migrate from the area of the article in contact with skin during the time of contact (for a screening assumption, consider 24 hrs). The essential parameters used for this model are:

- Weight fraction compound: the fraction of the compound in the total product
- Amount product: the amount of total product applied to the skin
- The surface area of the exposed skin
- The migration rate of the substance
- The contact time of the substance
- Skin contact factor (set at 1 for default), a factor that can be used to account for the fact that the product is only partially in contact with the skin [cm$^2$].

Examples of such potential exposure situations are skin contact with substances in textiles (see Krätke & Platzek, 2004 for details) or printing ink from a newspaper or magazine. For migrating substances, only a fraction of the total amount of substance on the skin is able to reach the skin. It should be noted that it should be checked whether the estimated daily uptake exceeds the theoretical maximum. This maximum can be derived from the amount of product used (g), the concentration of the substance (g.g$^{-1}$) in the product, and the use frequency (d$^{-1}$). Extractability in simulated body fluids for several classes of dyestuffs and different fabric types has been evaluated by ETAD (1983).

The dermal load is calculated as:

$$L_{der} = \frac{Q_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot F_{contact} \cdot T_{contact} \cdot 1000}{A_{skin}}$$ **(Equation R.15-8)**

In case a surface density $Sd_{prod}$ for an article is available (in mass per unit area), the equation reverts to:

$$L_{der} = SD_{prod} \cdot Fc_{prod} \cdot Fc_{migr} \cdot F_{contact} \cdot T_{contact}$$ **(Equation R.15-9)**

The external dermal dose in mg per kg of bodyweight is then calculated as (Equation R.15-7):

$$D_{der} = \frac{L_{der} \cdot A_{skin} \cdot n}{BW}$$

**Table R.15-3 Explanation of symbols for dermal scenario B**

| **Input** | **Description** | **Unit** |
|---|---|---|
| $Q_{prod}$ | Amount of product used | [g] |
| $Fc_{prod}$ | Weight fraction of substance in product | $[g \cdot g_{prod}^{-1}]$ |
| $Fc_{migr}$ | Rate (fraction) of substance migrating to skin per unit time | $[g \cdot g^{-1}.t^{-1}]$ |
| $F_{contact}$ | Fraction of contact area for skin, to account for the fact that the product is only partially in contact with the skin (default = 1) | $[cm^2.cm^{-2}]$ |
| $T_{contact}$ | Contact duration between article and skin | [d] |
| $SD_{prod}$ | Surface density (mass per unit area) | $[mg \cdot cm^{-2}]$ |
| $A_{skin}$ | Area of contact between product and skin | $[cm^2]$ |
| $C_{der}$ | Dermal concentration of substance on skin | $[mg \cdot cm^{-3}]$ |
| BW | Body weight | [kg] |
| n | Mean number of events per day | $[d^{-1}]$ |
| **Output** | **Description** | **Unit** |
| $L_{der}$ | Dermal load on the skin that is expected due to migration | $[mg.cm^{-2}]$ |
| $D_{der}$ | Dermal dose per day and body weight | $[mg \cdot kg_{bw}^{-1} \cdot d^{-1}]$ |

### R.15.3.3 Oral Exposure

Oral exposure is expressed as external dose (mg/kg bw). The parameters used are:

- Weight fraction compound: the fraction of the compound in the product
- Concentration in the product as swallowed (if diluted)
- Amount ingested: the amount of total product swallowed

### R.15.3.3.1 Unintentional swallowing of a substance in a product during normal use

The concentration in the product as swallowed is calculated from:

$$C_{oral} = = \frac{C_{prod} \cdot 1000}{D} = \frac{RHO_{prod} \cdot Fc_{prod} \cdot 1000}{D} = \frac{Q_{prod} \cdot Fc_{prod} \cdot 1000}{V_{prod} \cdot D} \quad \textbf{(Equation (R.15-10)}$$

and the oral dose is then given by:

$$D_{oral} = \frac{F_{oral} \cdot V_{appl} \cdot C_{oral} \cdot n \cdot 1000}{BW} = \frac{Q_{prod} \cdot Fc_{prod} \cdot n \cdot 1000}{BW} \qquad \textbf{(Equation R. 15-11)}$$

If an undiluted product is swallowed, $D = 1$.

**Table R.15-4 Explanation of symbols for oral scenario A**

| Input | Description | Unit |
|---|---|---|
| $C_{prod}$ | Concentration of substance in product before dilution | [$g \cdot cm^{-3}$] |
| D | Dilution factor | [-] |
| $RHO_{prod}$ | Density of product before dilution | [$g \cdot cm^{-3}$] |
| $Q_{prod}$ | Amount of product before dilution | [g] |
| $Fc_{prod}$ | Weight fraction of substance in product before dilution | [$g \cdot g_{prod}^{-1}$] |
| $V_{prod}$ | Volume of product before dilution | [$cm^3$] |
| $V_{appl}$ | Volume of diluted product per event in contact with mouth | [$cm^3$] |
| $F_{oral}$ | Fraction of $V_{appl}$ that is ingested (default = 1) | [-] |
| BW | Body weight | [kg] |
| n | Mean number of events per day | [$d^{-1}$] |
| **Output** | | |
| $C_{oral}$ | Concentration in ingested product | [$mg.m^{-3}$] |
| $D_{oral}$ | Intake per day and body weight | [$mg.kg_{bw}^{-1}.d^{-1}$] |

These equations may also be used to estimate exposures arising from ingestion of the non-respirable fraction of inhaled airborne particulates.

Some examples how to use the algorithms presented in Sections R.15.3.1-R.15.3.3 in consumer exposure estimation are found in reference databases (Appendix R.15-3), for example chemical exposure estimation of school children when using school bags, toy bags, erasers and pencil cases (covers assessment of several chemicals (Miljoministeriet 2007)).

### R.15.3.4 Exposure to non-volatile substances

Non volatile substances having low vapour pressure can be released from products via migration (e.g. softeners) or by mechanical abrasion (e.g. elements, pesticides, flame retardants). Because these substances can be found in house dust, house dust may present an important path of exposure of non-volatiles. In small children, exposure via house dust can account for about 50% of the total exposure (Wormuth, 2006). Therefore exposure via house dust may need to be considered when preparing a chemical safety assessment for REACH.

It is anticipated that non-volatiles occurring in any products used in private households may contribute to accumulation in house dust. House dust itself may lead to dermal exposure and in small children to oral exposure due to mouthing behaviour. A conservative estimate of 100 mg has been proposed for house dust intake for children (Oomen, 2008).

In Tier 1 assessments, tools like ECETOC TRA enable assessing exposure to non-volatile substances in house dust (Section R.15.4.3). For higher tiers, the concentration of the substance of concern can be evaluated or measured in house dust and multiplied with the intake value mentioned above. For example, if the concentration of a substance in house dust is 1 µg/g, then the intake of the substance would be 0.1 µg/day.

## R.15.4 The ECETOC TRA consumer tool for exposure estimation at Tier 1

### R.15.4.1 Development of the tool

The new ECETOC TRA Consumer tool is the result of a substantial revision of the previous version TR 93 (ECETOC, 2004). The revised TRA combines the conservatism of first Tier assessment tool with the expert knowledge documented in the ConsExpo fact sheets (see Bremmer et al., RIVM, http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp#Fact_sheets and Section R.15.4.5). It uses default values taken from the ConsExpo fact sheets (except for the cases when no such value is available) and is largely based on the Tier 1 algorithms documented in Section R.15.3 with the following exceptions:

- For the inhalation route the ECETOC algorithm includes a parameter for modifying the fraction of substance released to air for substances with a vapour pressure < 10 Pa in non-spray applications.
- For exposure from articles via the dermal route, the assumed thickness of layer in contact with skin is reduced from 0.01 cm (widely accepted default for preparations and used already in EU existing chemicals risk assessment procedures) to 0.001 cm in order to take account of the reduced mobility of substances in an article matrix. The figure 0.001 cm was chosen based on expert judgement, as no scientific data was available.

The new ECETOC TRA Consumer tool aims to balance the Tier 1 assumptions and the generic applicability to a wide range of product categories in order to deliver reasonably plausible outcomes. The transparency of the tool has been improved; for each product use category a rationale is available that justifies the basis of the default values and assumptions. The assumptions used for TRA might be revised in the future, if data become available that justify such a revision.

### R.15.4.2 Consumer Product and Article Categories

The core concept of the TRA tool is to provide a setting of defaults for 46 specific product and article types relevant for consumer use. The product and article types driving the exposure estimate in the TRA are referenced to the broader product and article categories in the use descriptor system as presented in Chapter R.12. In the initial assessment the TRA enables to derive worst case exposure estimates for broad product categories (so called sentinels) which contain more specific product subcategories. If it turns out that adequate control of risk cannot be demonstrated on this basis, an assessment of the more specific product type can be launched. More than one sentinel product/article and/or product subcategory can be evaluated simultaneously, but the tool will not aggregate the exposure estimates. The product/article categories and subcategories for which a TRA exposure estimate can be derived are listed in Appendix R.15-1. This list does not at present include all types of consumer products and articles. A registrant under REACH cannot rely on this list as giving the complete overview on which consumer uses of the substance he potentially has to assess. If a category of interest is not addressed by the TRA, then the registrant could check whether his products and use conditions can be approximated by some TRA categories, and if so make use of the TRA with appropriate justification of any deviations and adaptations. The registrant could also consider assessing the exposure by Tier 1 algorithm calculations (Section R.15.3) or by Tier 2 tools.

### R.15.4.3 Algorithms

One algorithm per exposure route (dermal, oral, inhalation), each consistent with equations presented in Section R.15.3 is used to calculate the exposure for all consumer product and article categories. For the sentinel product/article, the exposure estimates for each route correspond to the highest exposure estimate of the individual product/article subcategories within the sentinel. The presentation of the algorithms follows the same terminology and appearance as in ECETOC Report 107 and in the tool. In Appendix R.15-2 the compatibility of TRA and the algorithms presented in Section R.15.3 is shown for each route, to improve the transparency and consistency of the methods.

***For inhalation route:***

The TRA calculates the inhalation exposure as

- concentration in room air (mg/m3) over a day, resulting from one or more events of product/article application.

Or as

- dose (amount per kg bodyweight) inhaled over the duration of the event (depending on the product category 20 min to 8h).

**Concentration:**

| **Parameter:** | **P**roduct **I**ngredient (g/g) | **A**mount Product Used per Application (g/event) | **F**re**q**uency of Use (events / day) | **F**raction Released to Air (g/g) | **C**onversion Factor | Room **V**olume ($m^3$) | **Exposure Air concentration mg/m3** |
|---|---|---|---|---|---|---|---|
| **Algorithm:** | **(PI x** | **A x** | **FQ x** | **F x** | **1000)** | **/ V** | $C_{inh}$ |

**Dose:**

| **Para-meter:** | **P**roduct **I**ngred. (g/g) | **A**mount Product Used per Application (g/event) | **F**re**q**uency of Use (events / day) | **F**raction Released to Air (g/g) | **E**xposure **T**ime (hr) | **I**nhalation **R**ate ($m^3$/hr) | **C**onversion Factor | Room **V**olume ($m^3$) | **B**ody **W**eight (kg) | **Exposure Inhalatory dose mg/kg/day** |
|---|---|---|---|---|---|---|---|---|---|---|
| **Algo-rithm:** | **(PI x** | **A x** | **FQ x** | **F x** | **ET x** | **IR x** | **1000)** | **/ (V x** | **BW)** | $D_{inh}$ |

The substance transfer to air is assumed to take place instantaneously. The released substance distributes in the room volume equally, and ventilation or other factors potentially changing the concentration over time are not taken into account. For substances with a vapour pressure < 10 Pa in non-spray application, only a fraction of the substance in the products or article is assumed to be transferred to air (vapour pressure bands A to D, see table R.15-5).

**Table R.15-5 Vapour pressure bands**

| Vapor pressure of compound of interest | Release of compound of interest | Band |
|---|---|---|
| > 10 Pa | all compound | A |
| between 1 and 10 Pa | 10 % of the compound | B |
| between 0.1 and 1 Pa | 1 % of the compound | C |
| < 0.1 Pa | 0.1 % of the compound | D |

Any substance with a vapour pressure higher than 10 Pa is assigned a transfer to air factor of 1, the substance is considered to be completely released into air instantly.  For substances with low volatility only a fraction of it is assumed to be released into the air. However, for all spray products it is assumed that substances are released fully and instantly into the air.

Compounds with vapour pressures <$10^{-4}$ Pa are non-volatile. The value revealed by one of the inhalation scenarios of the TRA tool describes the release of non volatile compounds, such as flame retardants and plasticizers in house dust. It is assumed that 0.1 % of the compound evaporates immediately and is inhaled in the small room (without ventilation). Therefore this exposure covers not only the inhalation exposure, but also the dermal and oral exposure of compounds in house dust.

***For dermal route:***

| Parameter: | Product Ingredient (g/g) | Contact Area ($cm^2$) | Frequency of use (events / day) | Thickness of Layer (cm) | Density ($g/cm^3$) | Conversion Factor (mg/g) | Body Weight (kg) | Exposure Dermal dose (mg/kg/day) |
|---|---|---|---|---|---|---|---|---|
| Algorithm: | (PI x | CA x | FQ x | TL x | D x | 1000) | / BW | $D_{der}$ |

The algorithm for the calculation of the dermal dose does not take into account any duration factor and assumes 100% transfer of substance from the product or article contact layer (0.01 and 0.001 cm respectively) to the skin instantaneously.  The dermal absorption is set at 100 %.

The skin contact areas linked to product/article subcategories can be expressed in one of eight categories each characterized by a default surface area for adults and children (see Table R.15-13).

- 1 - fingertips
- 2 - inside (palms) of both hands / one hand
- 3 - hands
- 4 - hands and forearms
- 5 - upper part of the body
- 6 - lower part of the body
- 7 - whole body except feet, hands and head

- 8 - whole body

The user of the tool can select two parameters: the fraction of substance in the product (= product ingredient) or article and the skin contact area (if defaults are not suitable for the assessment).

**Example R.15-3 Calculating dermal exposure to a substance in a solution by TRA**

**The identified use "Washing and cleaning products" (The same example as Example R.15.2 in Section R.15.3.2.1)**

The concentration of the substance to be assessed for dermal exposure in the undiluted product is 5%. In the diluted product the concentration is 0.25% due to a 1:20 dilution with water. In Tier 1 scenario default parameters leading to worst-case assessment are applied. Accordingly, the body surface area of males, but the body weight of women (60 kg, Appendix R.15-5) are applied. Table- R.15.13 in Appendix R.15-5 gives as the area of contact $A_{skin}$: hands (fronts and backs) for males 840 cm². The layer thickness $TH_{der}$ is 0.01 cm (Section R.15.4.1).

By using the algorithm on previous page:

Dermal dose $\mathbf{D_{der}}$ **= (PI *CA * FQ* TL *D*1000) /BW**

=0,025*840 cm²*1*0,01 cm 1 g/cm$^3$*1000/60 kg = **0,35 mg/kg bw**

***For oral route:***

| Parameter: | Product Ingredient (g/g) | Volume of product swallowed (cm$^3$) | Frequency of use (events / day) | Density (g/cm3) | Conversion Factor (mg/g) | Body Weight (kg) | Exposure Oral dose (mg/kg/ day) |
|---|---|---|---|---|---|---|---|
| **Algorithm:** | **(PI x** | **V x** | **FQ x** | **D x** | **1000)** | **/ BW** | $D_{oral}$ |

REACH does not deal with accidents or assessment of consumer exposure to food, food-related, and pharmaceutical products. This limits the relevance of consumer oral exposure to situations where: i) substances as such or in preparations are unintentionally swallowed (for example. ingestion through hand-mouth contact) or ii) where articles are mouthed by small children.

For some product categories exposure due to hand mouth contact is calculated. The volume of product swallowed is related to the oral contact area **CA** (default area depending on the part of the hand in contact with mouth, see table of defaults in TRA) and the thickness of product layer **TL** on that part of the hand (default 0.01 cm). It is assumed that 100% of substance present on the hand is transferred and available for ingestion.

For some article categories exposure related mouthing is calculated in the TRA. The volume of product swallowed is calculated based on the article area in contact with the mouth **CA** (default 10 cm2) and the thickness of article layer **TL** assumed to be in contact during mouthing (default 0.01 or 0.001 cm). It is assumed that 100% of substance present in the contact layer is transferred and available for ingestion.

**V** (volume product swallowed) **= CA x TL**

Based on the substance amount swallowed during the mouthing or ingestion events during the day, a systemic exposure dose for a child is calculated.

The defaults for oral contact area and thickness layer (0,001 or 0,01 cm) are given in the defaults table of the TRA tool.

### R.15.4.4 Determinants of exposure

For all three algorithms the user of the TRA tool has to select a product/article category and subcategory. Volatility of the substance is needed for inhalation exposure assessment. The assessor may use the given defaults (presented in the defaults table of the tool) for the fraction of substance (product ingredient) in consumer product or article or he can choose to use his own values. In addition, the dermal contact surface area, the 'mouthed' surface area, and the amount of product used per application are parameters for which the user can overwrite the default values suggested by the tool.

### R.15.4.5 Default values

Default values associated with subcategories, such as amount of product used per application and exposure time, were obtained from the RIVM (The National Institute for Public Health and the Environment, Netherlands) fact sheets for specific products, in order to build consistency with ConsExpo. For certain parameters such as frequency of use, suitably conservative assumptions were made. When product specific fact sheets were unavailable, values were derived using expert judgment. The supporting reference for the default values used to calculate exposure can be viewed for each subcategory in the 'defaults' table. Only potentially significant exposure routes are 'flagged' for exposure assessment. A qualitative justification of why a particular route is not relevant for a particular product is provided in the documentation of the tool.

In some cases one route is more dominant than others. Then only the most dominant route is described, for instance dermal exposure for greases, inhalation exposure for spray application and dermal for fertilizers. This is important to realize, especially for situations when the most dominant route can be excluded, e.g. due to product characteristics. Exposure for the other route should then still be considered. This means that it needs to be checked, whether the contribution of the second route gets significant if exposure is largely reduced for the primary route.

According to their potential exposure to consumers a use scenario has been defined for all the product and article subcategories. The used defaults are presented in the "defaults" table of the tool. The references for the defaults (RIVM reports, conservative expert estimates) are specified in the Appendix E of the ECETOC Technical report 107 (ECETOC 2009). Default values such as body weight and surface area were obtained from the RIVM general fact sheet (Bremmer et al., RIVM Report 320104002/2006).

### R.15.4.6 First refinements of TRA consumer exposure estimates

Like all Tier 1 assessments, the new TRA generates rather conservative exposure estimates. Simple reality checks can be applied to provide exposure estimations that are closer to plausible values.

The simplest refinement is to replace the defaults in the User Input sheet by more realistic values. These 'selectable' parameters are the fraction of substance in a consumer product or article, the contact area for the dermal and oral routes and the amount of product used per application for the inhalation route. The use of product subcategory will result in a lower exposure value for all scenarios except the ones upon which the sentinel product is based.

Some additional possibilities for refinement at expert level are described in Section R.15.6.1.

## R.15.5 ConsExpo lower tier models

The ConsExpo (version 4.1) computer tool (downloadable from www.consexpo.nl) is a well-known tool for consumer exposure assessment. It includes higher tier models (see Section R 15.6.2) but also the equations that are described in Section R.15.3. All equations are published in the ConsExpo manual (Delmaar et al., 2005). The associated database with default factors does not refer to the lower tier models, but merely to the higher tier models

In fact, ConsExpo contains a number of models for the various exposure routes. For each exposure route the complexity (tier) of the models can be selected. The following models are included:

***Inhalation:***

The instantaneous release model assumes direct evaporation. When the ventilation rate is set at 0, this will result in the tier 1 estimation as described in Section R.15.3 and is comparable to the ECETOC TRA.

***Dermal:***

The instant rate model describes a low tier estimate. This equation does not include the product layer thickness parameter that is included in Section R.15.3 and ECETOC TRA.

The program also includes the migration model described in Section R.15.3 and ECETOC TRA.

***Oral:***

The direct intake model describes a low tier estimate, and is comparable to the algorithm in Section R.15.3 and to the ECETOC TRA.

## R.15.6 Advanced refinements, higher tier models and measurements

More advanced refinement of Tier 1 exposure calculation and higher tier models may include for example the consideration of time dependent processes of migration and release of the substance from a matrix, the deposition (adsorption) to other matrices (e.g. dust) and its release (desorption) as well as the disappearance from the medium (e.g. by decrease of room air concentrations due to ventilation or degradation). These assessments should normally be conducted by expert assessors.

The higher tier consumer exposure estimation is using more sophisticated and detailed and more realistic parameters than Tier 1 tools. Therefore a detailed description of the scenario and reference to the models used for calculations, including all assumptions and results should be reported in the CSR.

### R.15.6.1 More advanced refinements for ECETOC TRA consumer tool

***General considerations to refine default parameters***

These refinements could be considered as a form of 'Tier 1.5' iteration of the exposure estimates made by the TRA tool. A number of such refinements are discussed in ECETOC report 107 (ECETOC 2009). They relate to possibilities for revising certain parameters if appropriate. These refinements on TRA consumer exposure should be conducted by expert assessors.

For each scenario, there are default parameters that can be readily modified and also a number of fixed defaults. When a user has a reason to alter these, he can choose to do so, providing justification. For locked defaults the user can apply a manual calculation.

Input of sector specific additional data on operational conditions such as duration of use or amount of product per use from Sector specific Tier 2 tools (SDA (The Soap and Detergent Association, 2005) and HERA (Human and Environmental Risk Assessments on ingredients of household cleaning products, 2005) may be used. These data can be entered into a TRA format to give a more realistic refined screening exposure estimate. Since some of the parameters (fraction released, conversion factor, body weight) are locked in ECETOC TRA tool, the user will need to perform manual calculations outside of the tool.

In several scenarios, using the most conservative assumptions (small room size and high use volume) result in combinations of input values that are mismatched. For example, for the lubricant scenario, while the amount of product used (5000 g) may be representative of lubrication of a larger motor, such a scenario would not take place in a default room of 20 $m^3$ but in a larger garage or outdoors. If such combination of conservative defaults occurs, the registrant is free to replace the values with more realistic assumption if he can provide a suitable justification.

***For inhalation route:***

*Use of saturated vapour concentration as a limit on exposure*

For non-aerosol products, instantaneous release of 100% of any substance with vapour pressure >= 10 Pa is assumed. This assumption can result in concentrations that exceed the upper bound saturated vapour concentration for many scenarios in the tool. The impact of this assumption on the estimated exposure increases linearly with exposure duration. The calculation of saturated vapour concentration as an upper bound can be applied to non-spray products. The algorithms and guidance how to use them are presented in ECETOC Technical report 107.

*Inclusion of air change rates*

Even in homes with closed doors and windows and no active ventilation a certain low level of air exchange occurs. Mean values for Air Changes per Hour (ACH) include 0.6 (RIVM General Fact Sheet, Bremmer et al. 2006) and 0.45 ACH (US EPA Exposure Factors Handbook 1997).

***Dermal***

*Use of dermal absorption*

In principle the dermal uptake of a compound can be estimated using either a fixed fraction uptake model or a skin permeation uptake model.

• The fixed fraction model is a simple model for which the only parameter required is the uptake fraction ("percentage absorbed via skin"). Experimental results are hardly available and therefore 100% absorption has to be assumed as default value.

• Skin permeation uptake values can be calculated using different algorithms, and the user of the application should have expert knowledge to choose the appropriate defaults and algorithms.

*Introduction of additional manual transfer factors*

Users can make simple modifications, such manual transfer factors, to make more realistic exposure estimates (SDA (2005) and HERA (Human and Environmental Risk Assessment 2005)).

***Checks on mass balance***

The TRA tool provides conservative assumptions for each exposure route which should be checked for mass-balance particularly when estimating multi-route exposures for a single product. For example, the inhalation route assumes 100% of product is released to air and the dermal routes assume that 100% of the product in contact with skin is absorbed via skin. The user may consider if, in application, "double-counting" occurs and should be adjusted for. In many consumer product and article uses it is possible to define the main exposure route, and the amount of substance through other exposure routes can be decreased. All the assumptions have to be documented.

*Checks with product purpose / lifetime*

For example, for the TRA subcategory 'fillers and putties', the default assumptions are that the weight fraction is 1 and 100% volatilizes for the inhalation exposure estimate; under these assumptions the product would be ineffective for the intended use.

*Reality check on exposure activity patterns*

The TRA tool assumes daily product use, but for many of the products typical frequency of use is much lower (1-5 times/year). Based on the knowledge of the use, modifications to worst-case assumptions related to exposure duration and frequency could be made, applying manual calculation (ECETOC Technical report 107, Table F-2). These considerations may be important e.g. when rather short duration (1 hour) exposures occurring 1-2 times/year are being compared with chronic systemic DNELs. Here again, documentation on the assumptions and justifications is important.

### R.15.6.2 ConsExpo

The ConsExpo (version 4.1) computer tool (downloadable from www.consexpo.nl) is a well-known higher Tier tool for expert consumer exposure assessment. All equations are published in the ConsExpo manual (Delmaar et al., 2005). An evaluation of the higher tier models showed that ConsExpo has a reasonable coverage of many other available higher tier models (Park et al., 2006). If parameters are specified as distributions, ConsExpo can perform a distributed (Monte Carlo) calculation. The program will draw a set of random numbers from the specified distributions (uniform, normal, lognormal, triangular) for distributed parameters and calculates the endpoint of choice with this set. For the non-distributed parameters the specified point value is taken. Exposure and dose distributions reflect stochastic parameters and these distributions can be depicted and percentiles can be quantified. The program can provide sensitivity analyses for each stochastic parameter, where mean exposures or doses as function of the value of a selected stochastic parameter are depicted and analysed. The ConsExpo model contains an associated database, which contains default parameters for a large number of consumer products and scenarios (higher tier, see www.consexpo.nl).

***Inhalation exposure***

The concentration of a chemical in the room air will depend on the amount of chemical present in the room, the room size, ventilation of the room air, vapour pressure of the compound and the rate at which the compound is released into the air. A refined estimation should consider time. Modelling exposure therefore requires data that describe the duration of use and the duration of primary and secondary exposure. For instance, 1 kg of paint may be used over a period of 2 hours, followed by secondary exposure of 10 hours, which must be considered by the model chosen for estimating this exposure. As a further additional variable, room ventilation has to be taken into account for inhalation exposure. Depending on the information available on physicochemical properties of the compound and the use of the product, different higher tier models are available in ConsExpo.

The constant rate model describes the release of a compound with a constant rate of release over a certain period of time. During this time, the compound is simultaneously removed from the air by ventilation of the room. In addition to the parameters used in the Tier 1 inhalation model, the constant rate model also uses the emission duration, i.e. the time during which the compound is released.

The evaporation model describes the release of the compound from the surface of the product by evaporation, and can be used if information on the application duration, the release area and the release rate of the compound from the product is available. The release rate is estimated from the temperature, the molecular weight, vapour pressure, and the mass transfer rate (the coefficient, which describes the transport conditions from the boundary layer immediately above the liquid surface).

Spray model describes the indoor inhalation exposure to slowly evaporating or non-volatile compounds in droplets that are released from a spray can. For volatile substances released from a spray can, the evaporation model should be used to calculate exposure to the volatiles. Inhalation is influenced by many factors such as the size of the droplets, the breathing pattern and human physiology. Only the droplets that penetrate to the alveolar region will reach the lung-blood barrier and give rise to inhalation exposure.
General exposure parameters needed for this model are spray duration, exposure duration, room volume, room height, ventilation rate and spray direction. The specific spray parameters are the mass generation rate, the airborne fraction, the weight fraction non-volatiles, the mass density of the total of non-volatile compounds, the weight fraction of the substance in the preparation, and the initial particle distribution.

***Dermal exposure***

For higher tier assessments, extractability of substances from articles e.g. textiles should be considered. For migrating substances, only the part of the total amount available to/in contact with the skin is able to penetrate the skin.

Constant Rate model. Similar to the Tier 1 'dermal scenario A' model, the constant rate model assumes that all compound in the product is directly applied to the skin. The model calculates the amount of product per surface area of skin or per kg of body weight over a period of time. Therefore, if a good estimate can be made of the time during which the compound is applied, this mode can be used instead of the instant application mode. Two additional parameters are required for this mode: the release duration and the rate at which the product is applied to the skin.

Rubbing Off model. This describes a secondary exposure situation in which a surface (table top, floor) is treated with a product and dermal exposure arises from contact with the treated surface. The additional parameters used in this model are the transfer coefficient (treated surface area in contact with skin/ time), the dislodgeable amount, the contact time and the rubbed surface.

Diffusion model. This describes the diffusion of substance into skin due to direct application of a product to the skin. After application, the compound diffuses through the product to the skin. The diffusion model can be used if the diffusion coefficient of the compound in the product is known or can be estimated. The model requires the following additional parameters: the diffusion coefficient, the layer thickness of the applied product and the exposure time.

The migration model. This describes the migration of a compound from a material to the skin when dermal contact with the material occurs. The migration is specified as a 'leachable fraction': the amount of substance that migrates to the skin per amount of product. Typically, this fraction has to be determined in extraction experiments with sweat simulant. This model can be used, for instance to estimate exposure to dyes leaching from clothing to the skin.

***Oral exposure***

A more refined oral exposure model takes into account that oral exposure can be:

Constant Rate model. This describes a scenario in which the compound is taken in over a certain period of time, e.g. to estimate (secondary) exposure originating from dermal exposure on the hands and subsequent hand-mouth contact. The additional parameters used in this model are ingestion rate and exposure time.

Oral Migration from Packaging Material. This secondary exposure model calculates the exposure to compounds from packaging material via food. The migration of the compound into the food is calculated from the concentration of the compound in the packaging material, the contact area of the packaging and the food and the initial migration rate. The oral exposure resulting from food consumption is subsequently calculated by assuming that the migrated compound is homogeneously distributed over the food and that the intake of the compound is therefore proportional to the fraction of packaged food consumed.

### R.15.6.3 Other tools

Several previous route-specific models and general consumer exposure models are now integrated in the US EPA E-Fast model (US EPA, 2007) (see Computer tools for estimation of consumer exposure, Appendix R.15-4).

The web-based GExFRAME system provided by the Joint Research Centre houses scientific data and high tier exposure models relevant to estimating exposures to chemical substances from consumer products, together with a means to calculate consumer exposure to chemical substances. The system: 1) can easily accommodate existing consumer exposure data and models, 2) can facilitate comparison of different exposure models applicable to specific scenarios with common inputs, and 3) allow efficient interaction with external data and reports. Access to the GExFRAME system is available via: http://gexframe.jrc.ec.europa.eu/Default.aspx. Access to the system will be made possible by following registration as an official user.

### R.15.6.4 Measurements

In general measured data are preferred over modelled data provided they are reliable and representative for the situation that needs to be assessed. For most consumer exposure scenarios, measurements of the actual exposure of consumers will not be available. However, it may be possible that for one or more of the parameters used in the estimations measurements are available and can be used to override the default values (see Appendix R.15-5 for room volumes, air exchange rates, migration rates, ad- and desorption as well as absorption rates). If needed, reasonable worst-case assumptions can be replaced by considering measured parameter values and their variability.

There may be measurements of external exposure (i.e. concentrations in the environment in which the contact takes place) as well as measurements of internal exposure (e.g. in blood or tissues). Non-volatile substances may accumulate in house dust. For such substances, release from consumer articles e.g. furniture, textiles, and building material may be monitored by measurements performed in house dust. The uptake is then calculated by multiplying the concentrations with dust uptake defaults. Monitoring data may be available e.g. on substances with a (potential) PBT or vPvB profile.

Biomonitoring or occupational exposure programmes may be valuable for consumer exposure estimations, although their number, representativeness and quality will often vary within wide ranges. Measured data from surrogate substances or analogues and surrogate scenarios (e.g. chamber measurements) may also be useful when estimating exposure levels. The measured data available should be evaluated by using expert judgement.

## R.15.7 Risk Characterisation

The Tier 1 exposure estimation and/or information from higher tier evaluations (if deemed necessary) can be used in the risk characterization (see Guidance E). A risk characterisation is required for each exposure scenario, differentiated according to routes of exposure and combined up-take by two or three routes (if relevant). An uncertainty analysis can help to indicate those exposure determinants with the largest influence on the risk (see Chapter R.19 on uncertainty analysis).

If a consumer is exposed to a substance via several consumer products or articles that are likely to be used in combination, the contribution of each product and the corresponding routes to the total risk should be summed. Normally the summation is done for each time scale separately (acute and long-term). The combined risk characterisation ratios for different products can be documented and evaluated under chapter 10 of the CSR. For more detail, see Guidance E on human risk characterisation.

Final exposure scenario

The outcome of the risk characterisation is used to decide whether safe use can be demonstrated or if further iterations are needed. Once the final iteration has shown sufficient control of risks for consumers, the exposure estimation, risk characterisation and uncertainty analysis can be finalised. The RMMs and operational conditions ensuring control of risk for consumers should be documented in final exposure scenarios.

If adequate control of risks is still not demonstrated several refinement options are still open. Further information can be gathered on hazard (including possible testing proposals), exposure or both, or RMM can be adapted to reduce exposure. If further iterations do not show control of risks even with higher tier exposure estimation models, it needs to be considered to use measured data, or to advice against the use. If certain consumer uses are not recommended due to health risks, this should be recorded in the CSR and eSDS.

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# APPENDICES TO CHAPTER R.15

## Appendix R.15-1 Consumer product and article categories

Guidance on information requirements and chemical safety assessment Chapter R.12 **Use descriptor system** provides pick-lists for the Product Categories (PCs) and Article Categories (ACs). Table R.15-6 lists those PCs and ACs which describe uses regulated by REACH and which are generally considered to potentially result in significant exposures to the consumers. These PCs and ACs with specific subcategories can be assessed by ECETOC TRA consumer tool. The tables were agreed on by ECHA consumer expert group comprised of representatives of ECHA, ECETOC, RIVM, BfR, INERIS and the Danish EPA during 2008-2009.

**Table R.15-6 Consumer products addressed in the consumer TRA**

| Descriptor | Product Subcategory |
|---|---|
| **PC1:Adhesives, sealants** | Glues, hobby use |
| | Glues DIY-use (carpet glue, tile glue, wood parquet glue) |
| | Glue from spray |
| | Sealants |
| **PC3:Air care products** | Air care, instant action (aerosol sprays) |
| | Air care, continuous action (solid & liquid) |
| **PC9a:Coatings, paints , thinners, removers** | Waterborne latex wall paint |
| | Solvent rich, high solid, water borne paint |
| | Aerosol spray can |
| | Removers (paint-, glue-, wall paper-, sealant-remover) |
| **PC9b:Fillers, putties, plasters, modelling clay** | Fillers and putty |
| | Plasters and floor equalizers |
| | Modelling clay |
| **PC9c:Finger paints** | Finger paints |
| **PC12:Fertilizers** | Lawn and garden preparations |
| **PC13:Fuels** | Liquids |
| **PC24: Lubricants, greases, release products** | Liquids |
| | Pastes |
| | Sprays |
| **PC31:Polishes and wax blends** | Polishes, wax / cream (floor, furniture, shoes) |
| | Polishes, spray (furniture, shoes) |
| **PC35:Washing and cleaning products (including solvent based products)** | Laundry and dish washing products |
| | Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners ) |
| | Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) |
| **AC5:Fabrics, textiles and** | Clothing (all kind of materials), towel |

| | |
|---|---|
| **apparel** | Bedding, mattress |
| | Toys (cuddly toy) |
| | Car seat, chair, flooring |
| **AC6: Leather articles** | Purse, wallet, covering steering wheel (car) |
| | Footwear (shoes, boots) |
| | Furniture (sofa) |
| **AC8:Paper articles** | Diapers |
| | Sanitary towels |
| | Tissues, paper towels, wet tissues, toilet paper |
| | Printed paper (papers, magazines, books) |
| **AC10:Rubber articles** | Rubber handles, tyres |
| | Flooring |
| | Footwear (shoes, boots) |
| | Rubber toys |
| **AC11:Wood articles** | Furniture (chair) |
| | Walls and flooring (also applicable to non-wood materials) |
| | Small toys (car, train) |
| | Toys, outdoor equipment |
| **AC13:Plastic articles** | Plastic, larger articles (plastic chair, PVC-flooring, lawn mower, PC) |
| | Toys (doll, car, animals, teething rings) |
| | Plastic, small articles (ball pen, mobile phone) |

## Appendix R.15-2 Compatibility of Tier 1 algorithms in Section R.15-3 and ECETOC TRA

### Inhalation exposure

**Table R. 15-7 Symbols for inhalation exposure (concentration) algorithms**

| **Input parameter TRA** | **Input parameter R.15.1** | **description** | **Unit** |
|---|---|---|---|
| $Cinh = \frac{PI \cdot A \cdot FQ \cdot F \cdot 1000}{V}$ | $C_{inh} = \frac{Q_{prod} \cdot Fc_{prod}}{V_{room}} . 1000$ | algorithm | |
| PI | $Fc_{prod}$ | Product ingredient | g/g product |
| A | $Q_{prod}$ | Amount product used per application | g/event |
| FQ | | Frequency of use | events/d |
| F | | Fraction released to air | g/g |
| 1000 | 1000 | Unit conversion | mg/g |
| V | $V_{room}$ | Room volume | m3 |
| **Output parameter** | | | |
| $C_{inh}$ | $C_{inh}$ | Concentration of substance in room air | $mg/m^3$ |

**Table R. 15-8 Symbols for inhalation exposure (dose) algorithms**

| **Input parameter TRA** | **Input parameter R.15.1** | **description** | **Unit** |
|---|---|---|---|
| $Dinh = \frac{PI \cdot A \cdot FQ \cdot F \cdot ET \cdot IR \cdot 1000}{V \cdot BW}$ | $D_{inh} = \frac{F_{resp} \cdot C_{inh} \cdot IH_{air} \cdot T_{contact}}{BW} \cdot n$ | Algorithm | |
| PI | | Product ingredient | g/g product |
| A | | Amount product used per application | g/event |
| FQ | | Frequency of use | events/d |
| F | | Fraction released to air | g/g |
| ET | | Exposure time | hr |
| IR | | Inhalation rate | $m^3/hr$ |
| | $IH_{air}$ | Ventilation rate | $m^3/d$ |
| 1000 | | Unit conversion | mg/g |
| V | Vroom | Room volume | $m^3$ |
| BW | BW | Body weight | kg |
| | $F_{resp}$ | Respirable fraction of inhaled substance | - |
| | $C_{inh}$ | Concentration of substance in room air | $mg/m^3$ |
| | $T_{contact}$ | Duration of contact per event | d |
| **Output parameter** | | | |
| $D_{inh}$ | $D_{inh}$ | Inhalatory dose (intake) of substance per day | $mg/kg_{bw}$ d |

**Dermal exposure**

**Table R. 15-9 Symbols for dermal exposure algorithms**

| **Input parameter TRA** | **Input parameter R.15.3** | **description** | **Unit** |
|---|---|---|---|
| $Dder = (PI \cdot CA \cdot FQ \cdot TL \cdot D \cdot 1000)/BW$ | $D_{der} = \frac{Q_{prod} \cdot FC_{prod} \cdot n}{BW} . 1000$ | Algorithm | |
| PI | $Fc_{prod}$ | Product ingredient | g/g product |
| CA | | | |
| FQ | | Frequency of use | events/d |
| TL | | Thickness of layer | cm |
| D | | Density | $g/cm^3$ |
| 1000 | | Unit conversion | mg/g |
| | $Q_{prod}$ | Amount product before dilution | g |
| BW | BW | Body weight | kg |
| **Output parameter** | | | |
| $D_{der}$ | $D_{der}$ | Dermal dose of substance per day | $mg/kg_{bw}$ d |

**Oral exposure**

**Table R. 15-10 Symbols for oral exposure algorithms**

| **Input parameter TRA** | **Input parameter R.15.3** | **description** | **Unit** |
|---|---|---|---|
| $Doral = (PI \cdot V \cdot FQ \cdot D \cdot 1000)/BW$ | $D_{oral} = \frac{Q_{prod} \cdot Fc_{prod} \cdot n \cdot 1000}{BW}$ | Algorithm | |
| PI | $Fc_{prod}$ | Product ingredient | g/g product |
| FQ | | Frequency of use | events/d |
| D | | Density | $g/cm^3$ |
| 1000 | | Unit conversion | mg/g |
| V | | Volume of product swallowed | $cm^3$ |
| | $Q_{prod}$ | Amount product before dilution | g |
| BW | BW | Body weight | kg |
| **Output parameter** | | | |
| $D_{oral}$ | $D_{oral}$ | Oral dose (intake) of substance per day | $mg/kg_{bw}$ d |

## Appendix R.15-3 Valuable sources on exposure data

### THE EIS-CHEMRISKS-TOOLBOX FOR DOCUMENTATION OF EXPOSURE DATA

The EIS-Chemrisks Toolbox has been developed by the EU-Joint-Research-Centre, Institute for Consumer Health Protection, Physical and Chemical Exposure Unit. The objective of the toolbox is to provide a platform for documentation and exchange of data on any exposures among experts from industry, agencies, scientific institutions and other stakeholders. The toolbox will be opened for interested parties on request. The data presentation is structured into the following sections:

- ExpoData (library of chemical specific exposure determinants, such as substance usage in specific products/articles and their typical concentrations, physical/chemical properties of substances, etc.),
- EU-ExpoFactors (library of non-chemical specific exposure determinants, such as human body weight and breathing rates for various types of consumers, residential air exchange rates for various types of apartments and homes, etc.),
- ChemTest (Exposure Testing Methods, such as methods to quantify emission of volatile chemicals from a consumer product, etc.),
- ExpoModels (library of existing Exposure Models and Algorithms, such as an algorithm for assessing dermal exposure to a chemical in a product used for a household cleaning task, etc.),
- ExpoScenarios (library of existing exposure assessments and scenarios for particular consumer products and articles and their chemicals, together with a scenario generator using standardised, user friendly process to develop new exposure assessments, etc.).

The idea of the EIS-Chemrisks toolbox is to exchange exposure data. Therefore, it is expected that the users retrieving data from the toolbox would also make available their own data. The most advanced information in the database is focused on textiles (clothing, carpets), automotive textiles, toys and non-woven hygiene products. The toolbox has been fed to start with more than 450 exposure scenarios, based on source documents from, for example, the existing chemicals regulation, the HERA project, and by other separated research projects. The database is retrievable for chemical agents, product categories, CAS-numbers, exposure pathways and risk management measures, to mention only a short number of items.

Access to the EIS-Chemrisks database is available via: http://web.jrc.ec.europa.eu/eis-chemrisks/toolbox/. Access to the database will be possible following registration as an official user.

### DESCRIPTION OF RELEASE OF A SUBSTANCE FROM CONSUMER PRODUCTS

Some examples of releases of substances which can be attributed to uses of consumer products with respect to the paths of exposure and a short description of the characteristics is given in Table R.15-11 below, including references to the relevant literature.

**Table R.15-11 Possible types of release from substances in a preparation or article**

| **Mechanism of release** | **Characterisation** | **Relevant exposure paths** |
|---|---|---|
| Evaporation from a liquid surface | Occurs if liquid consumer products (e.g. liquid cleaners, adhesives, bleaches, removers) containing volatile ingredients are applied which contain a high liquid fraction e.g. water, water soluble liquids or organic solvents. Normally, the release will lead to air concentrations that can be inhaled. Use can be short and long term. The release of volatile substances are evaluated in a number of publications (Chinn (1981), Dunn (1987), Dunn and Tichenor (1998), Gmehling et al. (1989), Sparks et al. (1996).<br>Computer programs that cover this scenario are ConsExpo, CEM (E-Fast). | Evaporation from a liquid surface leads to inhalation exposure as well as to dermal exposure via air. |
| Evaporation from a layer/coating | Very similar to evaporation from a liquid surface. The difference of this release scenario is that the matrix is based on a composition of substances that form a solid layer while the liquid part (solvents) evaporates. Occurs by the transport of a substance from a layer e.g. paint, adhesive to air and contacting skin. The layer may change its solidity with time. A migration of the substance through the layer takes place<br>Evaporation from a layer may occur after the following categories of chemical products (e.g. adhesives, paints, paint or rust removers) have been used. This release has also been evaluated in a number of publications. One is based on the model presented by Jayjock (1994), and is included as the "evaporation from pure substance" and the "evaporation from mixture" models in ConsExpo. Numbers of further evaluations covering thin film source emission, application of paint, emission from solid and liquid sources, VOC's have been published: Bjerre (1989), Bremmer et al. (2006), Clausen et al. (1990), Dunn and Chen (1992), Evans (1996), Guo et al. (1996), Guo et al. (1998), Tichenor et al. (1993), Sullivan (1975), Van Veen et al. (1999), Zimmerli (1982). | Evaporation from layer/coating leads to inhalation exposure as well as to dermal exposure via air. |
| Contact of layer (liquid/semi-liquid/semi solid) with body surface | This scenario can be applied for all uses where the skin comes into contact with liquids or semi-liquid products. There may be short-time-uses (cleaners, liquid soaps), and rarely long time contacts (e.g. lotions) with high frequency. There are some publications that evaluated dermal exposure: Howes (1975), Kasting and Robinson (1993), Thongsinthusak et al. (1999), as well as dermal absorption: Weegels and van Veen (2000), Wilschut et al. (1995). Dermal exposure may also be estimated by use of computer programs e.g. ConsExpo, MCCEM.<br>Models of dermal exposure by contact with fluids have been evaluated by McKone and Howd (1992). | Contact of layer (liquid/semi-liquid/semi solid) with body surface leads to dermal exposure and, sometimes to oral exposure by hand-to-mouth contact |
| Contact of skin with solid articles | Contact of skin by touching solid materials, in particular textiles, paper, toys. A publication of ETAD deals with the extractability of dyestuffs from textiles (ETAD (1983)); computer models: ConsExpo. Contact of skin with solids may also be applicable for dermal exposure to soil which has been evaluated for | Contact of skin with solid articles leads to dermal exposure and, sometimes to oral exposure by direct oral contact. |

| Mechanism of release | Characterisation | Relevant exposure paths |
|---|---|---|
| | modelling by McKone et al. (1990; 1992). | |
| Migration from articles | Migration of a substance from solid material with permanent emission. Exposure occurs indirectly via air, particles or food. This scenario estimates the amount of a substance which is migrating. It should be combined with the scenarios mentioned above. In many cases, measurements of room concentrations are available. This scenario may be attributed to emissions of chemicals from furniture, wood, and other solid materials in the home such as textiles (e.g. carpets). Some models have been published dealing with emissions from furniture (HCHO, (Panzhauser et al. (1992)), emission of VOCs from PVC flooring (Christianson et al. (1993)), release from carpets (Little et al. (1994), and studies on contaminant diffusion in the gas phase (Zimmerli (1982)). | Migration from articles may lead to inhalation exposure as well as to dermal and oral exposure. |

| Mode of release | Characterisation | Relevant exposure paths |
|---|---|---|
| Spraying | Exposure to clouds of substances due to the use of spray, the cloud distributes into the total room volume after finishing spraying. Exposure may occur via inhalation and via dermal route. It is valid for numbers of applications of consumer products e.g. adhesives, paints, cleaners, deodorizers, air fresheners, cosmetics. The exposure to aerosols has been evaluated in a small number of publications (Hartop et al. (1991); Jennings et al. (1987)), and is also considered in the ConsExpo model. | Spraying leads to inhalation exposure and to dermal exposure. Oral exposure by hand-to-mouth contact is also possible. |
| Contaminations | Many exposures to substances occur indirectly via contamination of food or drinking water. The pathways that lead to exposure should be described and exposure estimates may be performed taking data from measurements of substances in the above mentioned media. Food consumption data can be gathered from literature (e.g. AUH (1995); Andelmann (1985); Jennings et al. (1987), Legrand et al. (1991)), as well as data from national food consuming monitoring studies. | Contamination is the most important source for oral exposure. Skin exposure is also possible. |
| Solid particles in air | Transport of solid fine and ultrafine particles from a container to surrounding air<br>Adsorption of substances (in particular non-volatiles) to dust particles<br>Data that can be useful for estimating exposure to solid particles e.g. has been published by the German Ausschuss für Umwelthygiene (AUH, 1995), giving a critical overview on existing evaluations on dust intake. | Solid particles in air lead to inhalation exposure from particles<br>Exposure to particles may occur via inhalation of dust, as well by the dermal (by touching) dust/soil or orally (eating dust or soil). The latter exposure is of special importance in children. |

## ADDITIONAL SOURCES OF INFORMATION

**Table R.15-12 Additional sources of information**

| Acronym | Full name | Country | Remarks | Contact |
|---|---|---|---|---|
| AIHC | American industrial health council (1994). Exposure factors handbook | US | Anthropometric data on adults and children, behaviour data, given as distributions | Update coordinator, Suite 760, 2001 Pennsylvania Ave. NW, Washington DC 20006-1807 |
| | | | | |
| BgVV-ZEBS | Zentralstelle zur Erfassung und Bewertung von Stoffen in Lebensmitteln | D | Food monitoring, focus to Germany | Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin, Germany 49 1888 412 0 |
| BVL | Federal office for Consumer Protection and Food Safety Food monitoring, focus to Germany | D | Food contamination data from market surveillance programs | BVL Dienstsitz Berlin-Mitte Mauerstr. 39 – 42 10117 Berlin www.bvl.bund.de |
| CEPA | Air toxic Hot Spots Program Risk Assessment Guidelines Californian Environmental Protection Agency. | US | Part IV Technical Support for Exposure Assessment and Stochastic Analysis | www.oehha.ca.gov/air/hot_spots/finalStoc.html |
| CH-PR | Swiss product register | CH | Product information, given on request | Contact: Dr. P. Bormann, Swiss Federal Health Office, Bern, Switzerland www.parchem.bag.admin.ch/webinfo/global |
| ECETOC | Exposure Factors Sourcebook for European Populations (with focus on UK data) | EU | Probability analysis Anthropometrics Time activity patterns | www.ecetoc.org |
| IFL | Industrieverband Farben und Lacke | D | National industrial association, focus on paints, lacquors | www.farbeundlack.de |
| IKW | Industrieverband Körperpflege und Waschmittel | D | National industrial association, focus on household preparations | www.ikw.org |
| IVA | Industrieverband Agrar | D | National industrial association, focus on agricultural preparations | http://www.iva.de |
| JRC-IHCP | European Exposure Factors (ExpoFacts) Sourcebook (based on CEFIC-LRI project) | EU: 30 European countries: EU member states in addition to Iceland, Norway and Switzerland | Database of statistics and reference factors affecting exposure to environmental contaminants | http://expofacts.jrc.ec.europa.eu |

| | | | | |
|---|---|---|---|---|
| | http://www.mst.dk/English/ | DK | Study reports on chemicals in consumer products | The Danish EPA, www.mst.dk |
| PR-D | Product data base according to regulations of chemical law | D | Product information | Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin, Germany 49 1888 412 0 |
| PR-FIN (KETU) | Finnish product register | FIN | Product information | www.valvira.fi |

| **Acronym** | **Full name** | **Country** | **Remarks** | **Contact** |
|---|---|---|---|---|
| PR-S | Swedish product register | S | Product information | www.kemi.se |
| PR-D | Danish product register | DK | Product information | www.at.dk |
| SPIN | Nordic SPIN database | NO, SE, DK, FI, IS | Product information from the Nordic product registers | www.sft.no/produktregisteret; www.kemi.se; www.at.dk; www.valvira.fi; www.vinnueftirlit.is |
| RefXP | Exposure Factors Database Umweltbundesamt | D | Update of AUH data with probabilistic focus | http://www.umweltbundesamt.de/service-e/uba-datenbanken-e/index.htm |
| RIVM | Bremmer et al. (2006) | NL | General information, room volumes, room ventilation data | www.rivm.nl |
| RIVM-paint | Bremmer HJ, Van Engelen, JGM (2007) Factsheet paint | NL | Use data on paints, paint classification, characterisation of paint use, focus on NL | www.rivm.nl |
| RIVM-DIY | Ter Burg W. et al. (2007) Factsheet Do It Yourself products | NL | Use data on do it yourself products. | www.rivm.nl |
| US EPA | Environmental Protection Agency (1997). Exposure Factors Handbook. | US | Substantial compilation of exposure factors | www.epa.gov |
| HERA | Human and Environmental Risk Assessments on ingredients of household cleaning products | EU | Data on household cleaning products, collected by A.I.S.E and CEFIC | www.heraproject.com |
| VCI | Verband der chemischen Industrie | D | National industrial association (all chemical industries) | http://www.vci.de |

## Appendix R.15-4 Computer tools for estimation of consumer exposure

### INTRODUCTORY REMARKS

All the computer tools mentioned in this section can be helpful in performing exposure assessments. It has to be kept in mind while using them that they are designed from different perspectives on exposure monitoring and different concepts and thus reflect different scientific approaches. First of all, the assessor must be aware that the scenarios governing the model characterisation are different. For instance, the ConsExpo inhalation exposure scenarios (see Section R.15.6.2) are based on a one room spread-out with a user directed virtual volume, while the CEM program (US-EPA) considers exposure in a whole house with different rooms and differentiated scheme of times staying in the rooms throughout a day of users and non-users. It is clear that these differences of the scenario must lead to different results and the assessor has to document the reasons for favouring a specific model.

Note: This section does not discuss the models presented elsewhere in guidance text, namely ECETOC TRA (Section R.15.4), ConsExpo (Section R.15.6.2) and EUSES consumer exposure approach, since it follows the equations presented in Section R.15.3.

### US EPA WALL PAINT EXPOSURE ASSESSMENT MODEL (WPEM)

The Wall Paints Exposure Assessment Model (WPEM) estimates the potential exposure of consumers and workers to the chemicals emitted from wall paint which is applied using a roller or a brush. WPEM is a user-friendly, flexible software product that uses mathematical models developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. This is then combined with detailed use, workload and occupancy data (e.g., amount of time spent in the painted room, etc.) to estimate exposure. The output of WPEM was evaluated in a home used by EPA for testing purposes and, in general, the results were within a factor of 2. The WPEM provides exposure estimates such as Lifetime and Average Daily Doses, Lifetime and Average Daily Concentrations, and peak concentrations.

Specific input parameters include: the type of paint (latex or alkyd) being assessed, density of the paint (default values available), and the chemical weight fraction, molecular weight, and vapour pressure. Occupancy and exposure data are provided by the model as default values but the model is designed to be flexible and the user may select other values for these inputs: activity patterns on weekdays/weekends for workers or occupants, and during the painting event; number of exposure events and years in lifetime; room size (volume); building type (e.g., office, single family home); number of rooms being painted; air exchange rates; etc. For those chemicals in which the mathematical emissions model does not apply, you can enter emissions data.

Status and availability

WPEM Version 3.2, a Windows-based tool is available. The model has been peer reviewed by experts outside EPA. This model was developed under contract for the EPA's Office of Pollution Prevention and Toxics, Economics, Exposure, and Technology Division, Exposure Assessment Branch. WPEM was developed under the Design for the Environment Program, Designing Wall Paints for the Indoor Environment. This project was accomplished in coordination and cooperation with the National Paint and Coatings Association (NPCA), in addition to paint manufacturers and chemical suppliers.

The model, user's guide and background document is available as a pdf file via: http://www.epa.gov/oppt/exposure/

## CONSUMER EXPOSURE MODEL (CEM)

The Economics, Exposure and Technology Division (EETD) of the Office of Pollution Prevention and Toxics (OPPT) of EPA is responsible for conducting specific activities in support of the Agency's risk assessment process. One of these responsibilities is to assess new and existing chemical substances under the Toxic Substances Control Act (TSCA). CEM, developed by Drewes and Peck (1999) is designed to provide EETD's Exposure Assessment Branch and Chemical Engineering Branch with an easy way to perform consumer inhalation and dermal exposure assessments for OPPT's new and existing chemical programs. The methods used to perform these assessments often involve generic screening-level techniques to allow exposures to be estimated rapidly. CEM has been programmed in C++/Windows and is designed to be run on a personal computer.

CEM is an interactive model which calculates conservative estimates of potential inhalation exposure and potential for absorption through dermal exposure to consumer products. Consumer inhalation exposures modelled in CEM use the same approach and calculations as the Multi-Chamber Concentration and Exposure Model (MCCEM), as well as scenarios depicted in the Screening -Level Consumer Inhalation Exposure Software (SCIES). Dermal exposures are modelled using the same approach and equations as the DERMAL Exposure Model. CEM allows for screening-level estimates of acute potential dose rates, and estimation of average and lifetime average daily dose rates. Because the model incorporates upper percentile and mean input values for various exposure factors in the calculation of potential exposures / doses, the exposure / dose estimates are considered “high end” to “bounding” estimates.

The dermal portion of CEM uses a film-thickness approach which assumes that exposure occurs from a thin layer of the consumer product on a defined skin surface area to determine potential exposure. Few data exist on the actual thickness of films of various products on human skin. Therefore, due to the uncertainty associated with the amount of product forming a film on the skin the dermal exposure estimates are considered less certain than those calculated in the inhalation portion of CEM. Absorbed dermal dose rates can be calculated using a permeability coefficient or a log octanol water coefficient, but these values and their use in calculating exposure also involves uncertainty. Absorbed exposure can only be calculated for the User-Defined Scenario in CEM.

The consumer exposure scenarios were selected for inclusion in the model by EETD because they are products or processes for which exposure assessments are most frequently performed during the new chemical review process. In addition to these scenarios, users are able to create their own scenario. CEM is user friendly and provides on-line help to assist the user in optimizing model use.

The CEM programme covers most of the scenarios needed for consumer exposure modelling. It should be noted that input data are needed for 50th and 95th percentiles.

CEM is now integrated in the E-Fast program, available via:

http://www.epa.gov/oppt/exposure/pubs/efastdl.htm

## US EPA MULTI-CHAMBER CONCENTRATION AND EXPOSURE MODEL (MCCEM)

Features

The Multi-Chamber Concentration and Exposure Model (MCCEM) Version 1.2 (GEOMET, 1995) was developed for the US EPA Office of Pollution Prevention and Toxics to estimate indoor concentrations for chemicals released in residences). The features of MCCEM include:

- MCCEM needs time-varying emission rates for a chemical in each zone of the residence and outdoor concentrations. The emission rates of pollutants can be entered into the model either as numbers or as formulas;
- inhalation exposure levels are calculated from the estimated concentration if the user specifies the zone where an individual is located in a spreadsheet environment;
- MCCEM has data sets containing infiltration and interzonal airflow rates for different types of residences in various geographic areas. The user can select from the data sets, or can input zone descriptions, volumes and airflow rates;
- concentrations can be modelled in as many as four zones (chambers) of a residence;
- the programme is capable of performing Monte Carlo simulation on several input parameters (i.e., infiltration rate, emission rate, decay rate, and outdoor concentration) for developing a range of estimates for zone-specific concentrations or inhalation exposures;
- the programme has an option to conduct sensitivity analyses of the model results to a change in one or more of the input parameters;
- the percentage of cases for which modelled contaminant concentrations are at or above a user-specified level of possible concern or interest is determined.

Theoretical

This multi-chamber mass-balance model has been developed by using air infiltration rates and corresponding interzonal air flows for a user-selected residence or a user-defined residence. This model provides a spreadsheet to the user for entering time-service data for emission rates in one or more zones, the zone of exposure, and concentration values of the contaminant outdoors.

Information assembled by Brookhaven National Laboratory concerning measured infiltration or exfiltration airflow, interzonal airflow, and the volume and description of each zone for different types of structures in various geographic areas has been incorporated in the software for access by users. Two generic houses represent average volume (408 $m^3$) and flow information in summer or fall/spring that has been compiled from a large number of residences. One generic house has a bedroom as the first zone and the remainder of the house as the second zone. The other, with the same total volume as the first, has a kitchen as the first zone and the remainder of the house as the second zone. The features of the generic houses are noted in the Exposure Factors Handbook (US EPA, 1997).

Remarks

The user's guideline listing good examples enable risk assessors to conduct the exposure assessment quite easily within MCCEM. In addition, MCCEM contains a database of various default house data that are needed to complete each calculation such as air-exchange rates, geographically based inter-room air flows, and house/room volumes. However, the so many data paremeters might cause a confusion to risk assessors who aim to evaluate exposure for a typical population at the first Tier approach.

The MCCEM model is available via http://www.epa.gov/oppt/exposure/pubs/mccem.htm

## Appendix R. 15-5 Data references

### DESCRIPTION OF PEOPLES BEHAVIOUR (TIME BUDGETS)

This TGD does not give parameters on time budgets. There are substantial differences between the European countries and regions that are not documented sufficiently. Some information on time budgets can be found in American Industrial Health Council (AIHC, 1994), Standards zur Expositionsabschätzung (AUH, 1995), Dörre and Knauer (1994), Dörre et al. (1999) or Groot et al. (1998).

### ANTHROPOMETRIC DATA

Body weight

For performing the calculations with the equations given in Section R.15.3 default body weights of 70 kg for adult males and 60 kg for adult females may in principle be used. For further analyses, particularly for estimations of children's exposure, more detailed compilations of body weights (including distributions) are available for Germany (AUH, 1995), The Netherlands (Bremmer et al. 2006, Bremmer and van Veen, 2000b), as well as for the US (AIHC, 1994; US EPA, 1997).

Surface area

An overview of distributions of body surfaces is given in the AIHC “Exposure Factors Sourcebook” (AIHC, 1994), in the EPA Exposure factors handbook (US EPA, 1997), in Standards zur Expositionsabschätzung (AUH, 1995), as well as in the RIVM publication “General fact sheet” (Bremmer et al. 2006, Bremmer and van Veen, 2000b).

The total body surface ($S_{der,tot}$) can be calculated from the bodyweight (BW) and the body height (BH) by the formula:

$$S_{der,tot} = 0.0239 \cdot BH^{0.417} \cdot BW^{0.517}$$ **(Equation R. 15-12)**

The mean of body surfaces, given for adult men and women, and referred to the different body parts, is given in Table R.15-13. For females, it was anticipated that the ratio of body part surfaces to total body surface is similar as for men. According to a report from the German Ausschuss für Umwelthygiene the 50$^{th}$ percentile of the body surface is 6,030 $cm^2$ for children between 2 and 3 years, 10,700 $cm^2$ for children between 9 and 10 years, and 14,700 $cm^2$ for adolescents (AUH, 1995).

**Table R.15-13 Body surface areas for adult humans (US EPA, 1997)**

| Body Part | Mean surface area, men (cm²) | Mean surface area, women (cm²) |
|---|---|---|
| head (face) | 1,180 | 1,028 |
| trunk | 5,690 | 4,957 |
| upper extremities | 3,190 | 2,779 |
| arms | 2,280 | 1,984 |
| upper arms | 1,430 | 1,244 |
| forearms | 1,140 | 992 |
| hands (fronts and backs) | 840 | 731 |
| lower extremities | 6,360 | 5,533 |
| legs | 5,060 | 4,402 |
| thighs | 1,980 | 1,723 |
| lower legs | 2,070 | 1,801 |
| feet | 1,120 | 1,001 |
| **total** | **19,400** | **16,900** |

Respiration volume

For performing the calculations with the equations given in Section R.15.3 a default respiration volume ($IH_{air}$) of 20 $m^3$ should normally be used (see Chapter R.8). It should be noted however, that persons are not necessarily staying at the same level of activity during the use of consumer products, neither for the whole day. Hence it may be necessary to adapt the default respiration rates for short-term or long-term exposures, the latter considering the daily changes of activity levels. The tables below provide some useful information on respiration rates for different subpopulations during different activity patterns.

**Table R.15-14 Respiration volume ($m^3$/day), related to activity levels (AUH, 1995)**

| subject | Body weight | Age | Resting | Light activity | Medium activity | Heavy activity |
|---|---|---|---|---|---|---|
| Adults females | XX | 20 – 30 | 6.5 – 8.6 | 23 – 27 | 36 | 130 |
| Pregnant women | XX | | 14 | | | |
| Adults males | XX | 20 – 33 | 6.5 – 10.8 | 29 – 42 | 62 | 160 |

**Table R.15-15 Respiration volume ($m^3$/day) for short-term exposures (AUH, 1995)**

| | Age | Body weight | Resting | Light activity | Medium activity | Heavy activity |
|---|---|---|---|---|---|---|
| Children | <1 | XX | 1.4 | 2.9 | 5.8 | 10 |
| Children | 1-3 | XX | 2.9 | 5.8 | 12 | 20 |
| Children | 4-6 | XX | 5.8 | 12 | 23 | 40 |
| Children | 7-9 | XX | 8,6 | 12 | 35 | 61 |
| Children | 10-14 | XX | 12 | 23 | 46 | 81 |
| Adolescents | 15-19 | XX | 13 | 26 | 51 | 91 |
| Adults | 20-75 | XX | 13 | 26 | 51 | 91 |

**Table R.15-16 Respiration volume ($m^3$/day) for a whole day exposure (AUH, 1995)**

| Age | <1 y | 2-3 y | 4-6 y | 7-9 y | 10-14 y | 15-19 y | 20-75 y |
|---|---|---|---|---|---|---|---|
| Breathing volume | 3 | 7 | 11 | 14 | 18 | 20 | 18 |

## DATA ON ROOM VOLUME AND VENTILATION

### Room volume

The room volume that needs to be used for calculating the exposure of consumer is of course related to where the activity takes place. No default values can be given. Some information on room volumes for the Netherlands and for Germany is given in Table R.15-17 below. This table shows that only minor differences exist between these countries. Further data considering room volumes are available from the US (Jennings et al., 1987) but not from other EU member states.

**Table R.15-17 Room volumes ($m^3$) in the Netherlands and Germany (medians)**

| **Room** | **Netherlands 1)** | **Germany 2)** |
|---|---|---|
| Living room | 58 | 64 |
| Room 1 | 40 | 43 (children's room) |
| Room 2 | 30 | |
| Sleeping room 1 | 16 | |
| Kitchen | 15 | |
| Toilet | 2.5 | |
| Bathroom | 10 | |

1) Bremmer et al. (2006), Bremmer and van Veen (2000).

2) The Statistisches Bundesamt (Wiesbaden) has published a list of means of room areas. From these data an estimate of room volume has been performed by multiplying the areas with a height of 2.8 – 3.5 m. The median of this estimate is 64 $m^3$. These data cannot be taken for worst-case scenarios, because they do not cover extreme values.

Room ventilation

An overview on room ventilation rates is given by Bremmer et al. (2006), Bremmer and van Veen (2000b) and Klobut (1993). The US-EPA is listing 0.18 $h^{-1}$ as a conservative estimate for room air ventilation. This value is representing the $10^{th}$ percentile of a number of studies performed throughout the US (US-EPA (1997), Chapter R.17). For The Netherlands, room ventilation varies between 0.5 and 2.5 ($h^{-1}$), depending on the room (Bremmer et al. (2006), Bremmer and van Veen (2000b)). According to evaluations made in a test house by Guo et al. (1995) the room ventilation rate accounts for 0.382 ± 0.084 $h^{-1}$ under “normal” conditions and 2.06, respectively 4.20 $h^{-1}$ when all doors and windows are kept open. In another experimental study van Veen (1995) estimated a room ventilation rate of 6.2 $h^{-1}$ (all doors and windows open). A conservative default of 0.2 $h^{-1}$ room ventilation could be applied in.consumer exposure estimation.