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GUIDANCE

Guidance on Information Requirements and Chemical Safety Assessment

Chapter R.15: Consumer exposure estimation

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LEGAL NOTE

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Guidance on Information Requirements and Chemical Safety Assessment
Chapter R.15: Consumer exposure estimation

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Preface

This document describes the information requirements under the REACH Regulation 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 the REACH Regulation.

The original versions of 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. After acceptance by the Member States competent authorities the guidance documents had been handed over to ECHA for publication and further maintenance. Any updates of the guidance are drafted by ECHA and are then subject to a consultation procedure, involving stakeholders from Member States, industry and non-governmental organisations. For details of the consultation procedure, please see:

http://echa.europa.eu/documents/10162/13559/mb_63_2013_consultation_procedure_for_guidance_revision_2_en.pdf

The guidance documents can be obtained via the website of the European Chemicals Agency at:

http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

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 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, p.1; corrected by OJ L 136, 29.5.2007, p.3).

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 was integrated into Chapter 15.4.	April 2010
Version 2	Chapter R.15.4 on the ECETOC TRA consumer tool for exposure estimation at Tier 1 was subjected to a major revision and update, with the inclusion of a new version of the ECETOC TRA consumer model.	April 2010
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) wasswitched.	April 2010
Version 2	All presentations on higher tiers were moved into a single chapter R.15.6 and an additional Appendix R.15-4	April 2010
Version 2	A new chapter R.15.6 on risk characterisation was introduced and all relevant texts from other parts were moved into it.	April 2010
Version 2	The introduction was updated	April 2010
Version 2	The chapter on RMMs (earlier R.15.3.2.1) was shortened, moved to Chapter R.15.2.7 and information which duplicated that in R.13 was deleted.	April 2010
Version 2	A new Appendix R.15-1 on consumer mixture and article categories that can be assessed with the ECETOC TRA was introduced	April 2010
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, was updated.	April 2010

Version 2	The default units for the algorithms in R.15.3 were updated to be consistent with other guidance (Chapter R.8) and modelling tools.	April 2010
Version 2	Further minor technical and language corrections	April 2010
Version 2.1	Corrigendum to: (i) replace references to the DSD/DPD by references to CLP; (ii) implement minor recommendations concerning nanomaterials arising from RIP-oN3; (iii) make further minor editorial changes/corrections.	October 2012
Version 3.0	• The description of the workflow has been streamlined • New specification of how to deal with infrequent uses has been introduced • Have removed "migration from article" as a tier 1 algorithm for dermal exposure • Have updated the information on modelling tools • Have harmonized the text with the updated Chapter R.12 of the IR & CSA Guidance • Have integrated relevant parts from Chapter R.17 (to be obsoleted)	XXXX 201y

1

2

Guidance for implementing this update

Most of the changes in the current update provide additional tools and parameters to support consumer exposure assessment and exposure scenario building under REACH, or are of an explanatory or an editorial nature.

A registrant having already finalised the consumer exposure estimation based on Chapter R.15 as published in April 2010 may therefore wish to take the following advice into account:

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

If the conclusion of the check is that neither is put into question, it is unlikely that the adaptation of the already existing Chemical Safety Report to this guidance update (version 2.1 to version 3.0) is of high priority. In this respect, it should be highlighted that previous version of the Tier I ECETOC TRA consumer tool (version 2, as described in the R15 Guidance, April 2010) is more conservative than the new ones developed more recently (Version 3.0 and 3.1, see Section R.15.4). Therefore an assessment carried out with version 2 of the TRA consumer tool can still be considered valid.

This updated guidance (version 3.0) describes how to deal with infrequent uses, in this respect assessment done in previous registration dossiers may need revision.

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 Guidance Document structure.

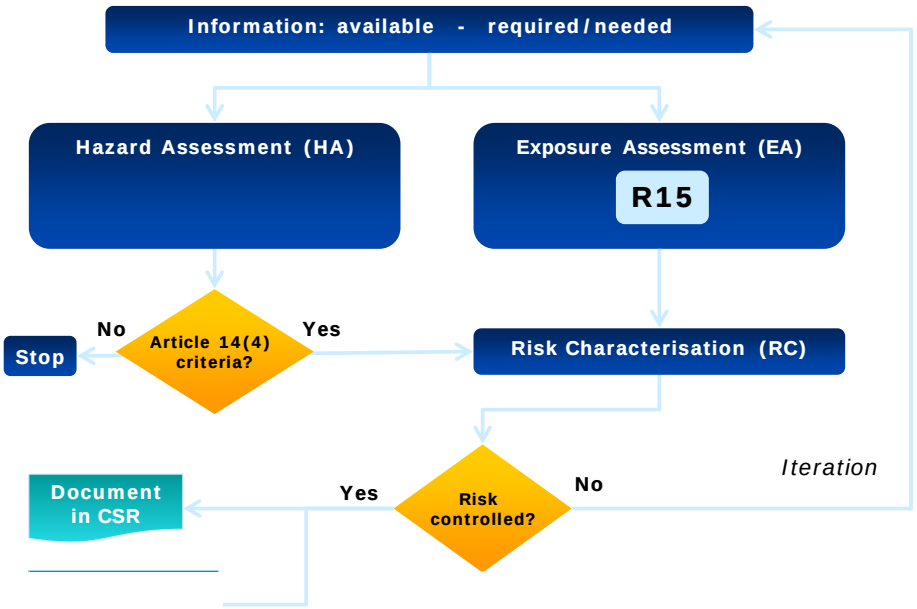


Table of Contents

Table of Tables

Table of Figures

Table of Examples

R.15. Consumer exposure estimation

R.15.1. Introduction

R.15.1.1. Aim

The aim of this guidance chapter is to describe an efficient, step-wise and iterative procedure for consumer exposure assessment under REACH, related to substances on their own, in mixtures or in articles. In this guidance, substances on their own or in mixtures that are used by consumers are called consumer products.

It consists of the following sections:

- Workflow for consumer exposure assessment (Section R.15.1.2)
- General principles 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)
- Higher tier models and measured data (Section R.15.5),
- Risk characterisation (Section R.15.6),
- Overview on information sources and available tools (Section R.15.5 and Appendix R.15.3, Appendix R.15.4 and Appendix R.15.5)

This guidance does not address prevention of serious accidents for example ignition of flammable products or drinking of oxidising, very corrosive products or poisonous products.

R.15.1.2. Workflow for consumer exposure assessment

Exposure assessment for consumers usually includes the following steps:

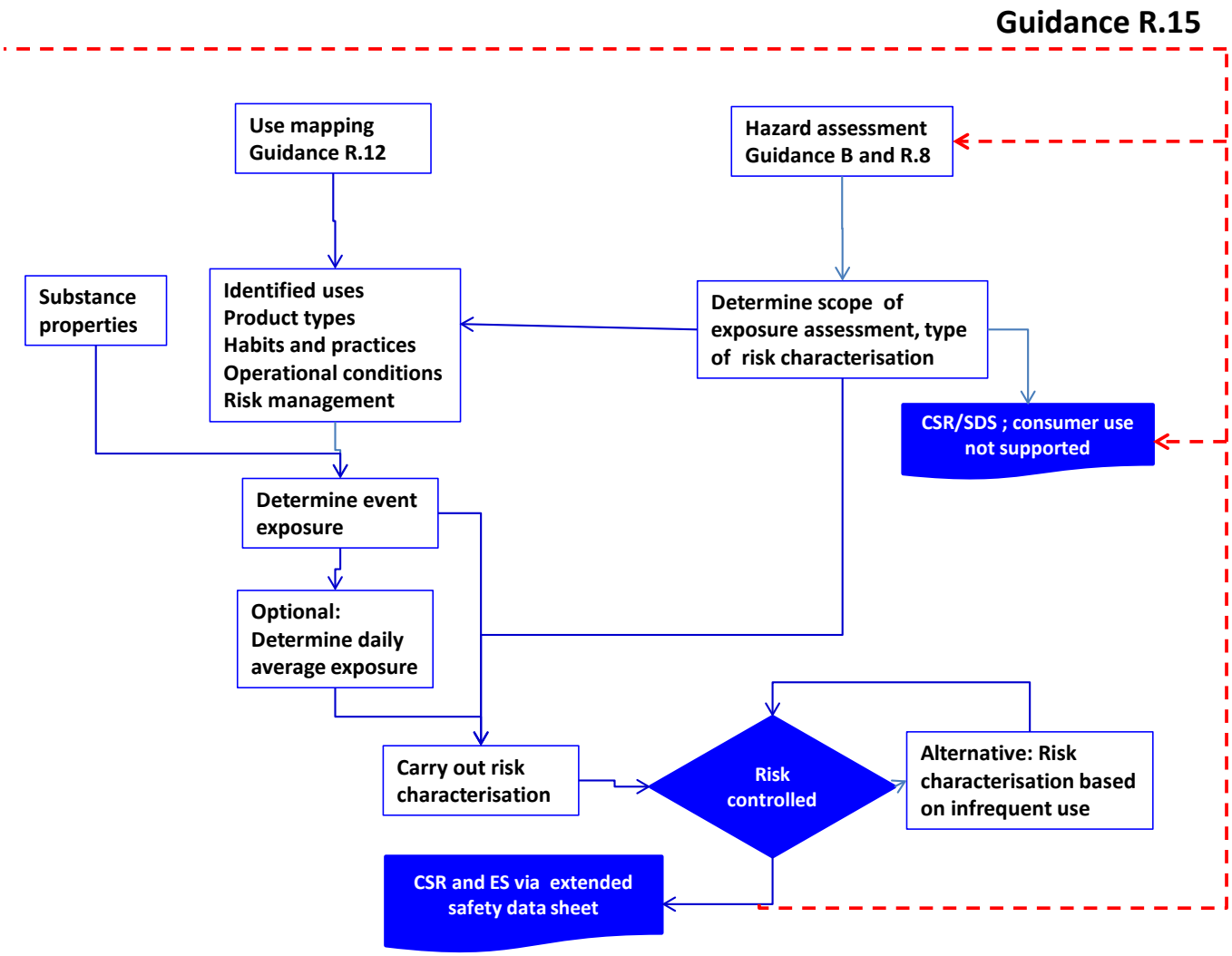
- Collect or generate information on the intrinsic properties of the substance and take into account use patterns and routes of exposure. This step takes place outside the exposure assessment and is not addressed in the current guidance. This includes:
  - toxicological endpoints (e.g. irritation or corrosion, sensitisation, acute and repeated dose systemic toxicity, genetic toxicity, carcinogenicity, reproductive toxicity);
  - endpoints regarding physicochemical properties (e.g. vapour pressure, water solubility)
- Determine the type and the extent of hazards by comparing with classification and labelling criteria and by “deriving no-effect levels” (DNELs); different from those for workers, this includes a DNEL for systemic effects via the oral route. Determine the leading hazard for each exposure route. This step also takes place outside the exposure assessment, however the conclusions at this step determine i) whether a substance should/must not be introduced to consumer uses at all (e.g. CMRs and acutely toxic substances) and ii) which hazards are to be addressed in the exposure assessment.
- Determine the scope of exposure assessment:
  - Determine whether serious local effects on skin and eyes may occur (e.g. due to irritation, corrosion or sensitisation).
  - Determine routes and types of effects for which exposure quantification is required (i.e. where a DNEL can be derived based on effects seen in the corresponding study(ies).
- Build an exposure control strategy, taking into account that control of consumer exposure should largely be based on the design of the product itself (e.g. concentration limits, packaging avoiding overdosing). Behavioural advice, instructions or personal protection equipment are not expected to be sufficiently effective to control the risks to consumers. Special attention is needed for products where a single exposure to eyes and skin may cause seri-

ous effects. If the registrant nevertheless intends to support consumer uses in his assessment, he needs to demonstrate that there is a negligible likelihood that such effects occur when used by consumers.

- Build/retrieve contributing scenarios for the product types (mixtures and articles) expected to contain the substance. Retrieve information from use maps and exposure assessment inputs (e.g. Specific Consumer Exposure Determinants [SCEDs], see Section R15.4.5) if available from DU sector organisations or single representative customers; ensure that the exposure scenarios sufficiently address skin sensitisation, corrosion and irritation, if relevant. Consider whether habits and practices of adult consumers may differ from the behaviour of child consumers and scope the contributing scenarios accordingly.
- Derive exposure estimates for all contributing scenarios (i.e. product (sub) categories) where needed to support the risk characterisation.
    - Derive exposure estimate for one use event starting with screening estimation based on Tier 1 model, and for risk characterisation compare with the DNELs for repeated or continuous exposure. If the risk characterisation ratio is < 1, the use can be considered safe, independently of any considerations on frequency over a year or over a day.
    - If the risk characterisation is > 1, refine the event exposure estimate with higher tier models or measured data. If the risk characterisation ratio is <1, the use can be considered safe.
    - If it is not possible to demonstrate safe use on such basis a registrant may i) average the event exposure concentration over the day (boundaries of this iteration strategy see Section R15.2.5) or ii) limit the (supported) consumer use of the substance to infrequent use only (boundaries of this iteration strategy see Section R15.2.5)
- Consider whether combined risks are to be addressed:
    - Risks via different routes of exposure are to be taken into account by summing the individual risk characterisation ratios.
    - Risks resulting from exposure to the substance via simultaneous use of different products should, where relevant, also be taken into account through summing of risk characterisation ratios.
- Conclude whether further refinement of assessment is needed, and finalise the risk characterisation (quantitative and/or qualitative).
- Document the assessment in the CSR and communicate conditions/measures for safe use down the supply chain to the formulators of consumer mixtures and the producers of consumer articles.

The following flowchart (Figure R.15- 1) illustrates the steps described above.

Figure R.15- 1: Workflow for the consumers' exposure assessment



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 state of health, may be exposed to a substance by **using** consumer products or articles, or by being present when others (e.g. professionals) are using products. 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. This includes also chemicals and construction material sold to both professionals and consumers (do it yourself products).

For consumer exposure assessment under REACH, the addressee of exposure scenarios is the formulator of the consumer products and / or the producer of the article. The means of controlling the exposure from consumer products are very limited and cannot normally be monitored, or enforced beyond the point of sale of the products.

Manufacturer/ importer (M/I) of substances may initially use a broad or general (conservative) exposure scenario, and he may, as a result, be unable to demonstrate control of risk at a ge-

neric, conservative approach. The producer of the mixture or the article may have specific information related to the formulation and end use of his product. By making this knowledge available to registrants (e.g. in the form of SCEDs), DU sectors can support registrants in developing more realistic exposure scenarios.

R.15.2.1. Scope of the consumer exposure assessment

Examples of human exposure 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;
- exposure to substances released from articles e.g. from use of baby bottles in child care or dyes in clothes;
- fragrance compounds purposefully released into the home from diffusers and from tumble drying clothes and emitting substances back into the home.

Additionally exposure may arise as a result of being near to where a substance is being used or has been used. These additional exposures capture any other human exposures which may not be seen as occupational or indirect 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);
- exposure to substances in public areas (e.g. swimming pools, recreational areas).

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. Indirect exposure 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 of the IR&CSA Guidance*.

Consumer 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 (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. the identification of the different phases of activity in handling the consumer product or article;
3. the duration and frequency of 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 additionally be made.

For example, consumers may over-dose (e.g. by increasing the amount of dishwasher detergent in relation to the doses recommended on the product), 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) or use the product for foreseeable other uses (e.g. dishwashing used to wash hands). Consideration of deliberate abuse is not part of the exposure estimation process. 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 determine the aggregated exposure across these products, in order to prevent underestimation of risk (see Section R.15.2.6).

Certain sub-populations may be exposed differently from 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 weight to surface area, compared to that of adults, will have an effect on the exposure estimates. Therefore, it has to be ensured that exposure scenarios chosen take into consideration exposure pathways for the identified 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.15.4 and Appendices Appendix R.15.3 Appendix R.15.4).

The identification of all reasonably foreseeable consumer uses for the substance in product is also important. In addition to the every-day use of household detergents and car maintenance chemicals, 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 also ascertain that consumer use has been assessed and safe consumer use can be assured. Environmental exposure assessment has to identify release scenarios from consumer use (see *Chapter R.16 of the IR&CSA Guidance*).

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 is inhaled, lands on the skin or is ingested. 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

R.15.2.3.1 Inhalation exposure

Inhalation exposure may occur in the case of substances reaching the breathing zone of consumers. This may happen either during the actual use of the consumer product or article (e.g. as the result of vaporizing solutions or aerosol-forming mixtures) 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 (by evaporation). Exposure by inhalation is expressed as the average concentration of the substance in the inhaled air, and is normally presented as an average concentration over a reference period of time (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 generate aerosols from the use of sprays. In this case the resultant exposure to the substance may be related to the characteristics of 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, as a concentration, usually in mg/m^3. For measurement of exposure to nanomaterials, information in relation to number concentration and surface area concentration is also considered to be of benefit (i.e. n/m^3 or cm^2/m^3).

R.15.2.3.2 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 (e.g. jewellery, textiles, straps, belts, shoes), 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).

R.15.2.3.3 Oral exposure

This refers to substances occurring in mixtures that can be ingested resulting in exposure by the oral route. Examples are the exposure from use of finger paints or ingestion of residues from dishwashing products remaining on dishes. Exposure by the oral route may also occur as a consequence of migration from articles through sucking, chewing or licking of toys, children's books, plastic articles or textiles, or by accidental ingestion of the article itself or parts of the article. This is of particular relevance to children due to their hand to mouth and/or mouthing behaviour.

A specific type of oral exposure for children is the uptake of dust and soil to which releases of substances from articles have absorbed, 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, building materials or computers, TVs. 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 strongly acidic or alkaline chemicals, strong oxidants or 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 R7a).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).

R.15.2.3.4 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, piercings or tattoo inks). In these cases, the exposure is expressed as the total amount of the migrating substance and is 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:

- preparatory activity, which includes tasks like handling and dilution of solid or liquid concentrates;
- application of product by the consumer, including handling of articles during their service life;
- 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 to the substance in a different physical state, or that exposure is to a different substance, e.g. reaction products of the substance;
- 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 phase 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 each of the activities. 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 are also relevant and practicable for the other phases of activity.

R.15.2.5. Frequency of use and duration of exposure

The large variety of consumer products and articles corresponds to a large variety in the frequency and duration of use and exposure. Exposure may occur during use and sometimes it continues after use for a certain time. Duration of exposure to substances in products can vary from seconds to hours per use event. The use events can take place rarely (e.g. once a year or less) or regularly/frequently (e.g. every day). The product specific time pattern of use will mostly be a distribution of consumer behaviour, and for many products the corresponding statistical information is not available. For some products, it may be possible to exclude more frequent use due to the technical purpose of the product.

Therefore, the default approach in consumer exposure assessment is to assume that the products containing the substance are used frequently (e.g. on a daily basis), and that control of risk should be demonstrated for this use situation (exposure scenario). The starting point for the assessment is therefore the exposure during one **use event**. All kinds of effects identified need to be addressed:

a) Local or systemic effects occurring after **short (single)** exposure time:
    - For acute systemic effects, an acute DNEL should be available. By comparing the event exposure to this DNEL, control of risk can be demonstrated;

- No threshold may be available for irritation and corrosion. For these types of effects, the registrant would need to develop a qualitative argumentation under which conditions of use the risk is controlled;

b) For local or systemic effects occurring after **repeated and/or continuous** exposure:
   - Usually for these effects (if not CMR), a long-term (chronic) DNEL is available. By comparing the event exposure to this DNEL, control of risk can be demonstrated. If sufficient information on habits and practices is available on the likely upper frequency of use over a day, it is appropriate to derive an average daily exposure (24 hours), and use this exposure concentration for the risk characterisation. Note: In order to apply this option, the type of effects should be taken into account, e.g. that the substance does not meet the criteria to be classified for CMR, for respiratory sensitisation, for acute systemic toxicity or neurotoxicity.

Infrequent uses

If the registrant can demonstrate sufficient evidence that the use to be assessed only takes place occasionally [infrequently, rarely], he may want to carry out a particular assessment for the infrequent use. This may in particular be relevant for substances or use conditions where the assessment based on the chronic DNEL for organ toxicity (systemic toxicity) fails to demonstrate control of risk even after refinement of the exposure estimates (e.g. use of higher Tier exposure models or measured data).

When a registrants decides to base his safety assessment for a consumer use on occasional [infrequent, rare] use only he needs:

a) either to have study data available enabling to derive a DNEL suitable to assess the single event exposure; or
b) to extrapolate from the risk characterisation based on repeated dose/chronic toxicity to a single event situation;.

For option b) the registrant may apply a generic factor of 0.2 to the chronic risk characterisation ratio (referring to the average daily exposure) to derive a risk characterisation ratio for the single infrequent event. This factor is based on generic toxicological considerations reflecting the uncertainties when extrapolation from a long-term DNEL to an acute DNEL (see Chapter R.8 of the IR&CSA Guidance, Appendix R.8.8). The factor is applicable and relevant under the following conditions:

- There are not more than 12 event-days per year, and the minimum time between two events is not less than a week. Note: In order to confirm this condition, the registrant also needs to take into account whether exposure to the same substance from other consumer products could occur.
- The critical endpoint determining the risk on all three routes is systemic toxicity, and the substance does not meet the criteria to be classified for CMR, for respiratory sensitisation, for acute systemic toxicity or for neurotoxicity.
- There I s no indication of particular long residence time of the substance in the human body (e.g. half-life in body > 30 h)

An example on how evidence for the infrequency of use for a consumer product can be demonstrated can be found at:
https://www.concawe.eu/uploads/files/sced/Lubricant_liquids_with_base_oils_CONCAWE_SCED_24_1_a_v1-2014-02693-01-E.pdf.

R.15.2.6. Combined risk

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 should be summed.

Risks resulting from exposure to the substance via simultaneous use of different products should, where relevant, be taken into account through aggregated exposure across different products.

R.15.2.7. Operational conditions and risk management

General information on the use of a substance in consumer products or articles is needed to identify the contributing scenarios to be assessed and the relevant exposure pathways. The brief general description of consumer uses should follow *Chapter R.12 of the IR&CSA. Guidance.*

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 products used 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. In particular:

- The duration of exposure for consumers should either be estimated as 24 hours per day as a worst case or by estimating the duration of the specific activities leading to exposure (e.g., cleaning of floor or manual dishwashing). For consumer products and articles, and especially in indoor situations, the duration of use is not the same as duration of exposure (e.g. in the case of painting). In the exposure estimation, it should be taken into account that exposure to a substance may also occur after application.
- The applied amount of chemical is found by multiplying the handled weight of the product with the weight fraction of the substance in the mixture. For using a mixture after dilution (e.g., detergent concentrate), the handled weight of the diluted mixture is multiplied with the weight fraction in the diluted mixture. The realistic maximum amount of chemical in use by consumers varies not only between consumer products but also between individuals. For certain types of products it should be assumed that some consumers use more than the recommended amount, because they expect a better product performance. In these cases, individually packed amounts (e.g. tablets or separate sachets) will ensure a constant use amount.
- The size of the receiving compartments, normally a room in a flat or a house represents one of the most important parameters for the exposure assessment. This descriptor of exposure is needed for tier 1 assessments. Also a very basic ventilation rate can be considered in the exposure algorithms.

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 mixtures or in articles. Substances of low volatility can be released by mechanical abrasion (rubbing off), via leaching (e.g. during mouthing) or by migration (e.g. due to elevated temperatures or interaction between the 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. For quantitative exposure estimation, only those RMMs which can be controlled by the manufacturer of the product should be considered. 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), maximum amount of product used (package size), and type of packaging – many dishwasher tablets are now sold encased as gel capsules.

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 by comparison to that in occupational settings where the employer has the duty to ensure 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 be effective and be well adhered to by consumers. For example, an RMM like "open windows to ensure a good ventilation" may be a useful advice to consumers but "good ventilation" should not be assumed when estimating the exposure. Increasing ventilation rates above default is not always a suitable option to iterate an exposure scenario for consumer uses, as adherence to the instructions cannot be guaranteed.

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, and caustic oven cleaners).

R.15.2.8. Habits and practices of children

For children's products and for some consumer products for which the habits and practices of children significantly differ from those of adults (e.g. mouthing and crawling behaviour), the assessor needs to take habits and practices of children into account and should derive contributing scenarios that are sufficiently protective for both children and adults.

R.15.3. Calculation of exposure

This section summarises the Tier 1 principles for consumer exposure estimation. The corresponding algorithms are detailed in Appendix R.15.2. The assessor may start the assessment by using tools that implement the Tier 1 algorithms. These tools are discussed in Section R.15.4 (Ecetoc TRA) and Section R.15.5.1(ConsExpo Tier 1), further tools are listed in Section R.15.5.2 and Appendix R.15.4.

Some examples of how to use the Tier 1 algorithms are found in reference databases (Appendix R.15.3), for example chemical exposure estimation for school children when using school bags, toy bags, erasers and pencil cases (covers assessment of several chemicals (Miljoministeriet, 2007)).

Tier 1 tools require information on very few parameters and apply conservative default values to them, in order to derive a "worst case", but not unrealistic exposure estimate. Depending on the substance properties and the use situation this may already be sufficient to demonstrate safe use. Otherwise, the assessment needs iteration by modifying the assumed conditions of use or the exposure estimate (using higher Tier approaches).

Exposure quantification may be relevant for three routes:

Inhalation: 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, like articles (e.g. wall wooden panels, PVC flooring). Tier 1 assessment assumes that all substance is released at once into a standard room (instantaneous

release) with immediate mixing, and no removal takes place due to ventilation. The main input parameter to be determined by the assessor is the amount of substance available for release in the standard room and the number of use events per unit time. The amount results from the product/article amount per use event and the concentration of the substance in it. Some Tier 1 tools enable release modification based on vapour pressure of the substance. The estimated exposure is expressed in mg/m^3, averaged over the exposure event or over the day (24 h).

Dermal A: The substance is contained in a mixture. This option is applicable when, for example, hands are put into a solution containing the substance under evaluation, or splashes occur (painting). Tier 1 assessment assumes that all the substance contained in a contact layer of 0.01 cm thickness will be available to form the dermal load on the skin surface.

The main input parameters to be determined by the assessor are the fraction of the substance in the mixture, the exposed skin contact area and the number of use events per unit time.

The estimated exposure is expressed as dermal load per use event, calculated as the amount of substance per unit surface area of skin or as an external dose in mg/kg of bodyweight (per use event or per 24 h)

Dermal B: The substance is contained in an article matrix and migrates to the skin surface. This option is for example applicable when residual dyes in clothing or additives in plastic articles are in contact with skin. Tier 1 assessment assumes that all the substance contained in a contact layer of 0.001-0.01 cm thickness (depending on the article) will be available to form the dermal load on the skin surface.

The main input parameters to be determined by the assessor are the fraction of the substance in the article, the exposed skin contact area and the number of use events per unit time.

The estimated exposure is expressed as dermal load per use event, calculated as the amount of substance per unit surface area of skin or as an external dose in mg/kg of bodyweight (per use event or per 24 h).

Oral A: The substance is contained in a mixture or in an article and a part of the product/ article is unintentionally swallowed during normal use,. This option is for example applicable for the use of finger paints or for residues from dishwashing on the dishes. The main input parameters to be determined by the assessor are concentration of the substance in product when swallowed, the amount ingested per event and the number of use events per time. Oral exposure is expressed as external dose (mg/kg bw).

Oral B: The substance is contained in an article and migrates to the surface. Licking and sucking (e.g. by children) may promote leaching of the substance from the article matrix. This option is applicable for example when a substance migrates from a pen, cutlery or textiles. The main input parameters to be determined by the assessor are the fraction of the substance in the article, the area subject to sucking or licking and the number of use events per unit time. Oral exposure is expressed as external dose (mg/kg bw). An alternative way of calculating oral exposure to substances in articles is presented in Appendix R.15.7

R.15.3.1. Exposure to non-volatile substances

Non volatile substances (i.e. substances having low vapour pressure) can be released from products via migration (e.g. softeners) or by mechanical abrasion (e.gpesticides, flame retardants). Because these substances can be found in house dust, house dust may present an important path for exposure to non-volatiles. In small children, exposure via house dust can account for about 50% of the total exposure (Wormuth, et al., 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. For example, the substance in articles may become available for inhalation due to rubbing or while handling or working with the article (e.g., building materials, hobby materials etc.). The resulting dust can be inhaled. Therefore, use specific exposure via house dust is difficult to predict. 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/day has been proposed for house dust intake for children (Oomen, et al., 2008).

In Tier 1 assessments, tools like ECETOC TRA enable the assessment of 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 - Tier 1

ECETOC has released different versions of the TRA Consumer tool during recent years to better capture exposure refinement options, while maintaining algorithms for exposure estimation, which are largely based on Tier 1 algorithms mentioned in Section R.15.3 and documented in Appendix R.15.2. Three recent versions of TRA are briefly described and compared with each other and to Tier 1 algorithms in Appendix R.15.5

References to be consulted for better comprehension of the TRA consumer tool are:

- Addendum to ECETOC Targeted Risk Assessment Report No. 93 - Technical Report No. 107 - (ECETOC, 2009);
- ECETOC TRA version 3: Background and Rationale for the Improvements - Technical Report No. 114 – (ECETOC, 2012)
- Addendum to TR114: Technical Basis for the TRA v3.1 - Technical Report No. 124 (ECETOC, 2014)

The above mentioned documentation is freely available at http://www.ecetoc.org/tra. The description in the following paragraphs always refers to the latest version of TRA tool, ECETOC TRA Consumer v.3.1.

ECTOC TRA consumer tool v.3.1 is integrated in the CHEmical Safety Assessment and Reporting tool (CHESAR) developed by ECHA.

R.15.4.1. 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 of the IR&CSA guidance*.

In the initial assessment the TRA enables derivation of 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 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.

Moreover, ECETOC TRA enables the user to define a new (sub)product or article type, e.g. one not covered by the list in Appendix R.15.1 or being a specific product for which habits and practices and related input parameters are defined at the sector organisation level (so called SCED, see Chapter R.15.4.5). Single registrants are advised to not select this functionality, unless they use the products type and related input parameters as contained in the SCED pro-

posed by sector organisations.

The user of the ECETOC TRA tool is advised always to check:

- If the use he wants to cover fits the (sub)category of product or article chosen
- If the scenario (e.g. target population covered, input parameters) described by the selected (sub) product or article category fits the use he wants to cover.

R.15.4.2. Algorithms, input and output parameters

One algorithm per exposure route (dermal, oral, inhalation) is used to calculate the exposure for all consumer product and article categories. For the sentinel product/article, the exposure estimates for each route corresponds to the highest exposure estimate of the individual product/article subcategories within the sentinel. The algorithms for each exposure route are fully described in ECETOC Technical Reports TR 114 and TR 124. In the following text only input and output parameters are described.

Inhalation route

Output parameters

The TRA calculates the inhalation exposure as

- concentration in room air (mg/m^3), resulting from one or more events of product/article application in the day of exposure;

Or as

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

Input parameters

- Product ingredient (g/g): TRA provides a default for each product or article type; this can normally be overwritten by the user;
- Amount of product used per application (g/event): TRA providesa default for each product or article type; this can be overwritten by the user, who has to support his choice with proper justification;
- Spray application: TRA provide provides a default for each product type (whether the product is intended to be sprayed or not); for some “not spray” products, the default setting can be modified by the user (from “not spray” to “spray”);
- Frequency of use (events/day): the default value is assigned for each product type (normally 1 event/day) and is not modifiable by the user;
- Exposure time (hr): the default value is assigned for each product type and is not modifiable, unless a new (sub)product category is defined by the user;
- Outdoor/indoor use: only when a new (sub)product category is defined, can the user select an outdoor instead of indoor use;
- Inhalation transfer factor: only when a new (sub)product category is defined, can the user choose to set the inhalation transfer factor to < 1. This factor may be used to reduce the used amount of substance (as such or in mixture) to the amount actually available for instantaneous release. For example, during tank filling with 70 l of gasoline, not all these 70l are available to be released into air. The use of the transfer factor needs to be accompanied by a proper justification;
- Frequency over the year: only when a new (sub)product category is defined, can the user choose to set the frequency band (frequent, occasional, infrequent, very infre-

quent) over the year. Compared to the frequent (daily) exposure the exposure is reduced by up to a factor of 100.

The chemical physical parameters needed to run the exposure assessment are reported below:

- Molecular weight (g/mol), which enables the calculation of the saturated vapour concentration
- Vapour pressure (Pa), which enables the calculation of the saturated vapour concentration and fraction released to air (see table below).

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- 1). The fraction released to air (driven by vapour pressure) should not be confused with the "inhalation transfer factor" mentioned above (amount of the substance actually available for being released into the air)).

Table R.15- 1: Vapour pressure bands

Vapor pressure of compound of interest	Released % of the amount available for instantaneous release	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 assumed to be completely released into air instantly. For a substance 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.

Note: for activities taking place at a temperature different from ambient temperature (e.g. dishwashing products), the vapour pressure of the substance should be adapted to the process temperature.

Compounds with vapour pressures $<10^{-4}$ Pa are non-volatile. The value used 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 standard room with standard ventilation. Therefore this exposure covers not only the inhalation exposure, but also the dermal and oral exposure of compounds in house dust.

Note: the tool does not cover exposure arising from dusty materials or from dust-generating consumers' activities, since releases from a product or articles are driven by the substance's vapour pressure.

Dermal route

Output parameter

External dermal dose (expressed in mg/kg bw / day) over the day of exposure, resulting from

one or more events of product/article application.

Input parameter

- Product ingredient (g/g): ECETOC TRA provides a default for each product and article type; this can be normally overwritten by the user
- Skin contact areas: TRA provides a default for each product and article type according to one of eight categories (see below), each one is characterized by a default surface area for adults and children. This can be overwritten by the user, who has to support his choice with proper justification; if the selected target group is children, then the dose is adjusted to the child body weight.
- Frequency of use (events/days): the default value is assigned for each product type (normally 1 event/day) and is not modifiable by the user
- Thickness layer (cm): represents the thickness of the layer in contact with the skin and it is set to 0,01 for mixtures and 0,001 for articles; it is not modifiable by the user
- Dermal transfer factor: The assessor can choose to set the dermal transfer factor to < 1, if there is evidence that the load on skin in the dermal contact area is smaller than the load resulting from the instantaneous release of all substance present in the 0.01 cm (respectively 0.001) contact layer. The use of the transfer factor needs to be accompanied by a proper justification.
- Frequency over the year: only when a new (sub)product category is defined, can the user choose to set the frequency band (frequent, occasional, infrequent, very infrequent) over the year. Compared to the frequent (daily) exposure the exposure is reduced up to a factor of 100.

Note: the dermal model only covers direct contact with the product or article, which in most cases can be considered the predominant route for dermal exposure; indirect dermal contact (e.g. via vapours or spray clouds) is not covered by the tool. 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:
1 – fingertips
2 – two fingerprints
3 – palm of one hand
4 - inside (palms) of both hands / one hand
5 - hands
6 - hands and forearms
7 - upper part of the body
8 - lower part of the body
9 - whole body except feet, hands and head
10 - whole body

Oral route

Output parameter

External oral dose (expressed in $mg*kg_{bw}^{-1}*d^{-1}$) over the day of exposure, resulting from one or more events of product/article application

Input parameter

- Product ingredient (g/g): TRA provides default for each product type; this can be normally overwritten by the user
- Volume of product swallowed: TRA provides default for each product or article type. The volume for some product or article categories depend on the contact surface area and thickness of the layer (see discussion in Appendix R.15.2– Oral route – Scenario B). In such cases, the user can overwrite default surface area, providing proper justification.

- Frequency of use (events/days): the default value is assigned for each product type (normally 1 event/day) and is not modifiable by the user
- Oral transfer factor: is set by default equal to 1 and the user can reduce it, while providing proper justification for his choice.
- Frequency over the year: only when a new (sub)product category is defined, can the user choose to set the frequency band (frequent, occasional, infrequent, very infrequent) over the year. Compared to frequent (daily) exposure the exposure is reduced by up to a factor of 100.

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

In relation to the transfer factors (oral, dermal, inhalation) introduced by ECETOC, it should be highlighted that:

- If transfer factors are set to a value different from the default (100%), the ECETOC TRA tool can no longer be considered as a first tier model; therefore, a scientifically sound and robust argumentation should be provided by the registrant to justify the value of the transfer factor proposed.
- It is very unlikely that the necessary knowledge to justify transfer factors would be available at the level of a single registrant; therefore, the advice is to use the transfer factors only in the context of SCEDs developed at the sector organisation level (e.g. consumer product formulators or article producers, see Chapter R15.4.5).

R.15.4.3. 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 exposure for fertilizers. This is important to realize, especially for situations where the most dominant route can be excluded, e.g. due to product characteristics. Exposure for the other route(s) should then still be considered. This means that it needs to be checked, whether the contribution of the second route becomes significant if exposure for the primary route is reduced to a large extent.

Use scenarios have been defined for all product and article subcategories according to the potential exposure of consumers to these (sub)categories.. The defaults used are presented in the "defaults" table of the tool. The references for the defaults (RIVM reports, conservative expert estimates) are specified in Appendix E of the ECETOC Technical report 107 (ECETOC 2009). Default values such as body weight, surface area, room volume and ventilation rate were obtained from the RIVM general fact sheet (Bremmer, et al., 2006)

R.15.4.4. Specific Consumer Exposure Determinants SCEDs

The SCEDs (Specific Consumer Exposure Determinants) provide "information input" into the registrant's consumer exposure assessment. They document the typical conditions of use for a substance incorporated into a specific consumer product. The conditions of use are expressed in a form that can be directly fed into the commonly applied exposure assessment tools, like for example the ECETOC TRA v.3.1. This includes information related to consumer habits and practices (e.g. quantity of product used, frequency of use, place of use…) and information related to product characteristics (e.g. concentration of substance, transfer of substance from product to skin surface).

While the SCEDs are initially foreseen for use under ECETOC TRA and Chesar, it is also possible to use the SCED information in other REACH consumer models (such as CONSEXPO). The SCEDs do not affect the algorithm inherent to the exposure model.

The SCEDs are developed by sector organisations to transparently document the ways in which their products are commonly used by consumers. The first SCEDs were made publicly available in 2014, further SCEDs followed in 2015. See:

https://www.concawe.eu/reach/specific-consumer-exposure-determinants-sceds-documents

https://www.aise.eu/our-activities/product-safety-and-innovation/reach/consumer-safety-exposure-assessment.aspx

Each value within the SCEDs has to be substantiated by reference to suitable information sources that, ideally, are open access and have been published and peer reviewed (the "rationale"). Preferably this will refer to European data sources and/or be already used in regulatory processes (within the EU or beyond e.g. EPA, IPCS). The SCEDs are designed so that the resulting exposure scenario as a whole represents conservative conditions of exposure. Where habits and practices significantly vary across European countries/regions, then the SCEDs will reflect those areas with the highest uses/exposure conditions.

The Guidance on SCED published by DUCC/Concawe can be downloaded from:
http://www.ducc.eu/documents/20140424-Guidance%20documents%20on%20SCEDs-Final-V1.pdf

R.15.5. Advanced refinements, higher tier models and measurements

More advanced refinement of 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). Expert assessors should normally conduct these assessments.

Higher tier consumer exposure estimation uses 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.15.5.1. 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 the equations used 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 MVDZ, 2006). If parameters are specified as distributions, ConsExpo can perform a distributed (Monte Carlo) calculations. The program will draw a set of random numbers from the specified distributions (uniform, normal, lognormal, triangular) for distributed parameters and calculate 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 a function of the value of a selected stochastic parameter are depicted and analysed. The ConsExpo model contains an associated database reflecting the RIVM factsheets, 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 room air will depend on the amount of chemical present in the room, the room size, ventilation of the room, 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 models are available in ConsExpo.

The instantaneous release model assumes direct evaporation. When the ventilation rate is set at 0, this will result in the Tier 1 algorithms as described in Appendix R.15.2. The model is comparable to the ECETOC TRA inhalation model.

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 esti-

mated 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). The tool is suitable to estimate releases from mixtures, not from articles; for the latter, a more targeted model (Section R.15.5.2.1) has been developed by RIVM.

The 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 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 of non-volatiles, the mass density of the total of non-volatile compounds, the weight fraction of the substance in the mixture, 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. The models estimating dermal exposure in ConsExpo are described here below.

The instant rate model describes a low tier estimate. The model does not include the product layer thickness that is included in Tier I algorithms in Appendix R.15.2 and ECETOC TRA.

Constant Rate model. Similarly to the Tier 1 ‘dermal scenario A’ model, the constant rate model assumes that any compound in the product is directly applied to the skin. The model calculates the amount of product per unit 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.

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 unit 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

The models estimating oral exposure in ConsExpo are described here below.

The direct intake model describes a low tier estimate, and is comparable to the algorithm de-

scribed in Appendix R.15.2 and in Section R.15.4 (ECETOC TRA tool).

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.15.5.2. Other tools

Several previous route-specific models and general consumer exposure models are now integrated into the US EPA E-Fast model (US EPA, 2015) (see Computer tools for estimation of consumer exposure, Appendix R.15.4).

There are also sector specific tools, largely based on Tier I algorithms, where habits and practices from sector organizations are specified and used as input parameters. Two models need to be mentioned:

- AISE (International Association for Soaps, Detergents and Maintenance Products) has developed a model, REACT Consumer Tool, which allows quantitative estimation of exposures to substances that are present in products (washing and cleaning - PC 35, air freshener – PC3 and polishes and wax – PC31) used by consumers. The tool calculates exposure via inhalation, dermal, and oral routes separately and also provides a summation of all the relevant exposure routes. The model uses as input parameter habits and practices coming from HERA Project (see Appendix R.15.3). It should be noted that the tool does not cover the evaporation of volatile substances from the product, since it considers the inhalation route relevant for spray applications only. The tool is freely available on the AISE website (www.aise.eu).
- ESIG (European Solvent Industry Group) has developed the EGRETconsumer tool (2010). The tool takes the default assumptions and algorithms (equations) described in the ECETOC TRA, but it introduces refined default values for those product categories relevant to solvents. Since the tool addresses all Product Categories (PC) potentially applicable to solvents, additional PCs (not assessed by ECETOC TRA) are covered by the ESIG tool (e.g. anti freezing and de-icing products – PC4, different fuels products – PC13, functional fluds – PC17). The tool presents some drawbacks. First, the refined default values are not fully justified and agreed among stakeholder (as is the case for the ECETOC TRA tool). Second, the model introduces automatic refinement if the event exposure exceed the long term DNEL. Some of these refinements consist in additional measures on the part of the consumer not easy to communicate or implement (e.g. “open windows”); or linear averaging of the event exposure over the day and over the year, which might be in contradiction with provisions reported in Section R.15.2.5. The tool is freely available at ESIG website (www.esig.org).

R.15.5.2.1 Substances in articles

Regarding the exposure to substance in articles, RIVM has developed (2010) the Emission Model to specifically estimate the inhalation exposure after release of chemicals from solid materials (Delmaar, 2010). The model takes into account the diffusion of a substance in a material, the mass transfer from material into air and removal of the substance from residential air

by ventilation. The tool simulates time profiles of the air concentration and mean air concentrations arising from emission. The model is based on well-established modelling of emissions from building materials, and is designed for specific shapes (i.e. slab like articles like panels, flooring, etc.); extrapolation to other shapes may introduce an unknown degree of uncertainty. The model, underlying assumptions and an overview of available input data and methods to estimate key input parameters are described in Delmaar, 2010. The program is freely available for download from www.consexpo.com.

Other potentially relevant tools are described in Appendix R.15.4.

R.15.5.3. Measurements

In general measured data are preferred over modelled data, provided that 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.

Exposure data, including releases from articles and room concentrations, might be generated within other legislation frameworks, i.e. product safety legislation. The latter could be very interesting for an assessor under REACH since they may be already available for a representative range of conservative scenarios. For example, the Construction Products Regulation (CPR) can be a relevant source of information to support the assessment of articles used as building materials under the REACH Regulation; for example, under this framework, some Member States require the execution of a “chamber test” which simulates the indoor concentration arising from the releases of a selected substance from construction products.

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) available. 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. Measured data have to be representative of the Exposure Scenario to be assessed, i.e. they reflect the conditions of use set in the ES.

Data from biomonitoring or occupational exposure programmes may be valuable for consumer exposure estimations, although their number, representativeness and quality will often vary widely. Measured data from surrogate substances or analogues and surrogate scenarios (e.g. chamber measurements) may also be useful when estimating exposure levels.

Several sources of measured data are reported in in Appendix R.15.3.

R.15.6. Risk Characterisation

Risk characterisation is expected to address both qualitative assessment (prevent exposure where no safe level can be established regarding serious health effects) and quantitative assessment (limit exposure to a safe level).

The Tier 1 exposure estimation and/or information from higher tier evaluations (if deemed necessary) can be used in the quantitative risk characterisation (see Part E of the IR&CSA guidance).

A risk characterisation is required for all uses and their contributing scenarios, differentiated according to routes of exposure. Combined risk across the three routes of exposure is to be characterised. For products designed for use by children or for consumer products for which the habits and practices of children significantly differ from those of adults (e.g. mouthing and crawling behaviour) particular risk characterisation for children should be provided.

If consumers are exposed to a substance via several consumer products or to articles that are likely to be used in combination, the risk due to aggregated exposure across these products needs to be considered and characterised in section 10 of the CSR. Depending on the frequency of use and the contribution of the different products, a risk for aggregated exposure can be calculated. Normally this should be done separately for each time scale (acute and long-term). For more detail, see Part E of the IR&CSA guidance on human risk characterisation.

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 assessment can be finalised. Adequate control of risk should be assumed if i) the exposure estimates are below the DNEL and ii) the likelihood of effects due to irritation, corrosion and sensitisation or other non-threshold effects is negligible.

The RMMs and operational conditions ensuring control of risk for consumers (i.e. mainly the characteristics of a safe consumer product and the underlying assumption on habits and practices) should be documented in final exposure scenarios.

If certain consumer uses are not supported or are advised against due to health risks, this should be recorded in the CSR and communicated via the extended Safety Data Sheet (extended SDS).

In order to produce a meaningful risk characterisation it is important for the assessor to understand and take into account the uncertainties associated with the information/data that is provided (related to both hazard assessment and exposure assessment). The registrant is expected [may want] to include a reflection on the most significant uncertainties in his assessment into section 10 of the CSR. Chapter R.19 of the Guidance on IR&CSA contains more information on using uncertainty analysis.

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Appendix R.15.1 Consumer product and article categories

Chapter R.12 (on Use description) *of the Guidance on IR&CSA* provides lists of the Product Categories (PCs) and Article Categories (ACs). Table R.15- 2 and Table R.15- 3 list those PCs and ACs which describe uses regulated by REACH and which are generally considered to potentially result in significant exposures of consumers. These PCs and ACs with specific subcategories can be assessed by using the ECETOC TRA consumer tool. The tables were agreed upon by the ECHA consumer expert group comprised of representatives of ECHA, ECETOC, RIVM, BfR, INERIS and the Danish EPA during 2008-2009. The Table R.15- 3 also provides cross references between ACs as provided in Chapter R.12 and a list of AC subcategories proposed by ECETOC for the assessment.

Table R.15- 2: 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
PC: Air care product	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

Descriptor	Product Subcategory
	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)

Table R.15- 3: Article Categories addressed in the consumer TRA and cross reference to Article categories reported in *Chapter R.12*

Descriptor	Article subcategory (ECETOC)	Article category (Chapter R.12)
AC5:Fabrics, textiles and apparel	Clothing (all kind of materials), towel	AC5f1: Fabrics, textiles and apparel : articles with intense direct dermal con-

Descriptor	Article subcategory (ECETOC)	Article category (Chapter R.12)
		tact during normal use: clothing
	Bedding, mattress	AC5f2: Fabrics, textiles and apparel : articles with intense direct dermal contact during normal use: bedding and mattresses
	Toys (cuddly toy)	AC5b: Fabrics, textiles and apparel : toys intended for children's use (and child dedicated articles)
	Car seat, chair, flooring	AC5e: Fabrics, textiles and apparel : furniture & furnishing, including furniture coverings Or AC5a: Fabrics, textiles and apparel : large surface area articles
AC6: Leather articles	Purse, wallet, covering steering wheel (car)	AC6g: other leather articles
	Footwear (shoes, boots)	AC6f: Leather articles : article with intense direct dermal contact during normal use
	Furniture (sofa)	AC6e: Leather articles : furniture & furnishing, including furniture coverings
AC8:Paper articles	Diapers	AC8f1: Paper articles: articles with intense direct dermal contact during normal use: personal hygiene articles
	Sanitary towels	AC8f1: Paper articles: articles with intense direct dermal contact during normal use: personal hygiene articles
	Tissues, paper towels, wet tissues, toilet paper	AC8f1: Paper articles: articles with intense direct dermal contact during normal use: personal hygiene articles

Descriptor	Article subcategory (ECETOC)	Article category (Chapter R.12)
	Printed paper (papers, magazines, books)	AC8f2: Paper articles: articles with intense direct dermal contact during normal use: printed articles with dermal contact in normal conditions of use
AC10:Rubber articles	Rubber handles, tyres	AC10e: Rubber articles: furniture & furnishing, including furniture coverings Or AC10g: other rubber articles
	Flooring	AC10a: Rubber articles: large surface area articles
	Footwear (shoes, boots)	AC10f: Rubber articles: article with intense direct dermal contact during normal use
	Rubber toys	AC10b: Rubber articles: toys intended for children's use (and child dedicated articles)
AC11:Wood articles	Furniture (chair)	AC11e: Wood articles: furniture & furnishings
	Walls and flooring (also applicable to non-wood materials)	AC11a: Wood articles: large surface area articles
	Small toys (car, train)	AC11b: Wood articles: toys intended for children's use (and child dedicated articles)
	Toys, outdoor equipment	AC11f: Wood articles: articles with intense direct dermal contact during normal use
AC13:Plastic articles	Plastic, larger articles (plastic chair, PVC-flooring, lawn mower, PC)	AC13a: Plastic articles: large surface area articles Or AC13e: Plastic articles: furniture &

Descriptor	Article subcategory (ECETOC)	Article category (Chapter R.12)
		furnishing, including furniture coverings Or AC13g: Other plastic articles
	Toys (doll, car, animals, teething rings)	AC13b: Plastic articles: toys intended for children's use (and child dedicated articles)
	Plastic, small articles (ball pen, mobile phone)	AC13f: Plastic articles: articles with intense direct dermal contact during normal use

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Appendix R.15.2 Calculation of exposure – General algorithms

Different Tier I algorithms are presented in this appendix:

Inhalation: Tier 1 assessment assumes that all of the substance is released as a gas, vapour or airborne particulate into a standard room. This may be due to direct release or to evaporation from a liquid or a solid matrix, such as articles.

Dermal, two options:

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

Oral, two options:

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

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, such as articles (e.g. wall wooden panels, PVC flooring). In the latter 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/m³) must be estimated; the inhalatory dose (mg/kg body weight/day) can then 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 or article will be released at once into the room and there is no ventilation. Please note that this tool has not yet been validated for use with nanomaterials (NMs). If the output of the model is used to estimate exposure for NMs, this should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation. The two essential parameters used that the assessor should know are:

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

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

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

When the inhalable and/or respirable fraction is known, it should be taken into account. If the product contains releasable nanomaterials then the assumption should be made that it is entirely within the respirable fraction if not otherwise known. The non-respirable fraction can be swallowed and oral exposure may also need to be considered (see Equation R.15- 8 and Equation R.15- 9, 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:

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

Table R.15- 4: Explanation of symbols for inhalation exposure

Input parameter	Description	Unit
Q_{prod}	Amount of product/article used	[g]
Fc_{prod}	Weight fraction of substance in product/article	[$g \cdot g_{prod}^{-1}$]
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.15.5.

Dermal exposure

Dermal scenario A: Instant application of a substance contained in a mixture

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 unit 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:

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

and the external dose Dder as:

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

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 rather on the concentration of the substance in the mixture 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:

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

The total dermal load L_{der} is then calculated using:

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

The dermal dose is then derived as:

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

Table R.15- 5: Explanation of symbols for dermal scenario A

Input parameter	Description	Unit
C_{prod}	Concentration of substance in product before dilution	[g·cm^{-3}]
D	Dilution factor (If not diluted, D =1)	[-]
RHO_{prod}	Density of product before dilution	[g·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·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·kg$_{bw}^{-1}$·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 also apply 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;

Example R.15- 1: 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 (C*prod* = 0.1 in Equation R.15- 5).

Exposure is calculated for a situation in which 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/cm^3.

$L_{der} = C_{der} \cdot TH_{der}$ (Equation R.15- 6 is applied to derive the dermal load to skin (L_{der}) by multiplication of 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- 5).

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

In a Tier 1 scenario, default parameters leading to worst-case assessment are applied. Accordingly, the body surface area of males is assumed, but the body weight of women (60 kg, Appendix R.15.6 is applied. Table R.15- 10 in Appendix R.15.6 gives as the area of contact A_{skin}: hands (fronts and backs) for males 840 cm².

Using the $D_{der} = \frac{L_{der} \cdot A_{skin} \cdot n}{BW}$ (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 a good practice to add this as a labelling instruction for consumer use. In Tier 1 assessments, exposure times are not taken into account.

Dermal scenario B: a substance migrating from an article

The Tier I algorithm to calculate dermal exposure (e.g. dermal dose) to substance migrating from an article is similar to the equation presented in the previous paragraph for mixtures (e.g (Equation R.15- 7)) where:

- C_{der}, A_{skin}, n is referred to the article (i.e. concentration C of the substance in the article, skin surface A in contact with the article)
- TH (Thickness of product layer on skin) is generally set to 0.001 for article (instead of 0.01 for mixtures)

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
Amount ingested: the total amount of product swallowed

Oral scenario A: exposure of a substance in a product during normal use

The concentration in the product as swallowed is calculated from:

$$C_{oral} = = \frac{C_{prod} \cdot 1000}{D} = \frac{RHO_{prod} \cdot Fc_{prod} \cdot 1000}{D} = \frac{Q_{prod} \cdot Fc_{prod} \cdot 1000}{V_{prod} \cdot D}$$ **Equation R.15- 8**

and the oral dose is then given by:

$$D_{oral} = \frac{F_{oral} \cdot V_{appl} \cdot C_{oral} \cdot n \cdot 1000}{BW} = \frac{Q_{prod} \cdot Fc_{prod} \cdot n \cdot 1000}{BW}$$ **Equation R.15- 9**

If an undiluted product is swallowed, D = 1.

Table R.15- 6: Explanation of symbols for oral scenario A

Input parameter	Description	Unit
C_{prod}	Concentration of substance in product before dilution	[g·cm^{-3}]
D	Dilution factor	[-]
RHO_{prod}	Density of product before dilution	[g·cm^{-3}]
Q_{prod}	Amount of product before dilution	[g]
Fc_{prod}	Weight fraction of substance in product before dilution	[g·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	**Description**	**Unit**
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.

For some products, exposure due to hand mouth contact can be calculated (e.g. finger paints). The volume of product swallowed is related to the oral contact area A_{skin} and the thickness of product layer TH 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.

Oral scenario B: exposure of a substance in an article during normal use

The Tier I algorithm for oral exposure to substance in an article is similar to those presented for a product. The only difference is how the amount (or volume) of product migrating from article and being ingested (Q_{prod} or V_{prod} in the previous algoritms) is calculated.

The volume of product swallowed is calculated based on the article area in contact with the mouth A_{skin} (default 10 cm2) and the thickness of article layer TH 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_{prod} (volume product swallowed) = A_{skin} x TH **Equation R.15- 10**

Appendix R.15.3 Valuable sources on exposure data

The EIS-Chemrisks-Toolbox for documentation of exposure

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 among experts from industry, agencies, scientific institutions and other stakeholders on any exposures. 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 initially been fed with more than 450 exposure scenarios, based on source documents from, for example, the existing chemicals regulation, the HERA project, and from other separated research projects. The database is searchable *inter alia* for chemical agents, product categories, CAS-numbers, exposure pathways and risk management measures.

Access to the EIS-Chemrisks database is available via http://web.jrc.ec.europa.eu/eis-chemrisks/toolbox/.Access to the database is enabled by 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- 7 below, including references to the relevant literature.

Table R.15- 7: Possible types of release from substances in a mixture 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 & Tichenor, 1998), (Gmehling, et al., 1989) (Sparks, et al., 1996)). 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 for 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 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. Numerous other 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 & Chen, 1992) (Evans, 1996), (Guo , et al., 1996), (Guo, et al., 1998), Tichenor et al. (1993), (Sullivan, 1975), (Van Veen, et al., n.d.), (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-term uses (cleaners, liquid soaps), and rarely long-term contacts (e.g. lotions) with high frequency. There are some publications that have evaluated dermal exposure: (Howes, 1975) (Kasting & Robinson, 1993), (Thongsinthusak, et al., 1999), as well as dermal absorption: (Weegels & Van Veen, 2001), (Wilschu, et al., 1995). Dermal exposure may also be estimated by the use of computer programs e.g. ConsExpo, MCCEM. Models of dermal exposure by contact with fluids have been evaluated by (McKone & 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 modelling by (McKone, 1990) and (McKone & Howd, 1992)	Contact of skin with solid articles leads to dermal exposure and, sometimes to oral exposure by direct oral contact.
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). Computer program that cover this scenario is the RIVM Emission Model	Migration from articles may lead to inhalation exposure as well as to dermal and oral exposure.

Spraying	Exposure to clouds of substances due to the use of spray, whereby the cloud distributes into the total room volume after finishing spraying. Exposure may occur via inhalation and via dermal route. It is valid for a number of applications of consumer products e.g. adhesives, paints, cleaners, deodorizers, air fresheners, cosmetics. 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 Adsorption of substances (in particular non-volatiles) to dust particles Data that may be useful for estimating exposure to solid particles has been published e.g. 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 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.

1
2

1 **Table R.15- 8: Further information**

Acro-nym	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	DE	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	DE	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
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	DE	National industrial association, focus on paints, lacquers	www.farbeundlack.de

Acro-nym	Full name	Country	Remarks	Contact
IKW	Industrieverband Körperpflege und Waschmittel	DE	National industrial association, focus on household preparations (mixtures)	www.ikw.org
IVA	Industrieverband Agrar	DE	National industrial association, focus on agricultural preparations (mixtures)	http://www.iva.de
JRC-IHCP	European Exposure Factors (ExpoFacts) Sourcebook (based on CEFIC-LRI project)	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
	The Danish EPA	DK	Study reports on chemicals in consumer products and articles	http://www.mst.dk/English/
ChEmiTecs	Swedish EPA	SWE	Research and studies on emission of organic chemicals from articles	http://www.chemitecs.se/
Kemikalieinspektionen	Kemi	SWE	Webpage on mass flow analysis of substances, statistics on use of chemicals in Sweden	http://www.kemi.se
PR-D	Product data base according to regulations of chemical law	DE	Product information	Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin, Germany 49 1888 412 0

Acro-nym	Full name	Country	Remarks	Contact
PR-FIN (KETU)	Finnish product register	FIN	Product information	www.valvira.fi
	Climate and Pollution Agency	NO	Webpage on various substances found in articles	http://www.klif.no
	Finland's environmental administration	FIN	Information of substances in textiles can be found here	http://www.ymparisto.fi/
DTU	Food. National food institute	DK	Information on migration from food packet materials.	http://www.food.dtu.dk
OECD	OECD Task Force exposure assessment		Work on consumer exposure ongoing	http://www.oecd.org/chemicalsafety/assessmentofchemicals/oecdactivitiesonexposureassessment.htm
EPHECT	VITO	BE	EU Project on consumer products to be potential sources of hazardous air pollutants in dwellings.	https://esites.vito.be/sites/ephect/Pages/home.aspx
RIVM	Emission tool report	NL	Information on emissions from articles related to consumer exposures	http://www.rivm.nl/dsresource?objectid=rivmp:24644&type=org&disposition=inline
PR-S	Swedish product register	S	Product information	www.kemi.se
PR-D	Danish product register	DK	Product information	http://www.at.dk/

Acro-nym	Full name	Country	Remarks	Contact
SPIN	Nordic SPIN database	NO, SE, DK, FI, IS	Product information from the Nordic product registers	www.sft.no www.kemi.se http://www.at.dk/ www.valvira.fi www.vinnueftirlit.is
RefXP	Exposure Factors Database Umweltbundesamt	DE	Update of AUH data with probabilistic focus	http://www.umweltbundesamt.de/service-e/uba-datenbanken-e/index.htm
RIVM	(te Biesebeek, et al., 2014)	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	DE	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 are based on 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.15.5.1) are based on a one room lay-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 in 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 the guidance text, namely ECETOC TRA (Section R.15.4), ConsExpo (Section R.15.5.1) and other tools such as RIVM Emission tool (Section R.15.5.2).

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 for which the mathematical emissions model does not apply, emissions data can be entered manually.

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 inter-zonal 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 inter-zonal 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, inter-zonal 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 parameters 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

INTERA – Cefic LRI Program

The INTERA computational platform is a web-based computer program that was developed in the framework of the CEFIC Long-range Research Initiative (LRI) funded INTERA project. It was developed to enable the exposure assessment of compounds in indoor settings over the "full-chain". The program offers a number of exposure models and a database containing several types of data. The data includes human physiological parameters, emission data from consumer products and from indoor concentration levels, and building characteristics. An exposure assessment in INTERA is a step-by-step process, starting with the basic information on chemical, products and the exposed population. Subsequently, suitable models are selected per exposure route, according to the product usage scenario.

All models for oral, dermal and inhalation route can be considered as higher tier models where for example release rates from products or sources is a requested input in the models. Moreover, most of the equations have been set in such way that they describe the internal exposure all as a function of time.

The model needs information on the substance of interest, the exposed subjects and residential settings and on the specific scenario. A scenario does not necessarily involve a consumer product or article and therefore the information requested is dependent on the scenario, following a step-wise approach. The input requested and not included in the database are substance-material specific release factors, such as the migration/release rates from products (oral and dermal), emission rates (inhalation), and concentrations in matrices (dermal and oral), this means that no default values are available for these parameters. Fraction absorbed from ingested quantities may also be requested from the user. Data included in the databases are human physiological data, residential settings and certain scenario parameters such as exposure durations, frequencies of use and skin areas contacted. For a number of substances, exposure information, e.g. indoor air concentrations of volatile substances are included in the database.

The output is given in amount of chemical taken up by the body as a function of time (µg/h or in mg/kg bw/d). Input and output can be presented as distributions. The user has the option to generate graphical representations of the exposure.

The driving factors for exposure are the concentrations in the matrices, the migration from the matrices and the duration of contact. If the internal exposure is calculated using a fraction, e.g. in case of ingestion where not all substance ingested will be taken up, then the fraction also is considered a driving factor for exposure. One of the basic assumptions is that the release from the matrices is constant over time, once contacted. In other words, the release of a substance is considered independent of its concentration in the matrix and no depletion of substance takes place (oral and dermal exposure). Diffusion process in materials is not taken into account. Regarding the air concentration, it is assumed that equilibrium will be reached immediately.

Uncertainty analyses are possible, since the use of distributions and Monte-Carlo Markov chain technique.

The INTERA computational platform is currently online at: http://www.intera.cperi.certh.gr/
The platform contains a user guide from which information can be obtained about the platform itself and the data and models that are included.

BAMA/FEA Indoor Air model

The BAMA Indoor Air Model is a simple but powerful tool, developed by British Aerosol Manufactures Association (BAMA) and European Aerosol Federation (FEA) that can be used to predict the concentration of aerosol components within a room after a suitable time interval after spraying. The Model can be used to rapidly generate predicted air concentrations for a wide range of use conditions for spray products. The model is particularly useful for generating time weighted values for estimating longer term exposure, for example longer than 90 minutes. Validation work shows that by that time, the volatile ingredients and aerodynamically stable particle (less than 10 μm) are well mixed in modelled volume (i.e. room) and larger particle have dropped out. Therefore, the model can be used to generate reliable estimates for exposure lasting more than 2 hours.

On the other hand, the tool has an important limitation when applied to the assessment of short term exposure, for example during the application of the spray product, since the model assumes an immediate and perfect mixing within the modelled room volume; in particular, for products sprayed away from the body or on horizontal surfaces, BAMA model is likely to overpredict short term exposure because the breathing zone will be outside the spray clouds. on the contrary, for products sprayed at the body or on vertical surfaces, the breathing zone will be in the spray cloud and the model will lead to an underestimation of the short term exposure.

Key parameters to run the model are: room volume, ventilation rate, ingredient fraction, discharge rate of the spray, duration of the spray.

The output parameters are different averaged air concentrations: 15 minutes, 4, 8, 16 and 24 hours averaged air concentrations in the room. Also exposure profile of the air concentration is given by the tool; it is also possible to model multiple spray events during one day.

The model is freely available at: http://www.bama.co.uk

Appendix R.15.5 Development of ECETOC TRA Consumer tool and comparison with Tier 1 Algorithms

ECETOC TRA Consumer tool version 2 (ECETOC, 2009) was the result of a substantial revision of the previous version TR 93 (ECETOC, 2004) TRA version 2 combined the conservatism of first Tier assessment tool with the expert knowledge documented in the RIVM fact sheets (see RIVM, http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp#Fact_sheets and Section R.15.4.3). It used default values taken from the RIVM fact sheets (except for the cases when no such value is available); main differences between ECETOC TRA consumer version 2 and the Tier 1 algorithms documented in Appendix R.15.2can be summarised as follow:

- 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 mixtures 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 ECETOC TRA Consumer tool version 2 aimed to balance the Tier 1 assumptions and the generic applicability to a wide range of product categories in order to deliver reasonably plausible outcomes. For each product use category a rationale is available that justifies the basis of the default values and assumptions.

In 2012 ECETOC released the TRA Consumer version 3.0 where some refinement of the exposure have been made possible, while keeping the same structure (based on product or article category and subcategories) and algorithm of the version 2; these refinement are summarised here below:

- The calculation of saturated vapour concentration as the upper bound value of concentration of substance in air of the room is applied to all of the inhalation scenarios for non-spray products.
- Inhalation exposure estimates account for basic ventilation (default value of 0.6 air exchange per hour) in the standard room (20 m^3).
- Dermal and oral transfer factors have been introduced to potentially reduce dermal and oral exposure. By default transfer factors are set to 1, assuming 100% of the substance is available for oral and dermal exposure; users with relevant, specific information or knowledge on the pattern of transfer of a substance from a product or article matrix to skin or mouth might reduce oral or dermal exposure by means of transfer factors.

In 2014 ECETOC released the TRA Consumer version 3.1, which incorporates all the changes mentioned above, with the possibility (already present in version 3.0, but now revised) for the user to create a new (sub)product or article category, setting all input parameters. This option has been introduced to support the creation of SCED (Specific Consumer Exposure Determinants) which are described in detail in Section R.15.4.4. The user, only while creating a new (sub)category, can also set the following new input parameters having an impact on the calculation of consumer exposure:

- The inhalation transfer factor (by default set to 1) in order to reduce the amount released to air during the use of the product or article; the user is advised to deviate from the default only when specific information supporting the choice is available.
- Select the outdoor scenario for consumer exposure; if selected, the “room” volume (100 m^3) and ventilation (2.5 air exchanges per hour) are increased compared to the indoor scenario, reducing the estimated air concentration.
- For short term and infrequent uses, is now possible to introduce a frequency over the

year less than once per day, reducing the exposure estimation according to a factor depending on bands set by ECETOC. These bands are defined as follow: frequent uses (at least once a week, no reduction of exposure), occasional uses (between once a week and once a month), infrequent uses (between once a month and once every six month) and very infrequent uses (no more than once every six month).

The differences between generic Tier I algorithms (Appendix R.15.2) and ECETOC TRA Consumer tool (v.2, v.3.0 and v.3.1) are summarised in the table below.

Table R.15- 9: Differences between Tier I algorithms and ECETOC TRA consumer

Route of exposure	ECETOC TRA v. 2	ECETOC TRA v. 3.0	ECETOC TRA v. 3.1
Inhalation	Modifying factor for inhalation according to VP bands for VP <10 Pa	Modifying factor for inhalation according to VP bands for VP <10 Pa	Modifying factor for inhalation according to VP bands for VP <10 Pa
		Basic ventilation rate taken into account to reduce air concentration in standard room	Basic ventilation rate taken into account to reduce air concentration in standard room
		Upper bound for air concentration based on saturated Vapour concentration	Upper bound for air concentration based on saturated Vapour concentration
			Inhalation transfer factor introduced. Unless default is used (=1), this reduces air concentration*
			Possible to select that use takes place outdoor, which reduces air concentration compared to indoor uses*
			Reduction of the exposure by frequency over the year according to frequency bands (occasional, infrequent, very infrequent)*

Dermal	For exposure to article, the thickness of layer is set to 0.001 instead to 0.01	For exposure to article, the thickness of layer is set to 0.001 instead to 0.01	For exposure to article, the thickness of layer is set to 0.001 instead to 0.01
		Dermal transfer factor introduced. Unless default is used (=1), this reduces dermal dose	Dermal transfer factor introduced. Unless default is used (=1), this reduces dermal dose
			Reduction of the dose by frequency over the year according to frequency bands (occasional, infrequent, very infrequent)*
Oral		Oral transfer factor introduced. Unless default is used (=1), this reduces oral dose	Oral transfer factor introduced. Unless default is used (=1), this reduces dermal dose
			Reduction of the dose by frequency over the year according to frequency bands (occasional, infrequent, very infrequent)*

1 * Only possible when creating new (sub)product or article category

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Appendix R.15.6 Data references

Description of people's 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

To perform the calculations with the equations given in Appendix R.15.2 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 & van Veen, 2000), (te Biesebeek, et al., 2014) as well as for the US (AIHC, 1994); (US EPA, 1997); (US EPA, 2011)

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); (US EPA, 2011) in Standards zur Expositionsabschätzung (AUH, 1995), as well as in the RIVM publication "General fact sheet" (Bremmer, et al., 2006), (Bremmer & van Veen, 2000), AND (te Biesebeek, et al., 2014).

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- 11**

The mean of body surfaces, given for adult men and women, and referred to the different body parts, are given in Table R.15- 10. For females, it was anticipated that the ratio of body part surfaces to total body surface is similar to that for men. According to a report from the German Ausschuss für Umwelthygiene the 50th 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- 10: Default values for body part surface areas for the infant, toddler, child & adult (US EPA, 2011)

	INFANT	TODDLER	CHILD	ADULT
	irrespective of gender	irrespective of gender	irrespective of gender	irrespective of gender

	(based on female 6 to <12 months old)	*(based on female 1 to <2 years old)*	*(based on female 6 to <11 years old)*	*(based on female 30 to <40 years old)*
Body Part Surface Areas				
Hands (palms and backs of both hands)	196.8 cm^2	230.4 cm^2	427.8 cm^2	820 cm^2
Arms (both)	Upper = 352.6 cm^2 Lower = 229.6 cm^2 **Total** = 582.2 cm^2	Upper = 412.8 cm^2 Lower = 268.8 cm^2 **Total** = 618.6 cm^2	Upper = 772.8 cm^2 Lower = 496.8 cm^2 **Total** = 1269.6 cm^2	Upper = 1141.2 cm^2 Lower = 1128.8 cm^2 **Total** = 2270 cm^2
Head	344.4 cm^2	403.2 cm^2	529 cm^2	1110 cm^2
Trunk (bosom, neck, shoulders, abdomen, back, genitals and buttocks)	1533.4 cm^2	1795.2 cm^2	3376.4 cm^2	5710 cm^2
Legs (both legs and thighs)	1041.4 cm^2	1219.2 cm^2	2741.6 cm^2	5330 cm^2
Feet (both)	246 cm^2	288 cm^2	604.9 cm^2	1130 cm^2
Total body surface area	4100 cm^2	4800 cm^2	9200 cm^2	16600 cm^2

Respiration volume

For performing calculations with the equations given in Appendix R.15.2 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 do not necessarily maintain the same level of activity during the use of consumer products, nor for the whole day. Hence it may be necessary to adapt the default respiration rates for short-term or long-term exposures, the latter taking into account 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- 11: 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- 12: Respiration volume (m^3/day) for short-term exposures (AUH, 1995)

Subject	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- 13: 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 a 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- 14 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- 14: Room volumes (m³) 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 & 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 m³. 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 & van Veen, 2000), and (Klobut, 1993). The US-EPA lists 0.18 h^{-1} as a conservative estimate for room air ventilation. This value represents the 10^{th} percentile of a number of studies performed throughout the US (US EPA, 1997). For The Netherlands, room ventilation varies between 0.5 and 2.5 (h^{-1}), depending on the room (Bremmer, et al., 2006), (Bremmer & van Veen, 2000). According to evaluations made in a test house by (Guo, et al., 1998) 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.

Appendix R.15.7 Demonstration of control of risks for Articles

The specifications for control of risks from substances in articles as outcome of the CSA can be expressed as exposure by a pathway (or any combination of pathways) that is below the DNEL.

The safety of an article for screening purposes can be demonstrated with worst case assumptions. For human exposure estimation, e.g. for oral exposure, it could be assumed that all of the substance contained in the article is released instantaneously and is available for oral exposure. If this does not lead to exceeding the DNEL for oral exposure, control of risks can be assumed.

Another approach for human exposure estimation of articles is to derive specific concentration limits (CL) for oral exposure (Van Engelen et al., 2006), based on the DNEL. By re-arranging the Tier 1 equations for oral exposure, it is possible to calculate the content limit as the concentration (mg/kg article material) in the article, assuming the entire article is swallowed (mostly applicable to small articles easily swallowed):

$$CL\left(\frac{\text{mg}}{\text{kg}}\text{article}\right) = \frac{\text{DNEL} \cdot \text{BW}}{\text{Atot} \cdot \text{v}}$$

Equation R.15- 12

Table R.15- 15: Explanation of symbols for CLs for oral exposure for substances in articles

Parameter	Description	Unit
DNEL	Derived No-Effect Level	[mg.kg bw-1.d-1]
BW	Body weight	[kg]
Atot	Total article weight (all ingested)	[kg]
v	use frequency = mean number of (ingestion) events per day	[d-1]

The body weight used should reflect the body weight of the population at risk, e.g. when assessing toys used by children. For further information on body weights, see Appendix R.15.6.

In analogy to methodologies used at EFSA for calculating release limits for food contact materials, it is also possible to calculate specific migration limits (SML) for oral exposure in mg/kg article material. The SML is based on the assumption that a maximum amount of article is ingested per day (Aingested) and all of the substance in the ingested amount

of article is available for oral uptake.

The SML that does not lead to exceeding the DNEL is then calculated as:

Equation R.15- 13

$$SML\left(\frac{mg}{kg}article\right) = \frac{DNEL \cdot BW}{Aingested \cdot v}$$

Table R.15- 16: Explanation of symbols for SMLs for oral exposure for substances in articles

Parameter	Description	Unit
DNEL	Derived No-Effect Level	[mg.kg bw^{-1}.d^{-1}]
BW	Body weight	[kg]
$A_{ingested}$	Article weight that is ingested per event	[kg]
v	use frequency = mean number of (ingestion) events per day	[d^{-1}]

Migration limits can also be expressed on an area basis [mg.kg-1.cm-2]. If risks are not controlled, product-integrated risk management measures or other RMM can be implemented to reduce the substance losses from the articles to humans or the environment. See Part D.