DRESS GUIDANCE DOCUMENT FOR ASSESSMENT OF DERMAL EXPOSURE OF CONSUMERS TO SUBSTANCES IN ARTICLES: SUGGESTIONS FOR REFINEMENTS OF ECETOC TRA / IMPROVEMENTS FOR THE DERMAL EXPOSURE ASSESSMENT STRATEGY

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SUMMARY

Dermal exposure is an important exposure route in regulatory risk assessment of consumer products and articles, as described in the REACH Regulation (EC No 1907/2006) and the Biocidal Products Regulation (EU) No 528/2012. The REACH Guidance recommends a tiered approach for (consumer) exposure assessment. For a first tier, aimed at screening, conservative methods, assumptions and data should be used to ensure that exposure and risk are not underestimated. For a Tier 1 estimation of dermal exposure of consumer, the ECETOC TRA (v3) modelling approach is available, which is intended to be conservative and is largely based on defaults. Higher tier models (e.g. ConsExpo, SprayExpo) are assumed to be able to calculate more realistic exposure estimates, although these models are more tailored towards dermal exposure to substances in products, and not to substances in articles. The lack of higher tier dermal exposure models to estimate exposure to substances from articles is not surprisingly given the scientific gaps in the understanding and quantification of the processes leading to release of substancesfrom articles and subsequent transfer to the skin (Clausen et al., 2014). Notwithstanding the fact that it is currently not yet possible to construct a widely applicable and validated higher tier dermal (consumer) exposure model for substances in articles, there are several options to on how to predict dermal exposure to substances beyond the defaults based ECETOC TRA approach.

This report aims to provide guidance on how to perform dermal an exposure assessment to estimate dermal exposure of consumers to substances from articles, based on and beyond the Tier 1 ECETOC TRA approach.
The guidance is intended to be generic in use for a broad range of articles. However, examples and parameterization of article-specific parameters are tailored towards the 3 article groups selected within the scoping phase of the DRESS project, namely textiles, PVC flooring and printed paper. For these article groups, experimental data was collected (WP 3.2) and consumer surveys were performed (WP3.1), allowing for the parameterization of the proposed approaches for dermal exposure assessment to substances in articles.

In **the first part of this report**, the ECETOC model and its underlying parameters for dermal exposure are highlighted, since this model is used as the starting point of dermal exposure assessment to consumer articles. From the equations underpinning the ECETOC TRA dermal consumer module for articles, it was derived that the (only) assumed mass transport process considered for dermal exposure to substances in articles is instantaneous emission of substances from articles into the skin contamination layer. This assumption can be regarded as a worst case approach for substances in articles, since release of substances from articles in general is a rather slow and not an instantaneous process. Thus a refinement of the ECETOC TRA approach by accounting for duration of contact and release could be considered as a way to generate more realistic predictions for dermal exposure to substances in articles.

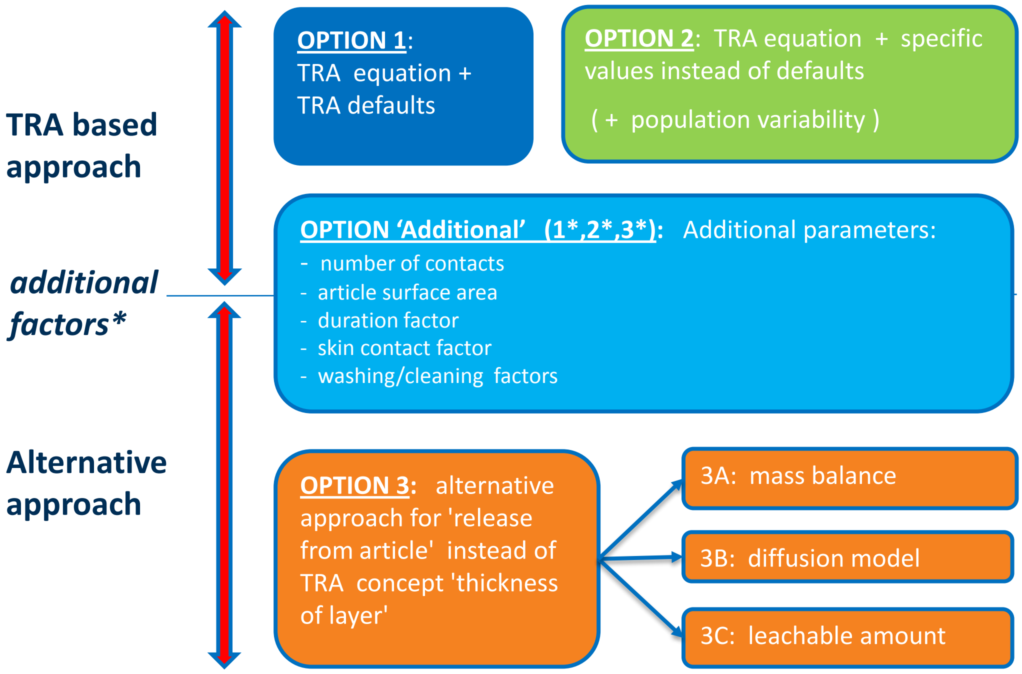
An analysis was made of the ECETOC TRA parameter values, in terms of support for defaults for the ECETOC TRA parameters, based on information from existing databases, including new data generated during the DRESS project. In general, the gathered data underpinned the conservative nature of the ECETOC TRA defaults for Skin Contact Area (CA), Body weight (BW), Frequency of Use (FQ) and Density (D) and Transfer Factor (TF). However, for one of the ECETOC TRA parameters, namely the 'thickness of contact layer' (TL), no data underpinning the ECETOC TRA default values could be found. This data inventory of TRA parameter values allowed for the derivation of specific values for TRA parameters, namely i) for population subgroups (age/gender/region) for the parameters CA and BW, and ii) specific

values for FQ and D for the three article groups (textiles, printed paper and PVC flooring) that were included in the consumer survey of the DRESS project (IPSOS, 2014). Specific values for TF were limited to a few combinations of chemical/articles groups tested in the DRESS project, and could not be generalized to other situations. Therefore, in many situations one has to rely on the default value for TF.
These specific values for TRA parameters can be used in the unmodified ECETOC TRA equation. The use of specific values instead of defaults for TRA parameters may enhance the accuracy of dermal exposure predictions.

In a **second part of the guidance,** possible additional factors and alternative approaches compared to the TRA equations are described.
Possible 'additional' factors are factors which may be used in combination (by multiplying) with the ECETOC TRA outcome; in essence, applying these factors does not alter the ECETOC TRA concept. Rather, these factors serve as a kind of refinement, and account for dermal exposure modifying factors which are not taken into account in the (current) ECETOC TRA equation for reasons of simplicity. These additional factors are compatible with the ECETOC TRA approach. An example of such additional factors are reduction factors forcleaning/washing. Also, additional factors for dealing with very short and frequent contacts between skin and articles are proposed, since these types of contacts are poorly addressed by ECETOC TRA as such. In addition, additional factors for dealing with articles for which the *skin Contact area* is considered to be a poor or even inadequate proxy for the article contact area are described in the Guidance (e.g PVC flooring or printed paper). Whenever possible, parameter values for such additional factors are listed in this report, or suggestions were made on how to gather data for parameterization for these factors.

A second type of alternative approaches deals with how to estimate *the amount of substance released* from an article during an exposure event. These approaches serve as a potential replacement for the '*thickness of layer* concept' of the ECETOC TRA equation for dermal exposure, for which we failed to underpin the ECETOC TRA defaults, and cannot find a way to measure directly. The alternative approaches for assessing the release of substances from articles include a very simple mass balance approach (tier 0), a diffusion-based model (tier 1) and estimated release based on extraction in artificial sweat (tier 2). The diffusion-based modeling concept is widely used in the field of emission from substances to indoor air and migration of substances from food packaging materials, and is also recently suggested by Delmaar et al. (2013) for application in the field of dermal exposure to substances from articles. In the higher tier approach, the use of experimental testing using artificial sweat extracts for estimating release of substances from articles to skin is described. This part of the Guidance describes the equations and its parameters of the alternative approaches, together with parameter values (and methods to estimate the parameter values such as diffusion coefficient) for the 3 article groups (textiles, printed paper and PVC flooring). In addition, limitations and data input required of the alternative approaches are discussed.

A schematic representation of the strategy as presented in the Guidance on refinements of the dermal exposure predictions based on the ECETOC TRA model is given below.



** additional factors might be used in combination with either the TRA-based approach or the alternative approach for assessing release from article*

Finally, the Guidance is demonstrated in three **case studies** (namely textiles, printed paper and PVC flooring), comparing for each of the case study the outcomes of 1) the default ECETOC TRA approach, 2) the ECETOC TRA approach by replacing the default valueswith specific parameter values, 3) incorporation of additional factors not included in the ECETOC TRA approach, and 4) alternative approaches for assessing release of substances from articles. Although the outcome of this excercise cannot be generalized beyond the investigated cases studies, it was observed that in general replacing defaults by specific values resulted in moderate changes (one order of magnitude) in outcome compared to the default based ECETOC TRA approach. When assuming that specific information on product ingredient will be available, there was a small impact of changing default values for by specific values for body weight and contact area, and a moderate impact for density and frequency of use. The largest impact (> 100 fold) was reached by replacing the default TF value by an article/substance specific value (in case of printed paper). Replacing the ECETOC TRA approach for release by alternative approaches to estimate the release of substances from articles (diffusion model based and sweat extractable approaches) resulted in exposure predictions up to 1000 fold lower than the default ECETOC TRA approache. In some situations the diffusion based model resulted in lower exposure estimates than the ECETOC TRA 'thickness of layer approach, while in other situations (for cases with high diffusion coefficients), the opposite trend was observed.

Obviously, increased efforts in experimental testing (for instance measuring artificial sweat extractable amounts or deriving an article-specific transfer factor) will lead to significantly lower estimated dermal exposure levels than when 'default' ECETOC TRA estimates would be performed.

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LIST OF ABBREVIATIONS

AC	Article Category
ASRA	Amount of substance released from article per unit area during an exposure event
CA	(skin) Contact Area
D	Density
$D_{(diff)}$	Diffusion coefficient
DF	Duration Factor
ECETOC TRA	ECETOC Target Risk Assessment Tool
FQ	Frequency of use
n_c	Number of contact
PC	Product Category
PI	Product Ingredient
SA	Total surface of article in contact with the skin
SA_c	average *surface area of article in contact with skin* per contact
SAF_{new}	Surface area factor for new contact
TL	Thickness of layer

1 INTRODUCTION

Dermal exposure is an important exposure route in regulatory risk assessment of consumer products and articles, as described in the REACH Regulation (EC/1907/2006) and the Biocidal Products Directive (98/8/EC). Various tools are used to model or measure dermal exposure and these results are amongst others used by risk assessors during the registration process.

Due to the very limited information, the degree of conservatism in the existing dermal exposure models is poorly characterized and may vary from one situation to another (ICPS, 2010). In addition, there is currently little consistency in the development and use of exposure models (Fryer et al., 2006), provoking the need for greater standardization.

The REACH Guidance recommends a tiered approach for (consumer) exposure assessment. For a first tier, aimed at screening, conservative methods, assumptions and data should be used to ensure that exposure and risk are not underestimated. For a Tier 1 estimation of dermal exposure of consumer the ECETOC TRA (v3) is available, which is intended to be conservative and is largely based on defaults. Higher tier models (e.g. ConsExpo, SprayExpo) are assumed to be able to calculate more realistic exposure estimates, although these models are more tailored towards dermal exposure to substances in products, and less to substances in articles. Mechanistic understanding, and especially quantification of the processes playing a role in dermal exposure to substances in consumer articles is poorly available. Knowledge is specifically limited in relation to migration and transfer factors (e.g. *release rate* of substances from articles, *transfer rate* of the released substances to the skin), and use patterns of products and articles, and how the latter affect and could be integrated in dermal exposure predictions.

In order to overcome these shortcomings and to better understand and quantify dermal exposure for consumer articles, a refined dermal exposure modelling strategy is needed. Therefore, the main objective of the project Dermal Exposure Assessment Strategies (DRESS) is to generate data to improve the understanding of (consumer) dermal exposure, and propose improvements / refinements with regard to the dermal exposure assessment strategy, that enable better estimations of the true nature of dermal exposures.

In the scope of the project, consumer dermal exposure processes and available models were analysed (De Brouwere *et al.*, 2013), and experiments were performed on migration in and transfer from a selection of article types (namely PVC flooring, textiles and printed paper) (Clausen *et al.*, 2014).
Also, a study of use patterns of these articles types in Europe was performed via an internet survey (Ipsos Public Affairs, 2013). All these information together is used for the purpose of providing a guidance document for improved dermal exposure assessment to substances in articles. Such guidance is the subject of this report.

1.1 AIM OF THE GUIDANCE DOCUMENT

Here the results from the project are used to derive a generic Guidance document for estimating dermal exposure during consumer use of articles. Since ECETOC TRA (v3) is - to our knowledge - the only available generic modelling tool for assessing dermal exposure to articles, this model will be used as a starting point. The main goals are 1) to identify for which parameters the derivation of new 'defaults' is warranted, 2) which deviations from defaults in the current model could be proposed for specific scenario's, 3) which factors could be used in addition to the current model, and 4) which other exposure models or approaches may be used in specific situations. If possible, specific examples are given for certain article (sub)categories.

1.2 Structure of Guidance Document

In chapter 2, the ECETOC model for dermal exposure is highlighted, since it is used as the starting point of dermal exposures assessment to consumer articles. In chapter 2, implicit assumptions and simplifications of the ECETOC TRA model in relation to the complex processes behind the dermal exposure process are discussed, together with our interpretation of definitions of ECETOC model parameters, and extensions with additional parameters important for dermal exposure, but not defined in ECETOC TRA.

In chapter 3, an analysis was made of ECETOC TRA parameter values, in terms of a) support for defaults for the ECETOC TRA parameters, based on information from existing databases, including new data generated during the DRESS project, and b) options and concrete examples for replacing defaults by specific values (specific for an article, use scenario, use population). These defaults and specific values can be used in the unmodified ECETOC TRA equation.

In chapter 4, possible additions and alternative approaches compared to the TRA equations are proposed. A first type of addition deals with how to deal 1) with very short and frequent contacts between skin and articles, since these types of contacts are poorly addressed by ECETOC TRA, and 2) how to deal with articles where the *skin Contact area* is a poor or even inadequate proxy for the article contact area.

A second type of alternative approaches deals with how to estimate *the amount of substance released* from an article during an exposure event, and serves as potential replacement for the '*thickness of layer* concept', for which we failed to underpin the ECETOC TRA defaults in chapter 2, and where we failed to derive specific values in chapter 3.

In chapter 5, a strategy is presented on how to refine the outcome of ECETOC TRA based predictions for dermal exposure to substances in articles, based on data and approaches reported in chapter 3 and chapter 4.

In chapter 6, the approach is demonstrated for case studies involving 3 types of articles (clothing, printed paper and PVC flooring).

2 ECETOC TRA DERMAL CONSUMER MODEL: PARAMETERS, DEFINITIONS

2.1 GENERIC MODEL FOR ESTIMATING DERMAL EXPOSURE OF CONSUMERS DURING USE OF ARTICLES: ECETOC TRA

The currently used generic models for estimating dermal exposure of consumers are mainly ECETOC TRA (version 3; ECETOC, 2009, 2012) and ConsExpo (version 4.1 or version 5[1]; Delmaar *et al.*, 2005). Because large uncertainties exist in the assessment of consumer exposure due to contact with article matrices, and the available estimates indicate a potential of high exposures (De Brouwere *et al.*, 2013), it was decided to focus on (large) articles. ConsExpo does not provide specific model estimates for exposure to substances incorporated into article matrices, although some models for 'post application' exposure to substances applied onto matrices (e.g. cleaning agents) are available. However, for substances in articles the process of release and transfer is different than when applying substances onto matrices. Since ECETOC TRA (v3) does include specific estimates for exposure to substances in articles, the ECETOC TRA model was used as the basis.[2]

ECETOC TRAv3 consists of three separate models for estimating exposures to workers, consumers and the environment. The TRA Tool is available in two forms: as an integrated exposure/risk assessment tool covering worker, consumer and environmental exposures and as a standalone consumer exposure estimation tool. The consumer module accounts for three exposure routes, oral, dermal and via inhalation. The product and article subcategories in ECETOC TRAv3 are linked with the product categories (PC) and article categories (AC) of the use descriptor system in REACH (ECHA, 2010). The user has the possibility to build his own new subcategories.

The ECETOC TRA v3 tool is in general applied as a Tier 1 screening tool, aiming to determine whether any further detailed assessment of risks is needed. The tool is supposed to be based conservative assumptions, and requires low levels of data input.

2.1.1 ECETOC TRA DERMAL EXPOSURE ALGORTIMS

The algorithm used for calculating dermal exposure estimates in ECETOC TRA (v3) is presented in Table 1 and Equation 1.

Table 1: Algorithm for dermal consumer exposure to products and articles (ECETOC TRA v3)

Parameter	Product ingredient (g/g)	Contact Area (cm^2)	Frequency of use (events/day)	Thickness of layer (cm^2)	Density (g/cm^2)	Transfer factor (-)	Conversion factor (mg/g)	Body weight (kg))	Exposure (mg/kg/d)
Algorithm	(PI x	CA x	FQ x	TL x	D x	TF	1000) /	BW =	

[1] Version 4.0 is the last version that is completely described in a manual. Version 4.1 is the most recent fully tested version, while version 5.0 is a beta-version.
[2] This work was largely done before version 3.1 of ECETOC TRA and the accompanying report were published. The model underneath version 3.1 is however still the same as that under version 3.0.

Exposure = (PI x CA x FQ x TL x D x TF x 1000) / BW *[Equation 1]*

Where: Exposure = external exposure (mg/kg bw/day)
PI = *Product Ingredient* = fraction of ingredient in product or article (g/g)
CA = *Contact Area* = area of skin in contact with product/article (cm^2)
FQ = *Frequency of use* = frequency of exposure events (1/day)
TL = *Thickness of Layer* (cm)
D = *Density* (g/cm^3)
TF = *Tranfer Factor* (unitless)
1000 = conversion factor from g to mg
BW = body weight (kg)

Definitions and interpretations of PI, CA, FQ, TL, D and TF are given in section 2.2 (see below). Because the interpretation of parameters is dependent on the rationale behind the model and the way the parameters are used in the model, the latter aspects are briefly described before the definitions and interpretation of the parameters.
Rationale/mechanism behind ECETOC TRA algorithm

The mechanism behind the ECETOC TRAv3 dermal exposure module is not explicitly mentioned in the ECETOC TRA v3 user guide, though it can be derived from the equations underpinning the ECETOC TRA dermal consumer module that the (only) assumed mass transport process is instantaneous emission of substances from products or articles into the skin contamination layer.

A '*given amount of substances* 'is assumed to be transferable from the article or product to the skin (= exposure mass), which is approximated in ECETOC TRAv3 as the amount of the substance present in the upper layer of the article or product in contact with the skin. The volume of this upper layer is in ECETOC TRAv3 addressed as the multiplication of two factors: 1) *Thickness of layer*, 2) *skin Contact area* and the weight of this upper layer is calculated by taking account of the third factor: *Density*. Basically, it assumes a *given amount of substances* present in the product/article is transferred immediately to the skin upon contact, so that duration of release from article and transfer to the skin exposure does not play a role
Moreover, the model does not take into account the influence of other physico-chemical properties (besides density) of substances and articles on release and subsequent dermal exposure.

The Thickness of layer is a parameter that is used as a surrogate for the fact that a substance in a matrix should be migrated towards the surface of the matrix before it is available for transfer to the skin. The combination of the parameters *Thickness of layer* and *Transfer factor* can thus be considered to represent respectively the release and transfer processes in and from the article matrix.

In addition, the *Transfer factor* is expressed as unitless in the ECETOC TRAv3 model, and, in line with the ECETOC TRAv3 equations, assumes an instantaneous transfer of the transferable fraction to the skin surface. This is probably a worst case assumption. In reality, release and transfer from articles to skin depends in general on duration of the contact between article/product and the skin.

2.1.2 DEFAULTS AND USER-MODIFIABLE PARAMETERS OF ECETOC TRA DERMAL EXPOSURE MODEL

ECETOC TRA uses a number of pre-defined product/article categories and subcategories for which defaults for all parameters are provided. Some of these defaults can be changed, others are fixed values. When using the pre-defined categories and subcategories, only the parameters *Product Ingredient* and *skin Contact area* can be changed. However, the user can also define new subcategories, for which also the *Transfer factor* and the *Frequency of use* should be provided, and thus the values can deviate from the defaults. The parameter *Thickness of layer* is always provided by the tool and the values vary from 0.01 to 0.001 (usually 0.001 in case of articles). For the *Density*, a fixed default value of 1 is applied in the tool. Obviously, one could overcome the use of fixed defaults for *thickness of layer, density* and other parameters by manual calculations of the ECETOC TRA equation for dermal exposure (instead of using the tool).

In general, it is assumed that an exposure assessor will have at least some information available on the *Product Ingredient* and on the *Density* of the article. Furthermore, the relevant *skin Contact area* can be estimated based on expert judgment of the skin area in contact with articles, which is further facilitated by the option (in the creation of subcategories in ECETOC TRAv3) to choose on the basis of parts of hands (palms, full hands) instead of on the basis of cm^2, although the estimated values will be very uncertain and can vary substantially, especially for larger articles.

A new feature of ECETOC TRAv3 compared to the previous version is that a user might take a *Transfer factor* (TF) of the product/article onto the skin into account, instead of default 100 % transfer. Transfer might be affected by pressure of the contact, roughness of the material and skin, skin conditions (moisture) and physico-chemical properties of the substance (De Brouwere et al., 2013). However, no guidance is given on how to determine and select an appropriate value for *Transfer Factor*. The estimation of *Transfer Factor* and *Thickness of Layer* is considered to be extremely difficult. Only very limited information is (publically) available with regard to release and transfer factors (De Brouwere *et al.*, 2013). Furthermore, no guidance presently exists on how to translate such information into a *Transfer factor* and Thickness of Layer.
Because *skin Contact area*, *Transfer Factor* and *Thickness of Layer* are parameters with a high uncertainty and a potential large variability, it was decided to focus on these parameters and their underlying processes (*i.e.* release and transfer), and hereby providing guidance how to refine these parameters (see further).

2.2 DEFINITION AND INTERPRETATION OF PARAMETERS IN THE ECETOC TRA DERMAL EXPOSURE MODEL

The model ECETOC TRA uses a number of parameters, see the previous paragraph. Some of these parameters are not fully defined in the model or its documentation, and thus leave room for interpretation. The exact interpretation of parameters influences how they are and can be used in dermal exposure modelling, and therefore determine what options for improvement exist. Therefore, we will first explain how parameters for dermal exposure have been interpreted within this project. In view of the scope of the project we do not only look at parameters (currently) used in the ECETOC TRA model, but also at potentially relevant parameters that are at present not part of the model.

2.2.1 PRODUCT INGREDIENT FRACTION BY WEIGHT

The *Product ingredient* fraction by weight (abbreviated as PI from Product ingredient) is the weight fraction (g/g) of the substance in the article. If the article consists of different physical distinct layers, only the fraction in the article of the outer layer of the article which is in contact with skin will be considered.

2.2.2 (SKIN) CONTACT AREA

The *skin Contact area*, in ECETOC TRA also called the *Contact area* indicates the area of the skin that will be in contact with a product or an article upon its use. The values for *skin Contact area* used in the ECETOC TRA model are based on areas of body part(s) that are assumed to be in contact with the article upon use of the article (e.g. the area of the inside of two hands in case of printed paper). *Skin Contact area* depends on the product or article, but also on the age of the exposed person, more specifically on whether the person is an adult or a child. [3]

It is noticed that the ***skin** Contact area* (of body parts) and not the surface area of the ***article*** is used in the ECETOC TRA equation. Implicitly, the ECETOC TRA model assumes that the surface area of the article in contact with the skin is equal to the *skin Contact area* in touch with that article. Conceptually seen, this is not always the case, and it is not necessarily a conservative approach. For example, considering skin contact with rubber flooring, ECETOC TRA sets the surface area of article in contact with skin equal to the surface area of the exposed skin (hands and forearms); however, it is very likely that the exposed skin touches a surface area which is equal to several times the exposed skin area, considering that people move from one piece of the flooring to the next during a day of exposure. By choosing a *skin Contact area* that is larger than just the footsoles, the conservative nature of the assessment is enhanced.

In other cases, especially for articles much smaller than exposed body parts, the implicit assumption that the *skin Contact area* is equal to the *article surface area* is rather conservative. For example, *skin Contact area* for small articles (e.g. ball pen) is set equal to the area of the inside hand (one hand) (35.7 cm²).

2.2.3 FREQUENCY OF USE

Frequency of use in the ECETOC TRA model has the unit 'events per day'. Presently, none of the defaults in ECETOC TRA are above one, although there are a number of predefined subcategories in the tool for which a higher *Frequency of use* might be expected, such as diapers or cuddly toys. The report TR 107 (ECETOC, 2009), which describes version 2 of ECETOC TRA states that for some parameters: "… suitably conservative assumptions were made (e.g. for paints, it was assumed exposure occurred once daily rather than once per year as stated in the RIVM fact sheet)". The reasonable cases are partly based on a report from EPA in which all values for *Frequency of use* are in units of 'number of events per year'. Appendix G of report TR 114 (ECETOC, 2012; the description of version 3 of ECETOC TRA) indicates: "The TRA tool currently assumes product use occurs daily. In reality, however, many products are used infrequently." In the addendum to report TR 114 (ECETOC, 2014) it is clarified that *Frequency of use* can have values higher than one too: "If the number of events per day is higher than one, then the actual value is applied (2, 3, or any other as appropriate)." The combination of descriptions indicates that the *Frequency of use* should be interpreted as the number of 'periods or use' or 'use events' per day, which is not the same as the number of contacts per day.

[3] The defaults used by ECETOC TRAv3 can be found in the sheets 'Defaults' and 'Defaults2' in the separate Consumer exposure tool.

2.2.4 Thickness of layer

The *Thickness of Layer* as defined in ECETOC TRA represents a hypothetical article/product layer containing substances from which substances are available for transfer to the skin and does not represent the thickness of article/product itself.

In other words, the *Thickness of Layer*, is a hypothetical layer that sets the boundaries for exposure to a substance contained in the article. Based on the text in report TR 114 (ECETOC, 2012), which states: "In TRAv2, 100% of the substance in the thickness layer in contact with the skin was assumed to transfer from the product or article to the skin", and based on direct input from representatives of ECETOC, this parameter is interpreted as the thickness of the layer of the product or article in contact with the skin from which (a fraction of) the emitted substance of can be transferred to the skin during duration of exposure (cm). In other words, ECETOC TRA considers that (amounts of) substances present in this contact layer or outer shell of the article are likely or potentially to be released to the skin within the time frame of an exposure event, while (amounts of) substances present in the article beyond this contact layer are unable to reach the skin within the time frame of an exposure event.

ECETOC TRA provides default values for *Thickness of layer* (TL), which are either 10 or 100 µm depending on the article or product category. The choice of the defaults for TL for articles is motivated as: "*… the assumed thickness of a layer in contact with the skin is reduced from 0.01 cm (widely accepted default for preparations) to 0.001 cm for most articles in order to take account of the reduced mobility of substances in the article matrix. Unless articles have prolonged contact with the skin, a layer of 0.001 cm is considered.*

The value of 0.001 cm as default for Thickness of layer was chosen based on expert judgement, as no scientific data was available (ECHA, 2010a; Delmaar et al., 2013).

Whereas the ECETOC TRA model and its defaults are designed as first tier screening tools, and therefore meant to be conservative, there is a lack of argumentation for the level of conservatism of the TL defaults of 0.01 cm and 0.001 cm. For very thin articles (for instance thinner than the assumed 'contact layer'), the level of conservatism is obviously more adequate than for thicker articles, since for thick articles, a major fraction of substances in the article is regarded as not available for dermal contact and thus dermal exposure.

2.2.5 Density

This is interpreted as the density of the relevant part of the material (g/cm^3). Note that this is not density of the substance.

2.2.6 Dermal transfer factor

The (dermal) *Transfer factor* is the fraction of the 'released substance' (or transferable amount of substance) that is actually transferred to the skin (unit less). This factor assumes that the exposure of the skin can be thought to exist of processes in the article that lead to the release of the substance (approximated in ECETOC TRA by a combinatation of 'thickness of layer', 'density', and 'PI') , and, subsequently followed by the process of transfer of a part of that released substance to the skin.

Since the *Transfer factor* is a unit less, relative metric (relative to the release amount), it is important to keep in mind the way how the 'released substance' is addressed. In ECETOC TRA, this is the amount of substance present in the TL (and not the total amount of substance present in the article).

2.2.7 Conversion factor

A conversion factor of 1000 is used in order to have an adequate match of units and metrics used for the different parameters used in the ECETOC TRA model equation. Obviously, the conversion factor should not be regarded as a dermal exposure determinant, and will not be taken forward in remaining parts of this document.

2.2.8 Body weight

This is interpreted as the *Body weight* of the exposed (sub)population (kg). There may be differentiation in *Body weight* based on age, gender, and geographical region.
Body weight should not be regarded as a determinant for dermal exposure. Instead, it is used in the ECETOC TRA equation as a way to *convert* dermal exposure expressed as mass per unit skin area (or as mass per exposed person) to dermal exposure expressed as mass per kg body weight. The latter metric is especially relevant for evaluation of systemic doses in Risk Characterisation Ratios (RCR) under REACH.

2.2.9 Exposure

The output of ECETOC TRAv3 is dermal exposure expressed as *external exposure* (mg/kg bw/day), and not as exposure mass (mg) or exposure loading (mg/cm^2).

2.3 Parameters not defined in the ECETOC TRA dermal exposure model but considered relevant for dermal exposure assessment

A number of potentially relevant parameters that can be used to describe and estimate dermal exposure are not included in the ECETOC TRA model (v3). Some of those that appear important are described below, and it will be shown further in the guidance (chapters 4 and 5) how these factors can be taken into account for making predictions of dermal exposure to substances in articles (replacing or appending some parts of the ECETOC TRA dermal exposure concept). Next to the parameters defined below, other parameters may be important for the actual dermal exposure process, such as e.g. contact pressure or roughness of an article surface area. However, only those parameters for which some relevant information was available to actually enable some (indirect) use in an improved equation are described below.

2.3.1 Released substance / Transferable amount

The *released substance* or *transferable amount* is not a parameter in version 3 of the ECETOC TRA model. However, implicitly, the model limits the amount that can be transferred during an 'exposure event' to the amount present in the layer that is represented by the parameter *Thickness of layer*. This amount can be called the *released substance/transferable amount* based on the fact that transfer from the article to the skin can only occur when the substance is released from the article. If another concept of dermal exposure processes is used, that does not include a *Thickness of layer* that limits the exposure, the concept of *released substance/transferable amount* can still be used, e.g. to indicate the amount that diffuses from the body of the article to the surface of the article during the exposure event. Depending on the concept of exposure process, the *released substance/transferable amount* can be expressed as mass (mg), as mass per surface area (mg/cm^2), or as mass per time (mg/min), or as mass per surface area per time (mg/cm^2/min).

Alternative approaches to assess the *released substance/transferable amount* are described in section 4.2

2.3.2 DAY OF USE

ECETOC TRA has a parameter for the number of events per day (*Frequency of use*), which, by default, is one in the predefined subcategories, but can be set at higher values for more events in one day and at lower values for infrequent uses (less than once per day). If a lower value is used, the calculated exposure value will be an averaged value over more than one day. However, it may also be relevant to know the exposure value on a 'day of use'. Therefore, there is a need to also define a *day of use*. Within this project a *day of use* is defined as a day in which there is contact with the product or article, *i.e.* the product or article is either actually 'handled' or there is unavoidable skin contact. For instance, a piece of clothing is actually handled during wearing or during doing the laundry. A carpet is usually not 'handled' as such, but there is unavoidable contact when walking on the carpet.

2.3.3 EXPOSURE EVENT

The ECETOC TRA model (v3) has 'events per day' as the unit for *Frequency of use*. However, the term 'event' is not further defined. In our study we define an *exposure event* as one more or less continuous period of handling or contact with the material. Therefore, we assumed that there can be more than one *exposure event* per day. If there is a clear period without handling or contact between two periods of handling or contact this is considered to separate two *exposure events*. The precise cut-off for a time period without handling or contact between two *exposure events* on one day depends on the particular article. For example, being active in a house with PVC flooring in large parts of the house partly covered by e.g. a carpet or a rug will be considered one *exposure event* related to PVC flooring, even if there are short periods of walking on the carpet or sitting on a chair. However, if the consumer goes out for shopping between periods of being active in the house, there are two *exposure events* related to PVC flooring. Similarly, reading a book during a period constitutes one *exposure event*, even if the book is put on a table for a short while to drink a cup of tea or answer a telephone. However, the sequence of activities of reading a book, cleaning a part of the house, reading again, going for a walk and reading again will be considered to contain three *exposure events* related to reading a book.

2.3.4 CONTACT

Contact between skin and an article is in our project defined as the actual contact of the bare skin with the article without any material (or air) between skin and article. *Contact* creates the opportunity for transfer of substances from the article to the skin. A *contact* starts as soon as skin and article touch each other and ends as soon as there is no part of the body (or the relevant body part) in touch with the article anymore. Within an *exposure event* there can be one to many *contacts*. A child jumping up and down on PVC flooring will have many *contacts*, but the whole period jumping up and down and walking around on the flooring is considered to be one *exposure event*.

2.3.5 NUMBER OF CONTACTS

The *number of contacts* is the number of times there is a separate period of skin and article touching each other. The *number of contacts* can be assessed per *exposure event*, or per *day of use*. Depending on the goals of a research project or an assessment, it may be relevant to look at contacts per body part separately. For example, if a research project wants to study whether the total internal concentration at the end of a day depends on the multiplication of the *number of contacts* times the *skin Contact area*, it may be necessary to derive different values for *number of contacts* and *skin Contact area* for different body parts. A hand may contact a book multiple times, while e.g. the book may rest on the upper leg for only one or two times during the exposure event. Using one value for *number of contacts* and *skin Contact area* for the whole person would not lead to proper differentiation in such a case.

2.3.6 DURATION OF EXPOSURE

Duration of exposure is not an explicit parameter in the ECETOC TRA consumer model (v3). *Duration of exposure* is apparently partially (and implicitly) accounted for in ECETOC TRA by defining a bigger *Thickness layer* (i.e. 0.01 cm) for articles with prolonged contact, such as clothing. Unless products have prolonged contact with the skin, then a layer of 0.001 cm is considered (REACH guidance R.15). However, it could be considered as very rough and speculative approach to say that release upon prolonged versus short exposure events differ a factor 10 from each other; moreover, no definition of 'prolonged' versus 'short' contact is given in the ECETOC TRA documentation. Obviously, there is room for improvement to account more explicitly and precisely for *duration of exposure* in dermal exposure assessment. Especially, the factor *released substance/transferable amount* should be considered as a duration-dependent parameter.
Exposure levels resulting from an *exposure event* or from a *day of use* may be dependent on the duration of the exposure event or the total duration of the contacts during the *exposure event* or the *day of use*. Because it is the intention to estimate exposure per day (of use) as the basic estimate, we will focus on duration of exposure during the day, *i.e.* for all events on one day combined.

2.3.7 SURFACE AREA OF ARTICLE IN CONTACT WITH SKIN

The ECETOC TRA model (v3) does not contain a parameter for the surface area of an article that comes into contact with the skin during an exposure event or during a day of exposure. Implicitly, the model appears to assume that the *surface area of the article in contact with the skin* is equal to the *skin Contact area* in touch with that article (the *Contact area* in the model). However, this is not always the case, and it may not be a conservative approach. For example, for dermal exposure to printed paper, the model assumes a *skin Contact area* equal to the inside of two hands. However, when reading a full newspaper, many pages of paper may be partly touched and the *surface area of the article that comes into contact with the skin* during the *exposure event* or the *day of use* can be (much) larger than the *skin Contact area*.
It is clear that the parameter *surface area of article in contact with skin* is distinct from *skin Contact area* and that this parameter may be relevant for the exposure process. Therefore, we define the *surface area of the article in contact with the skin* as the total area of an article with which there is contact during either an *exposure event* or a *day of use*. Because we focus on exposure during a day, the total surface area contacted during all exposure events on a *day of use* is the most relevant factor for our project.

3 (NEW) DEFAULTS AND/OR REFINEMENTS FOR ECETOC TRA PARAMETERS VALUES

Defaults are (generic) values that are used when no specific input value for a parameter in a model is available, which can be replaced by more specific values, preferably based on actual information, or better estimates when available. The ECETOC TRA model (v3) contains several defaults to be used in dermal exposure assessment for consumers. However, defaults tend to be based on limited information and sometimes largely on expert judgment. When new data is available, it may be possible to set new default values that are better supported by science. Also, for some parameters the defaults may change in time. This is e.g. true for parameters related to humans (body surface, and weight), since there appears to be a tendency of the population to get taller and heavier. But also some other parameters may change in time, e.g. frequency of use, e.g. for printed paper, due to e.g. shift of use of printed paper to electronic devices (e-readers, tablet).
Also, defaults are presently set for rather broad (sub)categories of articles, while it may be possible to define subcategories of these (sub)categories that can have their own defaults for certain parameters. There are e.g. many subcategories of 'clothing', which itself is a subcategory of textiles, that may have different values for parameters such as *Density*, *surface area of article in contact with the skin* and even *Transfer factor* (e.g. due to different material of the pieces of clothing). Furthermore, the present ECETOC TRA model assumes that the whole EU population of adults is one group. This is a logical assumption for a first Tier tool. However, there may be differences in e.g. *Frequency of use* or in relevant anthropometric parameters between different subpopulations in Europe. If such differences in subpopulations coincide with differences in e.g. products used, the assessment of the full EU population as a whole may not lead to the optimum evaluation of the possible risks. For example, some specific types of flooring or furniture or maybe even toys may be common in parts of Europe, while they are very uncommon in other parts of Europe. In that case, the risk assessment should preferably be based on defaults for the exposed population and not for the full EU population. Therefore, it is considered relevant to gather information to either modify existing defaults or to indicate possible refinements of defaults for subcategories or subpopulations.

Within the DRESS project, information has been gathered that, in some cases, can lead to an improvement of defaults for certain type of articles. However, such defaults should be chosen in a systematic way to ensure their appropriateness and acceptability. In Annex 1, a general description is given of what and how defaults can be set. However, whether and how defaults are set is very much dependent on the availability of data.

This paragraph will describe those parameters in the ECETOC TRA dermal consumer exposure model for which it is considered possible to propose new defaults or refinements for certain subcategories of articles or subpopulations of consumers. Based on an overview of relevant data in comparison with the present defaults, conclusions will be drawn.

3.1 PRODUCT INGREDIENT (FRACTION OF SUBSTANCE IN THE ARTICLE)

ECETOC TRA contains defaults for the fraction of the substance in the article matrix (in the tool called '*product ingredient fraction by weight*', in equation called 'PI'). However, since tools such as

ECETOC TRA are mostly used in regulatory risk assessment for substances brought onto the market, it should be possible for the assessor to obtain at least a reasonable indication of the range of this *Product ingredient* as it occurs in practice. Usually, the producers of the material from which an article is made should be able to provide such information. And it is not in their interest to be confronted with extreme overestimates of risk due to lack of such information.
The existing defaults in ECETOC TRAv3 range from a fraction of 0.1 to a fraction of 0.5. Since there are many different subcategories of articles with many different substances, that each may have a different maximum fraction of substance in the article material, it was not considered useful to try and improve these defaults. Therefore, if the assessor cannot obtain specific information, it is recommended to simply use the existing ECETOC TRA defaults for this parameter.

3.2 SKIN CONTACT AREA

Before giving details on *skin Contact areas* of certain body parts, it is essential to give an overview of whole body surface area (BSA) data, since this is – together with estimates of percentages of body parts – the main building block for determining body part contact areas.

3.2.1 WHOLE BODY SURFACE AREA

In this study, measured BSA values of children and adults were collected from the following sources: Bremmer 2006, Expofacts, RIVM 1999, Tan 2011 and Tikuisis 2011. The total BSA is strongly related to the body weight and the body height. In all commonly used exposure assessment guidances, the surface area is calculated from the body weight and body height. Some widely used equations to estimate BSA are listed in Annex 5.
The default values for BSA used by ECETOC TRA (0.48 m^2 for children and 1.75 m^2 for adults) are 25^{th} percentile values calculated by Bremmer (2006). Besides these default values, Bremmer (2006) also gives recommended mean BSA values for men, women, adults and different age categories of children and teenagers (Table 4). Within each age category, the recommended value from the US EPA exposure factors handbook (2011) is higher or only little lower than the value recommended by Bremmer (2006) for the highest age within each age category. The values recommended by Bremmer (2006) and in the exposure factors handbook are 50^{th} percentiles.
REACH guidance R.15 (version 2.1) and the German Ausschuss für Umwelthygiene use data from older versions of the US-EPA exposure factors handbook, so the BSA from these two sources is not considered in the current document.
An overview of mean BSA values for adults and children is given in Table 2 and Table 3 respectively. The BSA values for Europe are calculated with the formula of the REACH guidance R.15 (Table A5- 1 in Annex 5). Mean of measured values for men and women are added for comparison in Table 2 . The comparison between measured values of BSA and the calculated ones (the latter forming the basis of ECETOC TRA) helps us to judge on the appropriateness of ECETOC TRA defaults for BSA. The measured BSA value differ 0,04 m^2 at the most from values of ConsExpo and the exposure factors handbook (US-EPA, 2011). This comparison shows that formulas based on body weight and height can quite well estimate the BSA. The European measured mean values (1.74 m^2 for women and 1.98 m^2 for men) indicate that there is no need to change the default of 1.75 m^2 in ECETOC TRA. The mean BSA values of ConsExpo for men (2,02 m^2) and women (1,78 m^2) are 0.04 m^2 higher than the mean values for European men (1,98 m^2) and women (1,74 m^2), maybe partly because of the use of only Dutch data for body height knowing that Dutch people are tall compared to some other European countries (Schönbeck, 2013). It has to be noted that in the calculations of BSA from body weight and body height, Bremmer (2006) assumed that the weights and lengths of boys and

girls within a certain age category are divided normally. This is not in line with the findings from measured data of the European population (Annex 4).

Table 2: Whole body surface area for adults (mean values in m²)

Population group	Age (years)	Europe	ConsExpo (Bremmer, 2006 Recommended values)	Bremmer (2006) 25th P	US-EPA, 2011	Measured (details in Annex 9)
Adult	21-70	1,86 (Europe) 1.90 (Northern Europe) 1.85 (Western and Eastern Europe) 1.81 (Southern Europe)	1,89	1.75 (also ECETOC TRA)	-	
Adult	70+	1,75			-	
Men	21-70	1,98	2,02	1.91	2,06	1,98
Men	70+	1,81			2,05 1,92 for 80+	
Women	21-70	1,74	1,78	1.68	1,85	1,82
Women	70+	1,69			1,77 1,69 for 80+	

Since BSA is calculated from body weight and body height, the BSA based on mean values per European region shows the same trend as for regional body weight and body height: highest in Northern Europe (1.90 m²), lowest in Southern Europe (1.81 m²) and in-between for Western and Eastern Europe (1.85 m²). These values are for adults aged 21-70 years.

Table 3: Whole body surface area for children and teenagers (mean values in m²)

Age (months)	Europe	Consexpo (Bremmer, 2006)	Bremmer (2006) and ECETOC TRA 25th P	Exposure factors handbook (US-EPA, 2011)
0	0,23			0,29
1 - 2	0,29	0,28 (1.5 month)		0,33
3 - 5	0,36	0,36 (4.5 months)		0,38
6 - 8	0,42	0,42 (7.5 months)		0,45
9 - 11	0,46	0,46 (10.5 month)		
Age (years)				
1	0,52	0,49 (13.5 months) 0,52 (1,5 year)	0.48 (children)	0,53
2	0,60	0,62 (2.5 years)		0,61
3 - 5	0,73	0,69 (3.5 years) 0,76 (4.5 years)		0,76
6 - 10	1,01	0,90 (6.5 years) 1,13 (9.5 years)		1,08
11 - 15	1,45	1,40 (12.5 years) 1,51 (13.5 years)		1,59
16 - 20	1,73	1,75 (16.5 years) 1,79 (17.5 years)		1,84

3.2.2 (Skin) contact area of body parts

The *skin Contact area* of body parts is mainly determined by the whole BSA and the proportion body part/whole body. Defaults are based on percentages of the total BSA. ECETOC TRA has default *skin Contact area* for some body parts groups ('upper part of body', 'lower part of body') and detailed values for the *skin Contact area* of hands and finger(tip)s. ECETOC TRA defaults are set for children and for adults (no gender distinction). These body part categories have been linked in ECETOC TRA to AC/PC; hereby assuming that for a given AC/PC the entire surface of the attributed body part is exposed.

The purpose of this section is twofold: 1) verifying and eventually refining ECETOC TRA defaults of body part categories included in TRA, and 2) providing data of CA of body part categories currently not included in TRA. The latter could be useful when the match between between the AC/PC and body part as attributed in TRA could be improved into more realistic estimates for a specific article. For example, for the subcategory 'clothing', the body part considered in ECETOC TRA is 'whole body except feet, hands and head, being based on worst case for clothing in general'; when for example doing an exposure assessment of a substance in T-shirt, one could use instead the CA of the body parts covered by a T-shirt (i.e. the trunk + arms). Hereto, we have in this chapter provided data also for body part categories not considered in TRA.
Measured values of body parts surface area for children and adults were collected from the following sources: Boniol 2008, Bremmer 2006, and Tikuisis 2001. Default and measured surface area values are presented in Table 4 . The proportions body part/whole body are presented in Annex 6.
For the proportion of body parts surface to total BSA of subgroups of children and of adults, it is recommended to use the updated exposure factors handbook (US-EPA, 2011) because:

- REACH guidance R.15 refers to the exposure factors handbook
- The exposure factors handbook is updated with conclusions of Boniol (2008) on over- and underestimation of the surface area of specific body parts
- The values of Bremmer (2006) for toddlers have a low quality score
- The body part/whole body proportions used by Bremmer for adults are from an older version of the exposure factors handbook (1996). The proportions are lower than in the current version (US-EPA 2011).

Mean body parts surface area values (in cm²) are presented in Table 4. Sources are the US EPA exposure factors handbook (recommended in REACH guidance R.15) (based on calculations of BSA and relative proportions; US population), Bremmer (2006) (BSA values based on Dutch population and relative proportions of the US-EPA exposure factors handbook of 1996) , Tikuisis (2001) (measured values (body scans) based on US population) and values calculated from the mean European BSA (Table 4) and the proportions of US-EPA (2011) (columns 'Europe' in Table 4).
The surface area of head+neck+trunk is remarkably lower in Tikuisis (2001) compared to the values in other sources. The largest difference, 2800 cm² for men and 2960 cm² for women is seen between Tikuisis (2006) and the exposure factors handbook (2011).
All the body parts surface area values calculated from the mean European BSA and relative proportion of body parts (columns 'Europe' in Table 4), are between the values of the US EPA exposure factors handbook (2011) and Bremmer (2006), except for the surface of the head and the arms of females which are respectively 50 and 100 cm² lower than the default values for the corresponding body parts of Bremmer (2006). The surface area of the hands of adults is 857.5 cm² in ECETOC TRA, which is about the same as the default for adults (860 cm²) of Bremmer (2006).
The proportions of Boniol (2008) and US-EPA (2011) are based on measured data from US people. It remains uncertain whether the same proportions can be applied on European measured data.

We propose two options, 1) use of body parts surface calculated based on European BSA data, in combination with US proportion of body parts, or 2) use the body parts surface area values of US-EPA (2011) as such. Based on the available data, is remains difficult to judge which of the 2 options will result into the most EU representative data; however, the impact of this choice on the exposure assessment will be low given the relative small differences (< 5 %) of two options; which will be obviously small compared to uncertainties in other parameters of the ECETOC TRA equation.

Table 4: Mean body parts surface area (cm²) for adults.

Body part	US-EPA (2011)	Tikuisis (2001)	Bremmer (2006) 25th P	Europe[1]	US-EPA (2011)	Tikuisis (2001)	Bremmer (2006) 25th P	Europe[1]
	Male				Female			
Head (face)	1360	1680 (including neck)	1220	1307	1140	1540 (including neck)	1130	1079
Trunk[2]	8270	5150 (without neck)	6950	7945	6540	4180 (without neck)	5850	6160
Head+neck+trunk	9630	6830	8170	9252	7680	5720	6980	7229
Arms	3140	3340	2730	3012	2370	2710	2320	2227
Hands[3]	1070	1040	940	1030	890	820	820	835
Legs	6820	7040	6020	6558	5980	6290	5530	5621
Feet	1370	1300	1240	1327	1220	1060	1160	1201

[1] Calculated from mean European BSA and the % of body parts to BSA of US-EPA (2011); [2] including neck; [3] 857.5 cm² for adults in ECETOC TRA v3

3.2.3 Overall conclusion on skin surface area

In the commonly used risk assessment guidances, body part contact areas are calculated from the whole body surface area (BSA) and estimates of percentages of body parts relative to the whole body surface. The whole BSA is strongly related to the body weight and the body height. Comparison with mean measured BSA values shows that there is no need to change the ECETOC TRA defaults of 0.48 m² for children and 1.75 m² for adults. Gender-specific values are available in Bremmer (2006): 1.91 m² for men and 1.68 m² for women. For age-specific BSA values for children the BSA values of ConsExpo are recommended.

Default values for surface area of body parts in ECETOC TRA are for hands and fingers, and the upper/lower part of the body (separate values for adults and children. There is no need to change these defaults. For those body parts that have no default in ECETOC TRA, it is advised to use 1) either the body parts surface area values of US-EPA (2011) for the dermal exposure assessment of those specific body parts, as recommended in REACH guidance R.15, or 2) to use the body part area values calculated from EU BSA data, in combination with US based proportion of body parts.
It's up to the exposure assessor to make (justified) assumptions on match between exposed body parts and articles.

3.3 FREQUENCY OF USE

Frequency of use in ECETOC TRA v3 is a non-modifiable parameter for pre-defined (sub)categories of articles, which is always assigned the value '1'. However, the user can add new subcategories of products or articles for which another value for *Frequency of use* can be entered. The unit for this parameter is 'events per day'. The tool does allow both multiples of 1 and fractions of 1 to be entered for user added subcategories.

In the consumer survey within the DRESS project, information was gathered on the use pattern of three types of articles: synthetic (PVC) flooring, textiles and printed paper articles. The survey resulted in information from more than 9000 persons, more or less equally divided over six EU Member States: Czech Republic, Denmark, Spain, Poland, Sweden and UK (Ipsos Public Affairs, 2013). A summary of the results per type of material is presented in Annex 2.

In general, 'reasonable worst case values' for parameters as used in the exposure model were interpreted as 75th or 25th percentiles of the distribution of values (for a population, subpopulation, article category or subcategory). Since a higher *Frequency of use* is expected to lead to higher dermal exposure levels, in this case the aim is to indicate the 75th percentile of the *Frequency of use*, *i.e.* the frequency below which 75% of the distribution of this parameter lies. For example, if the answers to questions are 'once per year': 5%, 'once per month': 43%, 'once per week': 40% and 'once or more per day': 12%, the reasonable worst case would be 'once per week', because more than 75% of the population uses the item up to once per week.

3.3.1 FREQUENCY OF USE OF PVC FLOORING

For PVC flooring, the consumer survey within the DRESS project indicated that the reasonable worst case frequency for being barefoot in the home (with PVC flooring) in summer was 'most of the times' (see Annex 2). This is interpreted as a clear indication that the reasonable worst case direct contact with PVC flooring is (at least) daily during summer.

The survey also indicated that, depending on the type of room, between 23 and 46% of the respondents reported that less than 25% of the surface area is covered by carpets, rugs or mats, *i.e.* generally more than 75% of the PVC flooring area is available for actual contact. Therefore, there is no need to modify the frequency of use to account for covering of the PVC flooring material by carpets, rugs or mats.

For PVC flooring, based on our study, there is no need to modify the default value for *Frequency of use*.

3.3.2 FREQUENCY OF USE OF CLOTHING

Many different types of clothing are worn. Some types of clothing are gender-related (e.g. bras and nightgowns) and for those the *Frequency of use* should be assessed for the relevant subgroup. Some types are mainly used in colder periods (*i.e.* hardly in summer), while others are used throughout the year. Furthermore, some types are mainly (partly) worn over other layers of clothing (e.g. coats), whereas other types are mainly worn directly on the skin (e.g. underwear). For this paper it is assumed that the *Frequency of use* during a longer period of the year (e.g. the summer or the rest of the year) can be used as the basis for the *Frequency of use* in the risk assessment. There is a relation between the type of fabric and the type of clothing worn. Fabrics such as cotton and polyester are common for many types of clothing, while wool and silk are usually found in specific types of clothing that are worn less regularly. Annex 2 provides a summary of the results of the consumer survey.

Table 5 shows the frequencies of use that were derived for the purpose of this paper, based on the consumer survey within the DRESS project. Frequencies of use for type of clothing as well as for type of fabrics are indicated whenever possible. The survey contained more detailed categories, but categories are combined to allow a meaningful analysis, forming the following final categories: 'daily' (at least once per day), 'weekly' (one or several times per week), 'monthly' (once every two weeks or once per month) and 'less than monthly'.

Table 5: Reasonable worst case Frequency of use for clothing items concluded from the survey (full population)

Clothing item	RWC *Frequency of use* [a)]	*Frequency of use* (Events/day)[b)]	Relevant for
Underwear, Socks, Pyjamas, Cotton T-shirts with prints, Vests/tank tops	Daily	1	Males + females
Bras, Nightgowns	Daily	1	Females
Trousers (both cotton and other materials)	Daily	1	Males + females
Cotton T-shirts without prints, shirts, jumpers	One or several times per week	0.5	Males + females
Tights/stockings	One or several times per week	0.5	Females
Type of fabric	RWC *Frequency of use* [a)]	*Frequency of use* (Events/day)[b)]	Relevant for
Cotton clothing [c)]	Daily	1	Males + females
Polyester clothing [d)]	Daily	1	Males + females
Woolen clothing [e)]	One or several times per week	0.5	Males + females

[a)] Reasonable worst case *Frequency of use*: Approximate 75th percentile, as calculated via the highest frequency of use that is (cumulatively) indicated by at least 25% of the respondents for at least one of the periods studied (summer/rest of the year)
[b)] The values from the consumer survey have been translated into values in the units relevant for ECETOC TRA, where 'daily' is translated to 1/day and one or several times per week is translated to 0.5/day
[c)] Cotton is the major material used in clothing items worn daily, while the next often used material is a mix of cotton and polyester
[d)] A mix of cotton and polyester or polyester alone is a type of material that is indicated to be used by more than 25% of the respondents for clothing items worn daily
[e)] Based on the fact that wool is only in small percentages in clothing items worn daily, but 48% of respondents indicate wool as main type of fabric for jumpers, which are worn one or more times per week

Most of the types of clothing studied are, or can be, worn for a large part on the bare skin. There are just a few types of clothing included in the survey that rather often are worn over another layer of clothing, for instance vests and jumpers. For those types of clothing, the effect of an intermediate article between the clothing and the skin may need to be taken into account. This is not necessary for the other types of clothing. Since wool is by far most often mentioned as the material for vests, it may be relevant to also account for an intermediate article between wool and the skin. However, wool is also often used for socks, which are in direct contact with the skin.

Based on the outcome of the survey, there is no need to modify the default value for *Frequency of use* for clothing.

3.3.3 FREQUENCY OF USE OF PRINTED PAPER ARTICLES

The consumer survey within the DRESS project also studied the frequency of reading or handling different types of printed paper. There are differences in *Frequency of use* between different subcategories of printed paper, but there are also some differences between the countries studied, age groups (differentiation made between 18-34; 35-54 and 55 and older) and men and women for some subgroups. The summary of the results of the consumer survey is provided in Annex 2.

Table 6 presents the conclusions from the consumer survey on *Frequency of use* of printed paper articles. Again, some categories in the original questionnaire have been combined.

Table 6. Reasonable worst case estimates (75th perc) of Frequency of use of printed paper articles for the full population studied

Item	Reasonable worst case *Frequency of use* [a]	*Frequency of use* (Events/day)[b]	Remarks regarding subpopulations or subcategories
Newspapers	Daily	1	• Poland and Czech republic: one or several times per week (0.5/day) • Age < 55 years: one or several times per week (0.5/day)
Books	One or several times per week	0.5	• UK and Spain: at least once per day (1/day) • Women: at least once per day (1/day) • Ages 55+: at least once per day (1/day)
Magazines	One or several times per week	0.5	
Brochures, catalogues	One or several times per week	0.5	
Paper receipts	Daily	1	• One or several times per week for receipts of clothing and accessories and of goods purchases occasionally (0.5/day)
Paper currency bills	Daily (2-9 times/day [c])	5	• One or several times per week for Sweden (0.5/day)
Home printed documents or photocopies - fresh [c]	One or several times per week	0.5	
Home printed documents or photocopies - older [d]	Daily	1	
Home printed photographs - fresh [c]	Less than once per month	0.1	
Home printed photographs - older [d]	One or several times per week	0.5	

[a] Reasonable worst case *Frequency of use*: Approximate 75th percentile, as calculated via the highest *Frequency of use* that is (cumulatively) indicated by at least 25% of the respondents

[b] The values from the consumer survey have been translated into values in the units relevant for ECETOC TRA, where 'daily' is translated to 1/day, 'one or several times per week' is translated to 0.5/day and 'less than once per month' is translated to 0.1/day

[c] Categories of events per day were once per day, 2-9 times per day and 10 or more times per day

[d)] Home printed documents, photocopies or photographs – fresh: contact with freshly printed paper printed by the respondent
[e)] Home printed documents, photocopies or photographs – older: contact with home printed paper not necessarily printed (that day) by the respondent

When estimates are needed for the whole population in Europe, the estimates in the second column of Table 6 can be used. However, for specific subgroups (lands within Europe) the deviating estimates of those subgroups in the third column can be used (based on the WP 3.1 survey results). Paper currency bills were the only type of printed paper for which a differentiation was made going up to a higher number of events per day than one.

Liao and Kannan (2011) made risk assessments for bisphenol A from paper articles. They did not study contact frequency but applied assumptions about this parameter. They assumed that the general population handles magazines, newspapers, napkins, paper towels or kitchen rolls and toilet papers ten times a day and other paper types (not specifically specified) five times a day. For paper currency bills, the only paper article for which we studied higher frequencies than 'daily', the assumption of five times a day fits with our reasonable worst case of 2-9 times/day. The reasonable worst case *Frequency of use* of newspapers from our consumer survey is 'daily' (1/day). However, 43% of the respondents indicated that they read a newspaper over several times and from those respondents, 43% indicates that this is within one day. This does not indicate whether 'ten times a day' is a reasonable assumption, but at least more than once a day occurs often. The other paper types for which Liao and Kannan (2011) assume ten times per day are not included in our consumer survey.
For several paper types the reasonable worst case derived from our consumer survey is one or several times per week (translated to 0.5/day), while freshly home printed photographs are handled less than monthly (translated to 0.1/day). Even though on a *day of use* the *Frequency of use* may be more than once, assuming five times per day (every day) for any paper is clearly too conservative.

3.3.4 Overall conclusions on Frequency of use:

The following conclusions can be drawn, based on the available information on *Frequency of use*. In general, a default of '1' for the parameter *Frequency of use* is considered reasonable for article types that are actually used by or consumers come into contact with on a daily basis. However, for some article types daily use is considered not realistic, and thus for these article types a default of one event per day (= daily use) is considered too worst case. In these cases lower values for this parameter should be considered, which can be derived from information from time activity patterns collected in the consumer behaviour survey as performed in the DRESS project.
A 'daily' *Frequency of use* (1/day) is a reasonable worst case for PVC flooring. A reasonable worst case assumption is that there is direct contact between skin and PVC flooring. For underwear, socks, pyjamas, cotton T-shirts with prints, vests/tank tops, bras, nightgowns, trousers (both cotton and other fabrics) and for clothing made from cotton or polyester, the reasonable worst case for *Frequency of use* is also daily (1/day). For bras and nightgowns, this is only for females. For vests, account should be taken of the fact that there is usually an intermediate article (another piece of clothing) between the vest and the skin.
One or several times per week (0.5/day) is considered a reasonable worst case *Frequency of use* for cotton T-shirts without prints, shirts, jumpers and tights/stockings, as well as for clothing items made from wool. For tights and stockings, this is only relevant for females. The reasonable worst case for *Frequency of use* for newspapers, paper receipts of goods and services purchased in everyday life, home printed documents (not printed on the day of handling) and paper currency

bills is daily (1/day). Most other studied printed paper articles have a reasonable worst case *Frequency of use* of one or several times per week (0.5/day), with the exception of freshly home printed photographs which are handled less than once per month (0.1/day).

3.4 THICKNESS OF LAYER

It was argued by Delmaar et al. (2013), based on theoretical considerations and calculations, that the ECETOC TRA defaults for a *Thickness of layer* of 0.001 and 0.01 cm are not made plausible, and therefore cannot be regarded as adequately conservative for the purpose of a Tier 1 screening tool. Therefore, derivation of better underpinned defaults for *thickness of layer* could be seen as an urgent need for supporting the ECETOC TRA dermal exposure model. Secondly, the development of article- substance property dependent defaults for *Thickness of layer* would contribute to improvements of the ECETOC TRA dermal exposure model. However, lack of an experimental technique to directly measure the “contact layer” hampers the data generation for this parameter, and hence derivation of (new) defaults.

In the ECETOC TRA equation, the factor *Thickness of layer* is multiplied with the concentration of the substance in the article (PI) and the *Density* of the article (D) to assess the *amount of substance released from the article per unit of area during an exposure event.* Experimental methods do exist to measure the *amount of substance released from the article per unit of area.* And although data on this subject was retrieved from literature and from the experimental part of this project (WP 3.2), the amount of available (experimental) data is insufficient to derive suitable defaults for “*amount of substance released from the article per unit of area during an exposure event”*, covering a wide spectrum of substances and articles, as well as for deriving (new) defaults for *Thickness of layer*.

Instead of underpinning and/or refining of defaults for *Thickness of layer*, or deriving new defaults for “*amount of substance released from the article per unit of area during an exposure event”,* as an alternative approach, efforts have focused on generating adequate estimates for “*amount of substance released from the article per unit of area during an exposure event*”.

This preference of the concept “*amount of substance released from the article per unit of area during an exposure event”* over the concept *of Thickness of layer* is motivated by the arguments that 1) experimental techniques are available to measure the former, not the latter, and 2) it’s a more easy understandable and mechanistic concept than the concept of the hypothetical layer.

3.5 DENSITY

ECETOC TRA uses a default, non-modifiable *Density* of 1 g/cm^3 for all article (and product) categories and subcategories. This parameter can also not be modified for new subcategories added by the user of the tool. Calculating values for materials with another *Density* can be done outside of ECETOC TRA by multiplying the outcome of ECETOC TRA with the *Density* of the material. The *Density* of a material is not a determinant of dermal exposure as such, but it is a parameter used to calculate the fraction of product ingredient between units of weight/weight and weight/volume. *Densities* or weight/surface ratios of materials are known to be highly variable. In this paragraph, the *Density* or weight/surface ratio will be provided for those materials for which migration experiments have been performed within the DRESS project. Data are available from the migration experiments. Furthermore, data from literature and websites will be used.

3.5.1 DENSITY OF PVC FLOORING

The PVC flooring material used in the migration experiments had a *Density* of 1.2 g/cm^3 (non-published information). Furthermore, the thickness of the four types of PVC flooring as included in the experiments was between 0.18 and 0.50 cm. In literature or websites some information on thickness and weight per surface area of PVC flooring as well as on *Density* of PVC in general was found. Most PVC flooring material appears to be around 0.2 cm thick, though specialty products can be up to 0.4 cm. The weights per m^2 found are in the order of 2600-3800 g/m^2. Calculated *Densities* based on these values range from 0.95 to 1.8 g/cm^3 of PVC flooring material.[4,5] According to Wikipedia, the *Density* of rigid PVC is between 1.3 and 1.45 g/cm^3 and of flexible PVC between 1.1 and 1.35 g/cm^3.[6] The typical *Density* of PVC flooring material appears to be in the order of 1.4 g/cm^3. It is recommended to use that value in the assessment of substances used in PVC flooring material.

3.5.2 DENSITY OF CLOTHING (TEXTILES)

The *Density* of the (polymer coated) textiles used in the migration experiments was between 1.3 and 1.4 g/cm^3 (non-published information) The weight of textiles is usually expressed in g/m^2 (or in ounces/square yard). A website of a producer of sewing threads provides information on the necessary needle thickness for sewing of different weight fabrics, which provides an indication of the variation in fabric weights. The information on the website differentiates between extreme-light, light, medium, medium-heavy, heavy and extreme heavy fabrics. Light fabrics are between 136 and 204 g/m^2, medium between 204 and 272 g/m^2 and heavy fabrics between 339 and 407 g/m^2.[7]

A producer of clothing reports the following weights for T-shirts [8]:

- Lightweight: 145 g/m^2
- Midweight: 150-160 g/m^2
- Heavyweight: 180-205 g/m^2
- Super Heavyweight: 215 g/m^2

The difference between light-, medium- and heavyweight may be largely caused by difference in thickness, *i.e.* the *Density* of the material may be the same.

There are no easily identifiable sources of information on actual thickness of different fabrics. Therefore, a number of publications was studied in which thickness and weight of fabrics was reported to obtain an idea of the variation of *Density*.

Sarkar (2004) presents data on three types of cotton weave, with resulting *Densities* between 0.34 and 0.39 g/cm^3. Behara (2007) studied a cotton fabric with a *Density* of 0.18 g/cm^3, Sata *et al.* (2013) studied a non-woven cotton with a *Density* of only 0.07 g/cm^3 and Altas and Ozgen (2013) a cotton fabric of 0.36 g/cm^3. Finally, Chidambaram *et al.* (2012) studied cotton fabrics of 0.11-0.20 g/cm^3. In total, 9 data points for cotton were found. Hasani (2010) studied the effect of several treatments on knitted cotton fabrics. He does not present precise values. However, his graph on fourteen samples of thickness and fabric weight suggests thicknesses around 1-1.2 mm and weights of around 150-175 g/m^3, which results in *Densities* of approximately 0.13-0.175 g/cm^3.

[4] http://professionals.tarkett.com
[5] http://www.eurostatgroup.com/fichiers/32-913-5xxx.pdf.
[6] http://en.wikipedia.org/wiki/Polyvinyl_chloride
[7] http://www.amefird.com/technical-tools/thread-size/fabric-weight/
[8] http://www.plaintshirts.co.uk/buyonline/hanes-clothing-size-guide.html

It appears that cotton fabric has a *Density* that is clearly below 1 g/cm^3. Since the *Density* does not appear to be a determinant of migration but rather a parameter used for unit conversion, a typical or average *Density* can be used for cotton fabrics. As a typical *Density* for cotton fabrics a value of 0.2 g/cm^3 is proposed.

Information on several combined fabrics has also been found, including linen/cotton in ratios of 22:78 to 80:20 with *Densities* of between 0.15 and 0.26 g/cm^3, which do not appear to be related to the ratio linen/cotton (Behara, 2007), cotton/silver (90:10) and cotton/Seacell (90:10) with a *Density* of 0.22 g/cm^3 (Altas and Ozgen, 2013) and cotton/bamboo (between 33:67 and 67:33) with a *Density* of between 0.09 and 0.19 g/cm^3. The number of data points on combined fabrics is rather low.

Bamboo is a relatively new material used for fabric because of its properties and its perceived environmental friendliness. Four data points were available on *Density* of bamboo. These were between 0.11 and 0.25 g/cm^3 (Altas and Ozgen, 2013; Chidambaram *et al.*, 2012). Though it appears that the values for bamboo are in the lower range of those for cotton, there are too few data points to derive a separate value for bamboo.

Behara (2007) presents four sets of data for linen. These indicate a *Density* of linen between 0.21 and 0.30 g/cm^3.

Altas and Ozgen (2013) also studied one fabric made from soybean fibers. This fabric had a *Density* of 0.24 g/cm^3.

A modern, very high strength fabric is the synthetic fabric aramid, which is not commonly used in normal clothing. However, for protective clothing, sports clothing and other materials it may be relevant. Eighty seven data points for thickness and weight of aramid fabrics have been found from one producer. The *Density* of this fabric is rather high compared to other fabrics, with values ranging from 0.41 to 0.94 g/cm^3 (JPS, undated). A very large number of values in the total set was between 0.7 and 0.8 g/cm^3. Therefore it is recommended to use a value of 0.75 g/cm^3 as a typical *Density* for aramid fabrics.

In an experimental study, Debnath and Madhusoothanan (2010) analysed a variety of physical characteristics of non-woven polyester fabrics. The *Density* of the fabric they measured was between 0.116 and 0.147 g/cm^3.

In general, most fabrics for which information was found have a *Density* in the range of 0.1-0.4 g/cm^3, with the majority of values below 0.3 g/cm^3. Therefore, if no further information is available for a specific type of fabric, it is recommended to use a value of 0.2 g/cm^3 in calculations. An exception is the very strong aramid fabric, for which a *Density* of 0.75 g/cm^3 is more relevant.
It appears that the polymer coated textiles studied in the migration studies have a rather different *Density* than normal clothing textiles. Therefore the values from the migration studies will not be used to indicate defaults for the ECETOC TRA model.

3.5.3 DENSITY OF PAPER ARTICLES

The 'density' or 'weight' of paper is often expressed in units of g/m^2. However, there is some information on the real *Density* of different types of paper, expressed in g/cm^3. In the experimental part of the DRESS project, the *Density* of the paper used was not determined. The website

'Paperonweb' provides an overview of typical *Densities* of paper and paperboard. The Densities range from 0.25-0.50 g/cm^3 for tissue paper to 1.16-1.52 g/cm^3 for 'Super Calendared Glassine'. For the types of paper studied in the consumer survey within the DRESS project the *Densities*, derived from this website, are [9]:

- Newspaper: 0.61-0.69 g/cm^3
- Books, magazines, catalogues (non-glossy): 0.72 g/cm^3
- Magazines, catalogues (glossy): Super calendared paper: 1.11-1.16 g/cm^3
- Home printing document paper: Fine paper: 0.78 g/cm^3

The *Density* of photo paper for 26 different types of professional photo paper was found to be between 0.57 and 1.09 g/cm^3. The lower values are rather exceptional, the median value was 0.90. It is therefore recommended to use this value for photo paper.[10]

3.5.4 Overall conclusions on density

The non-modifiable default *Density* of 1 g/cm^3 for all article (and product) categories and subcategories as applied in ECETOC TRA is considered to be not realistic in many situations, since it is known that *Densities* or weight/surface ratios of materials are known to be highly variable. In this paragraph, *Densities* or weight/surface ratio are provided for those article types included in the (migration) experiments performed within the DRESS project, also based on information from literature. It is assumed that this type of information is also available for most (other) articles. If so, it is proposed to use this more specific information during the exposure assessment instead of the default of 1 g/cm^3. However, this can only be done outside of the ECETOC TRA model itself, because the model does not allow to modify the *Density* values.

3.6 Transfer factor

The default value for *Transfer factor* in ECETOC TRAv3 is set at '1', indicating that all substance that is available for transfer at the surface of the article (the *'released substance/transferable amount'*) is transferred from the surface to the skin. However, for most product or article (sub)categories the value can be modified by the assessor. Therefore, more realistic information on *Transfer factors* can therefore be used directly in the present model.
The actual *Transfer factor* can be measured during experiments if it is possible to estimate / derive / calculate the *released substance/transferable amount*. In the experiments performed within the DRESS project, this *Transfer factor* is calculated for the wipe samples where substances were applied on substrate surfaces, *i.e.* to glass and aluminium, because for these experiments it can be assumed that transfer is the only process that plays a role in the transfer of the substance from the surface to the wipe (surrogate skin). It should be noted that these wipe experiments were performed by taking 3 wipes of 22 cm^2, each on a new part of the substrate surface, which took only a few seconds in total.

The worst case value for the *Transfer factor* of substances from surface to skin was estimated based on experiments with substances found in PVC flooring or printed paper applied to smooth glass and aluminium substrate surfaces. A summary of the results is presented in Annex 3.
The transfer from substances spiked on smooth glass or aluminium plates (*i.e.* the fraction of the applied amount that was transferred onto the wipes) is rather high, with 75th percentiles between approximately 0.3 (DEHP, dry wipe on aluminium) and 1 (DEHP, wipe with artificial sweat on glass).

[9] http://www.paperonweb.com/density.htm
[10] http://tecco-photo.de/EN/produkte.php

However, most values were between a factor 0.3 and 0.5 for the applied substances DEHP, DINCH and Disperse Blue 360.

Wipe experiments were also performed with real articles. During these experiments, both release processes and transfer processes play a role in the resulting amount wiped from the articles. Since the wiping experiments had a duration of only seconds, it cannot be expected that all of the substance in the article would have become available for transfer, even if migration is assumed to be a relatively fast process. It is therefore not surprising that the amounts of substances transferred from the real articles to the wipes are very low. Calculated as fraction of the total amount in the volume of the article underneath the wiped surface, only around $3.3*10^{-5}$ to $6.5*10^{-3}$ % relative transfer is actually found in the dry wipes and wipes with artificial sweat.[11] The ECETOC TRA model assumes a *Thickness of layer* of 10 µm, *i.e.* a relevant layer from which substances can be migrated and transferred to the skin. The amount wiped from the articles with dry cotton or artificial sweat was therefore also calculated as the fraction of substance that was originally present in the first 10 µm of the article. These results are also presented in Annex 3. The 75th percentiles of these values based on this calculation vary between 0.05 and 1.52 % relative transfer (relative to the total amount of substance present in the – assumed – 10 µm contact layer) for different substance and article combinations.

From the performed transfer experiments, not enough data is available to show whether there is a difference in the derived *Transfer factors* for substances in PVC flooring compared to substances in ink on printed paper, and thus to derive specific *Transfer factors* for these article and substance groups.

Transfer from textile to skin was not studied by separate testing of migration and transfer. The transfer from textile to skin is assumed to be a long-term process, caused by wearing clothing during a large part of the day. Within that long-term process, it will be impossible or at least very difficult to separate the migration and transfer processes experimentally. In real life, there will be a combination of processes within the time frame of wearing clothing. Even if it would be possible to do long term wiping of textiles, the results would therefore not be for transfer only. However, there are also rather substantial technical challenges for long-term wiping tests, which would e.g. need an automated wiping machine. Alternatively, studying transfer processes from textiles could be attempted by spiking textile surfaces with known amounts of substance, followed by short term wiping. However, this method will also lead to difficulties, because textile surfaces are not hard and closed surfaces on which the spiked substance will remain at the outside. If a fluid is spiked onto the textile surface, it will distribute within the textile as well and therefore make the spiked substance less available for transfer. On the other hand, the fluid that is dispersed into the textile may lead to extraction from the textile. Finally, wiping textile may lead to abrasion of the textile material, that may lead to an emission of substances that is not representative for the emission that occurs due to contact between skin and clothing. And this abrasion may lead to emission of more or other substances from the textile material than expected in real life, which could hamper proper chemical analyses. Therefore, it was concluded that the technical difficulties of studying transfer processes from textile surfaces separately were prohibitive within the context of this project. Only extraction tests were performed (with methanol and artificial sweat); however, these data refer rather to the 'amount of substance released', and not to the relative transfer factor (fraction of released substances actuallytransfer to the skin). Rodes *et al.* (2001) studied the transfer of particles from surfaces to skin. They included stainless steel as smooth surface, vinyl

[11] The transfer experiments with actual articles were also performed with cotton wipes with methanol. However, these results are considered not to be representative of a consumer exposure situation, and are therefore not included here.

flooring and medium pile carpeting as medium-rough and rough surfaces and they applied dust onto the surfaces. Transfer to dry, damp or 'wet' skin was made via pressure controlled pressing of the palm of the hand onto the surface. This short term transfer activity resulted in around 100% of the applied amount of dust being transferred from stainless steel, around 50% from vinyl flooring material and from approximately 3% to approximately 20% for carpet. These data cannot be used directly for drawing conclusions on transfer of substances from clothing in general, because the adherence from other (non-solid) substances to the textile surface may be very different from the adherence of dust. Furthermore, transfer may be dependent on the duration of the transfer activities, which are long-term for the situation of wearing of clothes and not short-term as in the study by Rodes *et al.* (2001).

Other sources of information on *transfer factors* from surfaces to skin were also studied. The US EPA Exposure Factors Handbook (US EPA, 2011) presents transfer efficiencies of substances (mostly pesticides applied indoors) to skin from a number of studies. Mean transfer efficiencies reported are in the order of 1-23% (based on different studies).
The Institute of Occupational Medicine produced a transfer efficiency database (Gorman Ng et al., 2012).[12] In this database, transfer efficiencies from various studies are described and a summary can be made after selection of several options. For studies of transfer of solids from surface to hands a 75th percentile of 14% is given (based on 134 records). However, several records from the same study are included, thus the data are probably not fully independent. For liquids or solids in solution, the database contains a too limited number of records to present a summary related to transfer from surface to hands. The available data set for transfer from surface to gloves consist of 13 records with a 75th percentile of the included transfer efficiencies of 58%. The studies covered in these sources are in general for substances applied to surfaces and migration within the articles therefore is considered not to be a part of the studied processes.[13]

3.6.1 Overall conclusions on Transfer factors:

The transfer of substances from surfaces to skin after application of the substances to (smooth) surfaces can be high. Based on the experiments with applied substances on glass and aluminium in the DRESS project, it appeared that in a given situation the worst case (75th percentile) can be 1 (100% transfer).
The measured transfer efficiencies for the transfer of substances from real article surfaces (in which substances are embedded) instead of spiked surfaces tend to be (much) lower than 1. Actually, the measured transfer efficiencies from real article surfaces reflect the combination of the release process of substance from articles to its surface, and the subsequent transfer from the surface to the skin. These transfer efficiencies can be very low if the transfer is calculated as fraction of the total content of the substance in the article. Since our transfer experiments had a rather short duration, it is not realistic to assume that the full amount of substance from the full article are available for transfer. Therefore, the factors were also calculated based on the amount of substance in the first 10 µm of the article (in accordance with the *thickness of layer* concept of ECETOC TRA) . Based on this calculation method, the highest 75th percentile as estimated based on the results experiments was around 0.015. However, all values are based on (very) small numbers of measurements, materials and substances and on very short transfer actions and therefore they can only be used as indicative values.

[12] http://www.iom-world.org/research/research-expertise/exposure-assessment/database-of-dermal-and-oral-transfer-efficiencies/
[13] The separate original sources referred to by these sources have not been studied, therefore it is possible that in some sources migration in the article may have played a role.

The reasonable worst case values from other sources on transfer from surfaces to skin or gloves (generally from applied substances with unknown level of binding to the surface) are in the order of 0.1 to 0.6.

The combined information indicates the following for deriving (new) defaults for the parameter Transfer factor from article to skin due to a short duration contact:
It is reasonable to assume that the full amount of a substance that is loosely available on the surface of an article can be transferred to the skin; i.e. the Transfer factor for substances applied to a surface, without significant bonding those substances to the surface, is 1.

It is not reasonable to assume that the full amount of substance that is present in an article or significantly bound to an article can be transferred to the skin due to a contact with a short duration. Based on the limited number of measurements in our experiments, the value is probably much lower than 1. Also, if calculated over the available amount in the first 10 µm of the article, in our experiments it was clearly less than 0.1, however this is based on a very low number of articles and substances studied. In addition, it should also be taken into account that the data from our transfer experiments are only relevant for short-term contact with a duration of only seconds.

Although the measured transfer efficiencies for substances in or significantly bound to articles in our study are up to values in the order of 0.004-0.02 (calculated from the first 10 µm of article), the number of articles and substances studied is considered too low to assume that a value in that range can be used. The number of data is also considered too low for the two types of article/substance combinations tested in our experiments. Furthermore, it is unknown whether a substantially increased duration of wiping would have led to a much larger total transfer. A precautionary approach would therefore be to still use the value of 1 for *Transfer factor*, in relation to the amount of substance in the *Thickness of layer* of 10 µm. This is actually the approach taken now in ECETOC TRA for articles. For PVC and printed paper, there are indications that a value below 0.1 in relation to the *Thickness of layer* of 10 µm would be more realistic.

3.7 BODY WEIGHT

3.7.1 DEFAULT VALUES FOR BODY WEIGHT OF ADULTS

Default values for body weight of adults are presented in Table 7. ECETOC TRA makes no distinction between men and women, and uses a default value of 60 kg for the body weight of adults. ConsExpo has a default for adults of 65 kg. Bremmer (2006) calculated 74.2 kg for men and 60.7 for women. These are 25th percentiles of a set of measured data from the Dutch population. ConsExpo rounded these values to 70 kg for men and 60 kg for women.
The default values in the REACH guidance on consumer exposure (R.15) are also 70 kg for male and 60 kg for female adults. The LRI-INTERA project calculated a mean body weight from Expofacts data of 65 kg for adults, 78 kg for men and 60.7 kg for women. The recommended value for body weight of adults in the exposure factors handbook (US-EPA, 2011) is 80 kg, based on mean measured values from 1999-2006.

3.7.2 DEFAULT VALUES FOR BODY WEIGHT OF CHILDREN

Default values for body weight of children are presented in Table 7. ECETOC TRA uses one default value of 10 kg for body weight of children. No age range is given. From comparisons with measured data, it can be seen that 10 kg is a realistic body weight for toddlers of about 1 year. Taking this value for babies may underestimate exposure while for preschoolers and older children, 10 kg may be too conservative and a more age-specific value can be used for refinement of a modelled risk assessment outcome in ECETOC TRA. ConsExpo has default body weight values for different subgroups going from 1.5 month to 17.5 years. These are 25^{th} percentiles of a set of measured data. The quality score of 4 indicating a good quality of relevant data and a reliable parameter value (Bremmer, 2006). The values of ConsExpo for specific ages can be used to assess the exposure of children of a specific age. The REACH guidance (R.15) gives no default value for children but refers to external sources such as Bremmer et al. (2006), the Ausschuss für UmweltHygiene (AUH, 1995) and the Exposure factors handbooks (US-EPA). The LRI-INTERA project calculated a mean body weight from Expofacts data for different age groups. For comparison with the European values and the recommended values for body weight of the exposure factors handbook (US-EPA, 2011) are included in Table 7. These recommended values are based on mean measured values from 1999-2006. In general it can be seen that the values in the exposure factors handbook are higher than those of ECETOC TRA, ConsExpo and INTERA.

Table 7: Default mean values for body weight (m=male, f=female, y=year)

Population group	ECETOC TRA	INTERA KMS project	Consexpo (Bremmer, 2006) (25^{th} percentile)	US-EPA, 2011	REACH guidance (R15)
infant (birth-<1y)		6.9 (f) 7.4 (m)	4.3 (1.5 month) 6.21 (4.5 months) 7.62 (7.5 months) 8.69 (10.5 months)	4.8 (birth-<1 month) 5.9 (1-<3 months) 7.4 (3-<6 months) 9.2 (6-<11 months)	The guidance refers to external sources.
toddlers (1-<3y)	10 (child)	11.4 (f) (1-<2 y) 12 (m) (1-<2 y)	9.47 (13.5 months) 12.5 (2.5 y)	11.4 (1-<2 y) 13.8 (2-<3 y)	
preschooler (3-6y)			14.1 (3.5 y) 16.3 (4.5 y)	13.8 (2-<3 y) 18.6 (3-<6 y)	
child (6-<11 y)		20.8 (f) (3-8 y) 21.2 (m) (3-8 y)	20.6 (6.5 y) 28.4 (9.5 y)	31.8 (6-<11 y)	
teenager		41.4 (f) (9-14 y) 41.2 (m) (9-14 y)	43.9 (13.5 y) 56.8 (16.5 y) 58.2 (17.5 y)	56.8 (11-<16 y) 71.6 (16-<21 y)	
adult	60	65 (f) (15-64 y) 78 (m) (15-64 y)	65 (adult) 60 (f) 70 (m)	80 (adult)	60 (f) 70 (m)

3.7.3 Measured values of body weight of adults

A wealth of measured body weight data of European people are available in the literature and databases. This wealth of data allows us to make refinements of defaults for body weight, when the assessment is targeted towards specific age/gender/region subpopulations.
The European countries for which data on body weights are considered in this document and the number of studies are listed per geographical region in Annex 7. Age, gender and region differentiations are taken on board in the discussion below.

For most of the measured body weight values of European adults, the mean value is reported. Since body weight is a parameter which results in a higher exposure value for lower parameter values, Bremmer *et al*. (2006) recommend to use the 25^{th} percentile as default value. The values for body weight recommended by US-EPA are mean values (US-EPA, 2011).

For **men** aged 21-80 years, the 25th percentile range for Europe is 64-76.6 kg. The default of 70 kg in the REACH guidance is comparable to the mean of this range (70.3 kg). For men aged 80+, the range is 60-68 kg. For **women** aged 21-80 years, the 25th percentile range for Europe is 51-67 kg. The mean of this range (59 kg) corresponds quite well with the default of 60 kg for women in the REACH guidance and the default of 60 kg for adults in ECETOC TRA.
The values reported in Table 8 are the means of body weight values measured in European countries. Mean body weight values of men and women aged 21-70 are higher (up to 5 kg) than the body weight of men and women aged 70+.
For **men** aged 21-70 years , the mean body weight is 79,4 kg. This value is nearly 10 kg above the default of 70 kg of the REACH R.15 guidance and ConsExpo. For **women** aged 21-70 years, the mean body weight is 65,6 kg. This value is about 5,5 kg above the default of 60 kg of the REACH R.15 guidance, ConsExpo and ECETOC TRA (60 kg for adults).
Overall the mean weight is higher for men compared to women of the same age, the difference is about 6 kg in the range 21-70 years, and 3 kg for adults aged 70+. This difference is smaller than the 10 kg difference of REACH Guidance R.15 and of ConsExpo.
The mean body weight of **adults** aged 21-70 years is 72.5 kg. This value is 12.5 kg above the default of 60 kg of ECETOC TRA. The mean measured data for adults confirm that the defaults in ECETOC TRA, REACH guidance R.15 and ConsExpo are conservative. There is no need to change the defaults for body weight of adults. However, it could be considered to add gender-specific defaults in ECETOC TRA and raise the default for adults to 65 kg. The mean value for European adults (72.5 kg) is lower than the recommended value of 80 kg of the exposure factors handbook, which is also a mean value (US-EPA, 2011). The latter value may be not conservative enough for European people and hence lead to an underestimation of the exposure in European risk assessment.

The geographical differences in mean body weight are not large (maximum 6.9 kg, average 5.6 kg) and are often within the standard deviation which usually is several kilograms. However the body weight values seem to reveal a geographical trend. The highest mean body weight for men and women aged 21-70 years, is found in N-Europe and the lowest in S-Europe. N-Europe is followed by E-Europe, which is followed by W-Europe. For adults aged 70+ the same trend is seen. This trend is logical since body weight is interconnected with body height and the N-Europeans are the tallest people in Europe while the S-Europeans are the smallest.

An overview of the mean body weight values for European countries, per geographical region and of the exposure factors handbook, based on the U.S. National Health and Nutrition Examination Survey (NHANES) data (US-EPA, 2011) is given in Table 8.

Table 8: Body weight values (mean values) for adults. For the European data[14] the number of studies is between brackets. The exposure factors handbook recommends to use mean values (25th percentile values are between rectangular brackets).

Population group	Age (years)	Northern Europe	Western Europe	Eastern Europe	Southern Europe	Europe	Bremmer, 2006 (25th P)	Exposure factors handbook (US-EPA, 2011) (mean and [25th P])
Adult	21-70	74.9 (97)	71.5 (88)	72.9 (42)	69.3 (22)	72.5 (235)	64.8	81.8 [67.2]
Adult	70+	72.0 (2)	69.7 (17)	70.8 (4)	66.3 (12)	66.2 (20)		79.5 [61.3]
Men	21-70	81.6 (49)	78.1 (37)	78.3 (21)	76.4 (11)	79.4 (118)	74,2	88.2 [75.3]

[14] Sources used to derive (N, W, E, S) European mean data for body weight for men and women are AUH, 1995; Bremmer 2006; Expofacts, INTERA-KMS, Krul 2010, van Engelen 2007, VUB and WIV

Population group	Age (years)	Northern Europe	Western Europe	Eastern Europe	Southern Europe	Europe	Bremmer, 2006 (25th P)	Exposure factors handbook (US-EPA, 2011) (mean and [25th P])
Men	70+	77.8 (1)	75.9 (6)	74.7 (2)	70.9 (6)	68.7 (5)		80 [70.2]
Women	21-70	68.2 (48)	65.2 (37)	67.4 (21)	62.3 (11)	65.6 (117)	60.7	75.6 [61.2]
Women	70+	66.1 (1)	64.2 (6)	66.8 (2)	61.6 (6)	63.7 (15)		67.5 [57.6]

3.7.4 MEASURED VALUES OF BODY WEIGHT OF CHILDREN:

A lot of measured body weight values of European children are available (Annex 8).
The mean and the 25% percentiles of the body weight values combined for boys and girls, per age category are presented in Table 9.
Body weights of European children are in general lower than the body weights of North-American children (US-EPA, 2011) of the same age category. For example, for teenagers of 16-20 years the difference is 9 kg. So it is recommended to use defaults based on European data as body weights in Europe and North-America may differ.
The value of 10 kg which is the default for children in ECETOC TRA, corresponds with the measured weight of children of 11-12 months, showing that the default is conservative. There is no need to change the default. However it could be considered to add age-specific body weight default values.
As expected, the 25th percentile values of Bremmer (2006) are lower than the mean measured European values. Although the defaults of ConsExpo (Bremmer, 2006) are merely derived from Dutch data, they can be considered to be valid as defaults for Europe, since the mean European values are above these defaults.
The geographical differences in mean body weight of babies are small (maximum 0.6 kg) and are often within the standard deviation which usually is several hundred grams. However the body weight values of babies seem to reveal a geographical trend. In W-Europe the mean body weight seems to be lower than in N- and E-Europe. There are no published mean values for babies of southern Europe.
The geographical differences in mean body weight of children and teenagers of the same categories are small (maximum 4 kg for 11-15 year teenager) and are often within the standard deviation which usually is maximum 8 kg. However the body weight values of children and teenagers seem to reveal a geographical trend. In S-Europe the mean body weight is higher than in the other European regions. The body weight of children (3+) and teenagers is lower in E-Europe than in the other European regions.

An overview of the mean and 25th percentile body weight values for European children, per geographical region and the values of Bremmer (2006) and the exposure factors handbook, based on the NHANES data (US-EPA, 2011) is given in Table 9.

Table 9: Mean body weight (kg) values for children. For the European data[14], the numbers of studies with mean values is between brackets. ConsExpo only uses 25th percentile values (25th P). The exposure factors handbook recommends to use mean values. (25th P values are between rectangular brackets).

Age (months)	Northern Europe	Western Europe	Eastern Europe	Southern Europe	Europe Mean [25th P])	Consexpo (Bremmer, 2006) (25th P)	Exposure factors handbook (US-EPA, 2011) (mean and [25th P])
0	3..6 (7)	3.3 (4)	No data	No data	3.5 (11)		4.8 [4.2]
1 – 2	5.0 (10)	5.0 (4)	4.8 (4)	No data	4.9 [4.6] (18)	4.3 (1.5 month)	5.9 [5.2]
3 – 5	6.8 (15)	6.3 (8)	6.9 (6)	No data	6.6 [6.1] (29)	6.21 (4.5 months)	7.4 [6.7]
6 – 8	8.5 (15)	8.0 (8)	8.5 (6)	No data	8.3[7.8] (29)	7.62 (7.5 months)	9.2 [8.3] (6 - < 12 months)
9 – 11	9.6 (11)	9.0 (8)	9.6 (6)	No data	9.4 [8.8] (25)	8.69 (10.5 month)	
Age (years)							
0	No data	7.6 (5)	No data	7.4 (2)	7.5 (6)		
1	11.3 (29)	10.7 (31)	11.3 (8)	11.7 (2)	11.1 [10.3] (69)	9.47 (13.5 months)	11.4 [10.3]
2	13.1 (8)	13.3 (22)	13.3 (4)	14.5 (2)	13.3 [12] (34)	12.5 (2.5 years)	13.8 [12.4]
3 – 5	17.4 (12)	17.5 (48)	17.2 (31)	18.8 (6)	17.5 [15.9] (94)	14.1 (3.5 years) 16.3 (4.5 years)	18.6 [15.8]
6 - 10	28.6 (40)	27.5 (66)	26.3 (52)	31.5 (18)	27.8 [25.4] (170)	20.6 (6.5 years) 28.4 (9.5 years)	31.8 [24.4]
11 – 15	48.0 (40)	47.0 (52)	45.8 (52)	51.7 (20)	47.4 [42.9] (158)	39.3 (12.5 years) 43.9 (13.5 years)	56.8 [45.0]
16 – 20	62.3 (15)	62.6 (41)	61.8 (46)	63.9 14)	62.4 [56.4] (111)	56.8 (16.5 years) 58.2 (17.5 years)	71.6 [58.4]

3.7.5 CONCLUSIONS ON BODY WEIGHT

Defaults of 10 kg (children) and 60 kg (adults) are used in ECETOC TRA. Comparison of ECETOC TRA defaults with 25th percentile values for European people show that there is no need to change these defaults. However, it could be considered to add gender-specific defaults in ECETOC TRA and raise the default for adults to 65 kg. An extension of the defaults for age-specific assessments is recommended. Such specific defaults are available in ConsExpo and are considered to be representative for the European population.

The geographical differences in mean body weight of children and adults are small, and often within the standard deviation. However the body weight values seem to reveal some geographical trends. In case an exposure assessment has to be performed for a specific region, it is recommended to use geographical specific 25th percentile data as default.

4 POSSIBLE ADDITIONS TO OR ALTERNATIVE APPROACHES FOR ECETOC TRA DERMAL CONSUMER MODEL

This chapter describes a number of alternative approaches for estimating part of the parameters or processes that are relevant in assessing dermal exposure of consumers. The equation used by ECETOC TRA at this moment is, of course, a simplification of the true processes of dermal exposure. It may be possible, if sufficient knowledge and information is available, to either add relevant determinants to the equation, replace one or more determinants by (scientifically) more appropriate ones or even to replace part of the equation by a different approach. There may theoretically be a very large number of possible additions or alternative approaches. However, only those have been described that have surfaced in the DRESS project as potentially being (very) relevant, based on either the information studied, the experiments done or the considerations that were made while analysing all the information.

Not all the possible additions and alternative approaches presented here can be used without further data gathering or research. In the cases where additions or alternative approaches are considered to be relevant, but cannot be used yet, due to lack of data or knowledge, the presentation of such additions or alternative approaches can be read as an indication of potentially relevant issues to study for future improvement of dermal exposure assessment of consumers.

4.1 TAKING INTO ACCOUNT ADDITIONAL PARAMETERS WHEN ESTIMATING DERMAL CONSUMER EXPOSURE

As indicated in Chapter 2, during the course of developing this Guidance, several parameters were identified that are considered potentially relevant for dermal exposure, but are not part of the ECETOC TRA model at present.

A first set of parameters deal with the duration of exposure. Duration of exposure plays a role in the diffusion based and sweat extractability based method to (as alternative approaches compared to TRA; see further in 4.2). Duration of exposure is influenced by the number of exposure events during a day; in its turn, there might be several numbers of contacts during an exposure event.

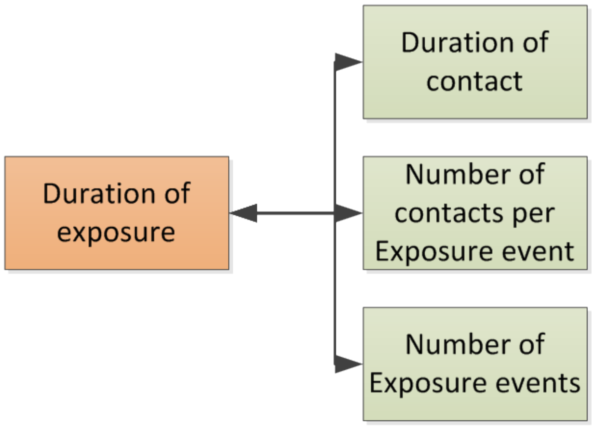


Figure 1: duration of exposure (on daily basis) is determined by the number of exposure events during a day; which in its turn is affected by the number and duration of contacts during an exposure event

4.1.1 Number of contacts

The *number of contacts* is at present not a parameter in the ECETOC TRA model (version 3). And although this parameter was also not specifically studied (no experiments performed) in this project, it is considered to be important when estimating dermal exposure. For printed paper, within the survey a question on the frequency of handling paper currency bills was included, with 75% of the respondents indicating handling paper currency bills up to 9 times per day. However, this is not a true measure of the number of contacts, because each handling can consist of more than one contact.

While the *number of contacts* may have an effect on the transfer from an article to the skin, this effect probably interacts with the effects of duration of contacts and *surface area of article in contact with skin*. The *number of contacts* is a determinant of both the total *duration of exposure* as well as of the total *surface area of article in contact with skin*. One contact can have a longer duration than another, but the total *duration of exposure* is the *number of contacts* times the average *duration of contact*. The relation between *number of contacts* and *surface area of article in contact with skin* is less clear, because several (or all) contacts can be with the same surface area. However, it can generally be assumed that there is an increase of *surface area of article in contact with skin* with *the number of contacts*.

In equations, the influence of *number of contacts* is indicated as follow:

$$t = t_c * n_c \qquad \text{[Equation 2]}$$

where: t = total *duration of exposure* (min)
t_c = average *duration of contact* (min)
n_c = *number of contacts*

and:

$$SA = f(SA_c * n_c) \qquad \text{[Equation 3]}$$

where: SA = total *surface area of article in contact with skin* (cm^2)
SA_c = average *surface area of article in contact with skin* per contact (cm^2)
n_c = *number of contacts*

No information is available on the type of function needed to describe this relationship exactly. Probably, there will be a different function for different types of articles. An approximation may be to use the following function:

$$SA = SAF_{new} * SA_c * n_c \qquad \text{[Equation 4]}$$

Where: SAF_{new} (Surface area factor for new contact) is a factor to indicate in how far each contact is with a new surface, running from $1/n_c$ (all contacts with the same surface) to 1 (all contacts with a new surface).

AuYeung *et al.* (2006) observed 38 young children's (1-6 year) hand contact during normal play activities via videotaping in primarily outdoor residential settings. They scored the number of contacts per hour of right hand, left hand and both hands (combination of results of left and right hand). They scored contact with surfaces in 'super-categories', such as 'animal', fabric (any kind), floor (including e.g. asphalt, dirt, rock/brick floor, carpet/mat), and 'metal' (including e.g. metal wall, furniture, tool or appliance). Although they did not specifically look at the types of printed paper as studied in our experimental work, they did score 'paper/wrapper'. A hand contact was defined as any contact with the fingers, palm, and/or back of the hands. The 75^{th} percentile of the frequency of (both) hand contacts per hour for a number of relevant types of articles was:

- Foot-wear: 4.7 times/hour
- Metal (wall, furniture, tool, appliance): 72.3 times/hour
- Plastic (wall, furniture, tool, appliance): 74.1 times/hour
- Toys (hard toy, porous plastic toy, fabric toy, wood toy): 201.3 times/hour
- Wood (wall, furniture, tool, appliance): 32.7 times/hour
- Fabric: 3.9 times/hour
- Floor (e.g. asphalt, dirt, rock/brick floor, carpet/mat): 7.2 times/hour
- Paper/wrapper: 7 times/hour

These data clearly show that the number of contacts of one or two hands with an article within an 'event' can be very high. However, the data is too specific (children playing outdoors) to be useful for drawing general conclusions on numbers of contacts with (types of) articles within an event.

Repetitive skin contacts on surfaces using fingertip presses on equivalently loaded, dust-laden stainless steel plates showed that the transfer factor from press-to-press gradually decreased by a factor of 3 as the skin surface became loaded. Also periodic losses of particles back to the contact surface were observed during successive contacts (Rhodes *et al.*, 2001). So considering that the same amount of substance is transferred during each consecutive short contact with the same or a different part of the article is considered to be conservative.

4.1.2 SURFACE AREA OF ARTICLE IN CONTACT WITH THE SKIN

Within this project no specific information on the *surface area of article in contact with the skin* was gathered. No data in literature could be found, and the type of surveys conducted to gather information on consumer behavior did not allow to ask people for such information. Such kind of information probably could be gathered by means of human observational studies (video recording and analyzing); this was beyond tools available within the DRESS team.
However, in the whole process describing dermal exposure, the parameter of surface area in contact is considered to be important for being able to come to a relevant estimate of dermal exposure. Based on other parameters studied in this project, some assumptions on *surface area of article in contact with the skin* can be made for the article types included in this study.

The *surface area of article in contact with skin* can either be estimated directly for an activity, or from the *surface area of article in contact with skin* per contact and the number of contacts, taking into account the fact that not all contacts will be with a new surface via a factor 'surface area factor new' (SAF_{new}) (see paragraph 4.2.1).

The value for SAF_{new} will have to be established for different types of articles, because this has not yet been studied in the past. The extremes will be values of 1 (all contacts with a new surface), and a value close to 0 (min : $1/n_c$) for all contacts with the same surface. Most activities will have a value in between the extremes, because neither extremes is very likely to occur.
It is expected that in most cases it will be more easy to make a general (conservative) estimate of SA at once than to calculate it from estimates of SAF_{new}, SA_c and n_c. In scientific studies it may however be possible to create reasonable estimates of distributions for these three parameters for certain activities.

4.1.2.1 PVC FLOORING

Of course, the maximum surface area of PVC flooring in contact with the skin on a day of exposure is the total surface area of the top surface of such flooring in the home of the consumer. However, this will depend on the size of the home and the size of separate rooms and with regard to performing a risk assessment, no general information is available for these parameters. Furthermore, it is extremely unlikely that a person will actually be in contact with the total surface area of PVC flooring in all rooms on one day. For example, the area under beds, cupboards, etc. will usually not be contacted. Furthermore, it is rather common that part of the PVC flooring is covered by carpets, rugs or mats. However, the reasonable worst case area covered by carpets, rugs or mats is less than 25% (based on information from the survey).
There is no information on reasonable worst case surface areas of rooms. The information in the ConsExpo factsheets cannot be used for this purpose, because this focuses on reasonable worst case for inhalation exposure. A smaller room size is more worst case for inhalation exposure, but a larger room size leads to a larger surface area of flooring and therefore is worst case for dermal exposure.

Therefore, at this moment no defaults can derived for surface area of (PVC) flooring in contact with the skin, due to lack of data.

4.1.2.2 CLOTHING ARTICLES

For clothing articles, it can be assumed that the reasonable worst case *surface area of article in contact with the skin* is equal to the surface area of the body parts covered by the clothing. This may be rather conservative for some types of clothing that are partly worn over other layers of clothing (e.g. trousers worn over underwear and T-shirts for ladies worn over bras). However it cannot be excluded that one wears a piece of clothing on the bare skin although it is not meant to be worn that way (e.g. a coat) or that substances migrate from the outer clothing to the inner clothing layer that is in contact with the skin.

It is recommended to use the surface area of the body parts covered as an estimate for the surface area of article in contact with the skin in risk assessment of clothing articles. In this case the surface area of article in contact with the skin can be assumed to be the same as the skin contact area; the latter parameter is defined in ECETOC TRA; and refinements for this parameter could be done based on information provided in 3.2.

4.1.2.3 PRINTED PAPER

In theory, the surface area of printed paper in contact with the skin can be the full surface area of the printed paper. However, for most items with a large surface area per sheet (e.g. newspapers) it is not very likely that the full surface area of the article will be touched on a day of use. On the other hand, the size of e.g. a book or a newspaper itself does not yet provide specific information on the surface area of article in contact with skin, even if it would be assumed that the full surface area can be contacted. Most printed paper items contain several to many pages that each can be touched individually, thereby increasing the total surface area with each page (compared to the surface area of the printed article as a whole).
The consumer behaviour survey did generate some information on the size of books and newspapers read by the participants. However, there are too many other factors (such as number of pages, places of contact with the pages) that influence the surface area of article in contact with the skin to enable using this information as an estimate for the surface area of printed paper articles in contact with the skin.

4.1.2.4 OVERALL CONCLUSIONS ON SURFACE AREA OF ARTICLE IN CONTACT WITH THE SKIN

It is assumed that the relevant *surface area of article in contact with the skin* is highly variable and very much dependent on the article type at hand. In general, there is insufficient information and knowledge to be able to derive reasonable worst case defaults for the surface area of article in contact with the skin. However, for specific cases, assumptions can be made. Furthermore, this type of information can be gathered via specific surveys looking at time activity patterns.

For clothing articles, it is recommended to use the surface area of the body parts covered by the clothing, which in most cases will be similar to the skin contact area, as the estimate for the surface area of article in contact with the skin.

4.1.3 DURATION OF EXPOSURE

Duration of exposure is a factor influencing dermal exposure, and can be used either as an additional scaling factor of the ECETOC TRA equation (see *equation 5* in 4.1.4) , and also plays a role when moving towards alternative approaches for assessing release of substances from articles. (see 4.2)

It is logical to assume that the total *duration of exposure* during a day of exposure, during an event or during a contact influences the dermal exposure levels. Because the ECETOC TRA model and the risk assessment process focus on exposure during a day, the *duration of exposure* on a day of exposure was studied in this project as part of the consumer behaviour survey.
It can be considered that duration of exposure is partly addressed in the present ECETOC TRA model by the difference in *Thickness of layer*, because a higher *Thickness of layer* is used for articles with an expected longer *duration of exposure*. For articles/products with a short duration of exposure a value of 0.001 cm is used, while for articles/products with an expected long duration of exposure a value of 0.01 cm is used (Guidance R.15). However, a more direct influence of duration of exposure might lead to a more appropriate model, assuming that sufficient information is available.

As indicated earlier, the total *duration of exposure* will depend on the average *duration of contact* and the *number of contacts*. When information or estimates on these parameters are available, calculations of total *duration of exposure* can be made. In some other cases, direct estimates of *duration of exposure* can be made, e.g. based on questionnaire studies, for which some examples are given in our consumer behaviour survey, or based on observational studies.

While and increase in *duration of exposure* is expected to lead to an increase in exposure levels, this increase is probably not linear, or at least not for a long duration of exposure. The skin can not retain an endless amount of substance. Furthermore, the migration in the article may be a limiting factor for long durations of contact. Therefore, it is assumed that there will be a ceiling effect of *duration of exposure* on the dermal exposure level.
As stated earlier, it is expected that the effect of *duration of exposure* is related to the effect of *number of contacts* and the effect of *surface area of article in contact with skin*. A combination of the three parameters, or the use of one of the three, may be the best method to account for the total 'increase of contact with contamination' that is common between an increase of the values these three parameters.

4.1.3.1 DURATION OF EXPOSURE PER DAY FOR PVC FLOORING

In the consumer behaviour survey, people with synthetic flooring were asked to report the time they spend barefoot in the home with contact with the floor. The 75th percentile of time that people spend (rarely or most of the time) barefoot in their home is 4 hours or more, with 25% giving this answer for time on the weekdays and 34% for time in the weekends. Four hours or more is also the reasonable worst case for children for spending time barefoot in a home with PVC flooring (29% on weekdays and 37% in the weekend).

4.1.3.2 DURATION OF EXPOSURE PER DAY FOR CLOTHING ARTICLES

The duration of wearing clothing articles per day was not studied in our consumer behaviour survey. However, for most clothing articles a long duration can be expected, because it is common practice to wear the same clothing for a whole period being awake and the same bed garments for the whole period spent in bed. No information was found on the reasonable worst case duration of wearing clothing articles, but an estimate is that clothing articles may often be worn up to 16 hours for a whole period being awake. On the other hand, a reasonable worst case duration for wearing bed garments is assumed to be 10 hours (e.g. in weekends).

4.1.3.3 DURATION OF EXPOSURE PER DAY FOR PRINTED PAPER

The duration of reading several types of printed paper per day was studied within the consumer behaviour survey. Based on the reported results, the reasonable worst case values are as follows:

- Books, magazines and newspapers: 30 min - 2 hours per day
- Brochures/catalogues: 15 - 30 min per day.

The duration of reading books tends to be longer than reading magazines and newspapers, with 9% of the respondents reporting reading books for 2 hours or more and only 1% in case of magazines and newspapers.

The duration of handling paper receipts per day can be calculated from the number of times a paper receipt is handled (reported to be 2-9 times in this survey) and the duration of holding the paper receipt per receipt. According to our survey, the reasonable worst case for holding a paper receipt is 30 seconds or longer. With 2-9 paper receipts per day the reasonable worst case duration can be estimated as at 1 – 4.5 minutes/day (assuming that a duration of longer than 30 seconds is not much longer than 30 seconds).

The reasonable worst case duration of handling both home printed paper or home printed photographs per event, according to the consumer behaviour survey, is 1-5 minutes.

4.1.3.4 OVERALL CONCLUSIONS ON DURATION OF EXPOSURE PER DAY

It is clear from the results of the performed consumer behavior survey that the *duration of exposure* per day is highly variable and very much dependent on the article type at hand. Therefore, it is not considered valid to derive a general default for '*duration of exposure* per day'.
Although only information on the types of articles as studied this project was available, it can be assumed that for instance information on duration of exposure to PVC flooring (for those people that have PVC flooring) is equally valid for other types of flooring (for those people that have such types of flooring).
The following 'defaults' for *duration of exposure* per day are considered to be used as reasonable worst case values in estimating dermal exposure levels for risk assessment for the article types as included in this study:

- Flooring (all types): at least 4 hours
  - The survey showed a duration of ≥4 hours and therefore the reasonable worst case is considered to be more than 4 hours but less than the full waking period; pragmatically a value of 8 hours per day could be used as estimator
  - Valid for both adults and children that live in a situation with a certain type of flooring and spend at least some time barefoot in their home
- Clothing articles – articles worn during the day: 18 hours per day
  - Estimate, based on the assumption that this is the reasonable worst case waking period
- Clothing articles – bed garments: 10 hours per day
  - Estimate, based on the assumption that this is the reasonable worst case time spent in bed
    - This estimate is not valid for people who are confined to their bed, e.g. due to illness
- Printed papers
  - Books, magazines, newspapers: 2 hours per day
    - This is the upper limit of the reasonable worst case category
  - Brochures, catalogues: 30 minutes per day
    - This is the upper limit of the reasonable worst case category
  - Paper receipts: 4.5 minutes per day
    - Based on calculations of the duration per receipt and the number of receipts handled per day
      - Home printed paper and home printed photographs: 5 minutes per day
    - This is the upper limit of the reasonable worst case category
  - These estimates are valid for those people reading or handling these kinds of printed paper

4.1.4 NUMBER OF CONTACTS, SURFACE AREA IN CONTACT WITH THE SKIN AND DURATION AS PART OF AN EQUATION

Based on limited data and expert judgement, it is expected that the relation between *duration of exposure* and *number of contacts* varies between two extreme options:

1. *Duration of exposure* and duration of contact are the same; there is only one (long term) contact during the duration of exposure; constant contact situations
2. Duration of contact is (very) short, while *duration of exposure* is long; there are many (short term) contacts during the duration of exposure; many short duration contact situations

Option 1 can be considered reasonable for clothing articles and bed linen, although in reality not all clothing will always be in direct contact with the skin (and neither will the complete surface of bed linen). Option 2 relates to situations with many contacts of a short duration per event, for instance playing children as studied by AuYeung et al. (2006). Most exposure situations are considered to be in between of these extremes. For instance, contact with PVC flooring can consist of periods of longer contact (standing or sitting at one place) combined with several (or many) short term contacts (walking around).

In case of a constant contact situation, the *duration of contact* in combination with the skin contact area are considered to be the most relevant parameters. In case of many short duration contact situations the total *surface area of article in contact with the skin* can be used as a proxy for the total 'intensity of contact'. For the situations in between the two extremes a pragmatic solution is to choose from one of the two approaches, based on the perception of whether that particular situation is closer to one extreme or the other.

Based on these considerations it is recommended to consider to improve the ECETOC TRA model in the future by providing a choice between the following two approaches, with a number of default choices.

1. Constant contact during prolonged time

$$DE = (PI * CA * TF * TL * D * DF * 1000) / BW \qquad \text{[Equation 5]}$$

Where:
DE = dermal exposure (mg/kg bw/day)
PI = *Product Ingredient* (g/g) = concentration of substance in the article
CA = skin *Contact Area* (cm^2)
TF = *Transfer factor*
TL = *Thickness of layer* (cm)
D = *Density* (g/cm3)
DF = Duration Factor: a factor between 0 and 1 to account for variable duration of contact

The *duration factor* should be chosen as 1 for a reasonable worst case maximum duration. In this approach, the *Transfer factor*, *Thickness of layer* and *duration factor* need to be coherently calibrated in such a way that a maximum combination of the three parameters leads to the expected maximum reasonable worst case exposure. Assuming that the present default *Transfer factor* of 1 is reasonable and that the *Thickness of layer* values that are now used are also reasonable (which is not necessarily shown yet), the use of a *duration factor* of less than 1 will lead to a lowering of the estimated exposure level for relatively short term duration of exposure within article types that in principle have a constant contact during prolonged time. For example, if the reasonable worst case *duration of exposure* for clothing articles is 18 hours per day, the default *duration factor* for clothing of 1 indicates clothing worn for 18 hours per day. If some types of clothing are worn typically for shorter periods (e.g. nightgowns, swim wear), the *duration factor* for these types of clothing should be lowered with a factor equivalent to the lowering of the duration of wearing compared to 18 hours per day. For a piece of clothing worn for 8 hours, this would result in a *duration factor* of 8/18 = 0.44.

Skin *Contact area* is in this case also a proxy for *surface area of article in contact with skin*, because for these types of articles it is assumed that there is only one or a few contacts and that during an event of contact the contact is all the time with the same surface area of article.

2. Many short duration contacts

*DE = (PI * TF * TL * D * SA * 1000) / BW* *[Equation 6]*

Where: PI = *Product Ingredient* (g/g) = concentration of substance in the article
TF = *Transfer factor*
TL = *Thickness of layer* (cm)
D = *Density* (g/cm^3)
SA = total *Surface area of article in contact with skin* (cm2) (as proxy for total intensity of contact)

In this approach it may be needed to also indicate the skin contact area, to enable recalculation from mg/kg bw/day to mg/cm^2.

It is noted that this proposed modified equation differs from the ECETOC TRA in that view that CA (skin contact area) is replaced by SA (*Surface area of article in contact with skin);* since the latter is a better approach for articles with many short term contacts.

4.1.5 WASHING OR CLEANING OF ARTICLES BY CONSUMERS

Several articles are regularly washed or cleaned by consumers in a way that may lead to a change in the potential for exposure. Article types such as clothing and other textile articles, but also e.g. tableware and kitchen utensils, are usually washed after one or more use events and in some cases also before first use. Several types of flooring and also tiles on walls can be cleaned by either dry or wet wiping. Such treatments can be expected to influence future exposure by consumers to substances from those articles. If substances can be transferred to the skin by contact with the skin, it is probable that these substances are also transferred to washing water of wiping material during cleaning. The effect on the next exposure event may be a reduction of the amount of substance available in the article or in the top layer of the article.

The consumer behaviour survey indicated that it is rather common to wash new clothing items before wearing them for the first time. However, this is different for underwear (58% of respondents indicating that they wash these first) compared to other items (between 4% for tights/stockings and 27% for T-shirts). Still, 19% of respondents indicate that they never wash new clothes before wearing. Clothing articles are also washed regularly after wearing them for a certain period, although some clothing articles more regular than others. Underwear was reported to be worn only once between two washings by 81% of the respondents, while 60% of the respondents reported wearing pyjamas four or more times between two washings. This suggests that, if the effect of washing on exposure might be different for different clothing articles.

Although considered relevant, the available information does not allow to draw any conclusions on the effect of washing or cleaning of articles on consumer dermal exposure. Until more knowledge is available, such an effect cannot be taken into account in risk assessment.

4.2 Alternative approaches for assessing release of substances from articles

In the ECETOC TRA equation, the *amount of substance released from the article per unit of area during an exposure event* (ASRA) is approximated by multiplying the factors *Thickness of layer*, the concentration of the substance in the article (PI) and the density of the article (D). As discussed above, there is a lack of scientific underpinning of the *Thickness of layer* concept, thus questioning whether ASRA is adequately addressed by the ECETOC TRA approach, and therefore, alternative approaches are proposed.

It is noted that release of substances from an article is not (only) a material intrinsic property. Since 'release' involves the movement of substance from one matrix (the article) to another matrix (the skin, or a layer of substances, such as sweat, dirt, etc., on the skin) it does not only depend on the properties of the article, but also on the affinity of the receiving medium (the skin/skin covering layer of substances) – to which the substance is released.

In fact, the "*amount of substance released from the article per unit of area during an exposure event*" (ASRA) results from a complex and interrelated action of processes like diffusion, solubility and removal. Each of these processes depend in turn on modifying factors such as physico-chemical properties of substances and materials and conditions of the receiving surface (skin).
Notwithstanding that these processes easily could fit into a conceptual framework for understanding ASRA, practical (empirical or mechanistic) models and data to describe and quantify the influence of (the joint working of) these processes on the "*amount of substance released from the article per unit of area during an exposure event"* are lacking in general.

Whereas it is, based on the current state of the art, and the experimental results from DRESS, not possible to construct one generic and comprehensive model for prediction of ASRA , we propose to use a tiered approach for this assessment. The tiered approach starts with low data input and ignores kinetic aspects, diffusion and solubility limitations in the first tier (based on mass balance principle), resulting in (over)conservative estimates. In a tier 1 approach (diffusion model), kinetic aspects and diffusion limitations are accounted for; in a later stage (sweat/skin lipids extraction model), external conditions of the medium to which the substances is release (skin) as the medium (solubility in skin) is additionally accounted for (by accounting for solubility of substance in relevant matrices). Moving from low to higher tier thus results in more realistic predictions, given the increasing consideration of release limiting factors. At the same time, moving from low to higher tier approaches relies increasingly on article-substance specific parameters, for which experimentally generated data is required (Figure 2).

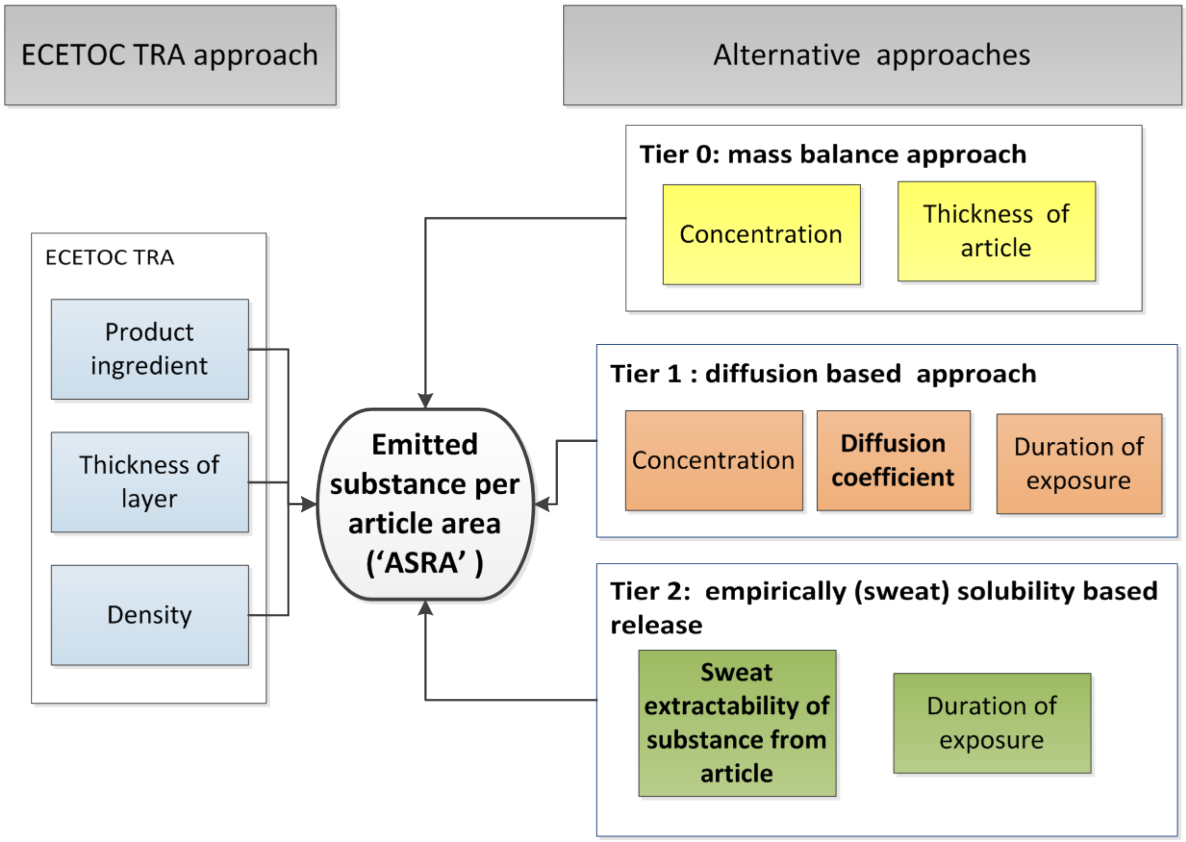


Figure 2 : Tiered approach for assessing "amount of substance released from the article per unit of area during an exposure event", as alternative to the ECETOC TRA approach for estimating the amount of substance released from an article."

4.2.1 Tier 0: Mass balance-based release

4.2.1.1 Model concept and equations

In an extreme situation, all substances present in the article may become released from the article to the skin during one exposure event. This is considered to be a very conservative approach, and contra-intuitive with the general assumption that when manufacturing of articles substances are added with the purpose of staying in the matrix (as such or as reaction products after interaction with other substances in the matrix), and in general not intended to be released from the articles (besides some exceptions such as fragrances).
However, in absence of any indications of factors limiting the release of substance from an article, the mass balance approach could be applied as an extremely conservative approach in data-poor situations. In the majority of cases this approach will probably lead to an unrealistically high estimate for the "amount of substance released from the article per unit of area during an exposure event". However, if these high estimations result in 'safe levels' in the risk characterization phase, there is no need to spend additional effort to estimate exposure in a more realistic way.

The mass balance approach can be mathematically expressed as:

$$A = C_0 \times V \qquad \textit{[Equation 7]}$$

Or expressed per unit surface area of the article:

$$A_s = C_0 \times Th$$ *[Equation 8]*

With

A = amount of substance released per article (mass, in g)
C_o = initial concentration of the substance in the article (mass/volume, in g/cm³)
C_o = PI x D
V = volume of the article (in cm³)
A_s = amount of substance released per surface area of the article (mass/area, in g/cm²)
Th = thickness of the article (in cm).

4.2.1.2 ASSUMPTIONS AND LIMITATIONS OF THE MASS BALANCE APPROACH

It is noted that the mass balance approach does not take into account time-dependency of release, and thus the relationship between release and exposure duration. The approach considers release as an instantaneous process, assuming that the whole amount of substance present in the article is released within the time frame of the exposure event, even for exposure events with a short duration.
In addition, the model does not take into account any limiting factors such as diffusion, solubility in skin relevant matrices.

4.2.1.3 ESTIMATION OF MODEL PARAMETER VALUES

Besides parameters that are already taken into account in the ECETOC TRA equation (C_0), one needs to estimate values for "thickness of the article" to enable mass balance calculations.
There is obviously a large variability in thickness of articles, from very thin (e.g. paper articles) to thick (e.g. massive plastic articles like a chair). Instead of providing defaults for this parameter for certain article categories (which are likely to also show a large variability within the category), it is advised to measure or estimate the thickness of the material of interest, or retrieve this information from the producer. The thickness is to be interpreted as the length of the article perpendicular to the surface contacting the skin.

It is noted that the ECETOC TRA approach for assessing "the amount of substance emitted per surface area of the article" is conceptually rather similar to the mass balance approach. The main difference is that ECETOC TRA uses "thickness of the contact layer" (10 or 100 µm) instead of "thickness of the article". In other words, the ECETOC TRA dermal exposure equation applies the mass balance principle, but limits this mass balance to the outer shell (10 or 100 µm; depending on article type) of the article.

4.2.2 TIER 1: SIMPLIFIED DIFFUSION MODEL-BASED RELEASE

4.2.2.1 MODEL CONCEPT AND EQUATION

The diffusion model based release is based on the idea that substances move from the article to the surface of the article; and that, once present at the surface of the article, this amount may be transferred to the skin.

This diffusion-based approach is based on the well-established theory of diffusion of substances in materials. Diffusion expresses the mobility of substances within articles. These physics-based emission models have been successfully applied in the field of emissions from building materials to the indoor air (Huang and Haghighat, 2002; Xu *et al.*, 2009), as well as in the field of migration of substances from packaging material into food stuff (Brandsch, 2002; Begley *et al.*, 2005). Delmaar et al. (2013) recently promoted a simplified diffusion model as first tier screening tool for dermal exposure to substances in articles, as an alternative approach for the ECETOC TRA dermal exposure equation.
The mathematical equation of the diffusion model, based on the Fick's 2nd law, can be expressed as (Delmaar *et al.*, 2013; Piringer, 1994):

$$\frac{dA}{dt} = S \times D_{diff} \times \left.\frac{\partial C}{\partial x}\right| surface \qquad \textit{[Equation 9]}$$

Where: A = amount of substance released per article (g)
C = concentration of the substance in the article (g/m^3)
S = surface area of the article (m^2)
D_{diff} = diffusion coefficient (m^2/s)
x = position in the material (m)
t = time (s)

To apply the complete diffusion model in a specific situation, appropriate initial and boundary conditions on the concentrations of the substance in the material, C(x,t), must be specified.
To approximate the diffusion in a material a simple diffusion layer model may be applied, based on a finite difference approach instead of the complete diffusion model. This simplified diffusion model considers an average distance '*l*' ($= \sqrt{2 \times D_{diff} \times t}$) over which a diffusing molecule will travel during time t, and therefore the original diffusion model can be simplified to the following analytical expression for slab-like articles (Delmaar et al, 2013; Piringer, 1994):

$$A(t) = C_0 \times S \times \sqrt{2 \times D_{diff} \times t}$$

Or per unit surface area of the article (A_s (t):

$$A_s(t) = C_0 \times \sqrt{2 \times D_{diff} \times t} \qquad \text{[Equation 10]}$$

This simplified diffusion model assumes that all substance that is able to reach the material surface within duration t will be emitted and available for transfer to the skin at duration t. In other words, this simplified model assumes diffusion to be the limiting factor for the availability of substances for skin exposure.

The concept of this 'average distance layer' *l* is comparable to the "thickness of layer" concept of ECETOC TRA, besides 2 aspects:
l is a time-dependant factor (depending on the duration of an exposure event)
l is based on a diffusion coefficient, thus reflecting a physical process. *Diffusion coefficients* which are substance-article specific values (which in generally are experimentally determined) are used instead of (arbitrary) chosen derived/assumed default values for TL.
It is noted that A(t) should be topped off by upper boundaries based on mass balance limitations.

4.2.2.2 Assumptions and limitations of the diffusion based model

Using the simplified diffusion-based model as a way to calculate the '*amount of substance released from the article per unit of area during an exposure event',* it is assumed that diffusion, being an inherent material property, is the limiting factor for exposure. By application of this model it is also assumed that the total amount of substance diffusing from the centre of the article to the outer surface of the article is immediately completely removed when it reaches the surface (no mass transfer limitations once the substance has reaches the surface). Consequently, the concentration at the surface drops again, and the concentration gradient over the article persists to be the driving force for diffusion. And although this approach is considered to be a reasonable approximation of the actual situation in other domains where diffusion modelling is used (e.g. emissions from material to indoor air), this is maybe less the case for estimation of dermal exposure. Absence of mass transfer limitations for dermal exposure would probably lead to an overestimation of dermal exposure because this implies the direct removal from the surface to amongst others the skin, which is not the case in practice.
Whereas the diffusion process is a substance-material inherent property, the mass transfer also depends on external conditions and the size of the medium ('receiver') to which the substance is transferred (for skin: sweat, skin lipids,… and for other receiving surfaces: roughness, moisture,…).

In addition, the model assumes direct contact between article and skin the only relevant process, ignoring potential other processes such as abrasion and subsequent dermal contact with the generated, abrased particles.

4.2.2.3 Model parameterizations

Besides parameters already involved in the ECETOC TRA equation (C_0), one needs to characterize values for "diffusion coefficient" and "duration of exposure" to be able to perform calculations using the simplified diffusion model.

Duration of exposure
Parameterization of duration of exposure is addressed in section 0.

Diffusion coefficients
Diffusion coefficients depend on physical-chemical properties of both the substance and the article matrix. Diffusion coefficients may be determined in laboratory experimental settings. Two types of experiments are commonly used to determine the diffusion coefficient: 1) based on sorption and desorption curves in test chambers (air) using a forced air stream and measuring the concentration of the substance in the air (e.g. Cox *et al.*, 2001); or 2) based on extractions in a liquid solvent (Piringer, 2008).

An overview of literature gathered diffusion coefficients, and experimentally determined diffusion coefficients on materials tested in this project is given in Annex 10. The majority of the data found in literature refer to (S)VOCs in plastic articles. It should be noted that the inventory of (publically available) diffusion coefficients in Annex 10 is given as illustration, and is not considered to be complete.

Mechanistic models to estimate diffusion coefficients do exist (Piringer, 2008, Mercea, 2000), and can be used instead of experimental testing. However, these are complex models and their utility in lower tier exposure modelling is considered to be limited (Delmaar *et al.*, 2013). Empirical models to estimate diffusion coefficients have been published for some groups of compounds, but their applicability domain is limited to these groups. For example, Cox *et al.* (2001) found a correlation between D and Molecular Weight for four alkanes, which can be used to estimate diffusion coefficients for other alkane VOCs.

Recently, Holmgren *et al.* (2012) published the following empirical model for prediction of diffusion coefficients, based on the Piringer equation, which is an empirical worst case calculation developed for predicting diffusion rates of additives from food packaging to food (Begley *et al.*, 2005; Piringer and Baner, 2008):

$$D_{diff} = exp\left(A_p - 0.1351(Mw)^{2/3} + 0.003Mw - \frac{10450}{T}\right) \qquad \textit{[Equation 11]}$$

With

- D_{diff} = diffusion coefficient
- Ap = material specific coefficient
- Mw = molecular weight
- T = Temperature (in Kelvin)

For some materials, *Ap* has to be adjusted to account for the temperature dependence of the activation energy, by using *A'p* and the temperature-dependent material-specific activation energy parameter *Tm:*

$$A_p = A'_p - \frac{T_M}{T} \qquad \textit{[Equation 12]}$$

Values for *A'p* and *Tm* are material-specific empirical values. Thus, these equations give room for estimating diffusion coefficients for a series of substances in materials. However, experimental data on material specific parameters (A'p and Tm) are still needed. An overviews of published values for A'p and Tm, as reported by Holmgren *et al.* (2012), are given in Annex 10.

In summary, the diffusion coefficient is an article- and substance-specific parameter. For various combinations of material and substance (mainly plastic articles and building materials) measured diffusion coefficients have been published in literature. In absence of an experimentally determined diffusion coefficient, one may use the empirical model of Holmgren *et al.* (2012). This model requires the molecular weight of the substance and material-specific parameter *Ap* as inputs. For a broad range of plastic materials, *Ap*-values have been published in literature (see Annex 10); however, for a broad range of other materials besides plastics, parameterization of Ap is lacking, thus requiring additional experimental efforts.

4.2.3 TIER 2: EMPIRICAL (SWEAT) SOLUBILITY – ARTIFICIAL SWEAT-BASED RELEASE

4.2.3.1 CONCEPT AND EQUATIONS

Extraction of articles with artificial sweat is a widely used approach to assess dermal exposure to substances in articles (Meinke *et al.*, 2009; Danish EPA, 2007). In contrast to the mass balance and diffusion model approaches, this approach does not explicitly take into account distinct physical processes. Instead, it is an operationally defined approach, mimicking the release of substances from articles when being in contact with a skin relevant medium (sweat) for a given duration. The amount of substance released from the article to (artificial) sweat is assumed to be the result of a

combined effect of intrinsic processes of the material (diffusion) and external processes such as mass transfer from one medium to another (transfer of substance from article into the artificial sweat extracting medium), and hence is affected by the solubility of the substance in sweat.
The amount of substances released to the skin using this approach can be expressed as:

$A(t) = C\ (t)_{artificial\ sweat} \times W$ *or*

$A_s(t) = C\ (t)_{artificial\ sweat} \times \frac{W}{S}$ or

$$A_s(t) = X\ (t)_{artificial\ sweat} \times \frac{W}{S} \times C_0 \qquad \text{[Equation 13]}$$

With

$C(t)_{artificial\ sweat}$ = artificial sweat extractable concentration of substance per mass unit of article at time t (g/g);
t = the extraction time (minutes or hours)
W = weight of the article (g)
S = surface area of the article (cm^2)
X = fraction of artificial sweat extractable concentration of the total (initial) concentration of substance in the article (%).

4.2.3.2 ASSUMPTIONS AND LIMITATIONS

Standard defined compositions of artificial sweat are commonly used (e.g. DS/EN ISO 105-E04; DIN 54020).The sweat simulant in DS/EN ISO 105-E04 consists of 1-histidine-monohydrochlorid-1-hydrate, sodium chloride, sodium dihydrogen phosphate and sodium hydroxide for adjustment of pH to pH 5.5. This composition may, however, be a too simplified simulation of sweat (Stefaniak & Harvey 2006).

The basic assumption underlying this artificial sweat extraction approach is that artificial sweat is an adequate medium to simulate mass transfer from material to the skin. This is probably a correct assumption for substances with a relative high water solubility, which will have a high tendency to be transferred from article to the artificial sweat. However, for hydrophobic substances, their low water solubility will hamper the transfer to artificial sweat. This was also shown in experiments in WP 3.2 of this project, where phthalates present in textile prints could not be detected in artificial sweat extracts.
However, hydrophobic substances might be transferred from the article to the (outer) lipids layer of the skin (a thin layer of lipids covering the skin (Nicolaides, 1974), irrespective of the presence of sweat. Therefore, artificial sweat extractions might underestimate the transfer and thus dermal exposure for hydrophobic substances. However, no adequate extraction procedures mimicking this skin lipid layer exists.

The influence of hydrophobic components on the release of substances from articles was also supported by a case where extractable amounts of DEHP from plastic sandals in artificial sweat were shown to be up to 150 higher for sandals in combination with sun lotion and a dynamic (shaking) extraction procedure compared to a static extraction of sandals with artificial sweat in absence of sun lotion (Danish EPA, 2007). However, the use of sun lotion cannot be generalized as a good proxy for skin lipid layer.

Overall, the artificial sweat extraction procedure is thus not considered an appropriate method for assessing release of hydrophobic substances from articles. Therefore, suitable extraction procedures taking into account the effect of skin lipids layers need to be developed. Directions towards such an approach are for example the use of lanoline impregnated cotton (mimic oils in skin) (used in the RAR of DEHP (EC, 2008)).
A second conservative assumption underlying the artificial sweat extraction method is that artificial sweat acts as a large sink compared to the limited amount of sweat normally present on the skin. This higher liquid/solid ratio (e.g. order of magnitude of L/S ratio 10 : 1) of the artificial sweat extraction experiments is assumed to enhance the release of substance to the liquid medium, thereby possibly overestimating the transferrable amount of substance.

4.2.3.3 MODEL PARAMETERIZATIONS

The basis for the assessment of "*amount of substance released from the article per unit of area during an exposure event'* is the determination of the artificial sweat extractable concentration of substance (per mass unit of article (g/g)). Since the release of substances from materials to artificial sweat is a time-dependant process, ideally the released concentration is determined after a duration representative for the duration of contact with the article. In practice, very often fixed time periods of 1, 8, 16 or 24 h are used. The determination of the amount or fraction of a substance released from articles to artificial sweat requires experimental testing. Experimental protocols such as S/EN ISO 105-E04; DIN 54020 or the BfR 2007 protocol (for textiles) could be used.
No generic mechanistic or empirical models are available to predict the levels of artificial sweat extractable amounts (or fractions) from articles. However, despite the absence of generic models to predict release rates, for certain categories/groups of articles and substances rules of thumbs to estimate the fraction of artificial sweat extractable amounts are described in literature. For example, for substances present in textiles Krätze and Platzek (2004) derived defaults based on a series of experimental data on substances present in textile materials (see Table 10).These defaults are also recommended by the BfR working group on textile[15].

Table 10: default migration rates for dyes and textile auxiliary substances (from Krätze and Platzek (2004)

Substance category	Migration rate*
Dye	0.5 %
Hydrophilic textile auxiliary	2 %
Hydrophobic textile auxiliary	0.1 %

*migration rate is defined by Krätze and Platzek (2004) as the ratio of artificial sweat extractable amounts to the initial content of substance in the textile, at a fixed time t (60 min.)

In summary, using artificial sweat extractable amounts as a way to quantify the ASRA is based on operationally defined approach, partially mimicking the release of substances from articles when being in contact with a skin relevant medium (sweat) for a given duration.
Results are article and substances specific, and experimental testing is generally required; with the exception of dyes and textile auxiliary for which some rules of thumb do exist.
Major drawback of this method is that it might lead to underestimation of ASRA for hydrophobic substances due to low solublity in artificial sweat, ignoring the compatibility of hydrophobic substances and skin lipids.

[15] http://www.bfr.bund.de/en/health_assessment_of_textiles-531.html

4.2.4 FURTHER OUTLOOK

Whereas the sweat extractable method could be considered as the method accounting (indirectly) both for diffusion (material intrinsic) and solubility into the skin relevant medium (artificial sweat), and thus offering probably leading to more realistic estimates that the mass balance and diffusion based model, it is requiring experimental efforts. Moreover, it does not offer mechanistic insight into the relative importance of diffusion (within article) versus solubility (from article to skin relevant medium). A next step forward in understanding and predicting release from substances could be to development of a mechanistic model based on diffusion and solubility.

5 GUIDANCE ON REFINEMENTS OF ECETOC TRA PREDICTIONS OF DERMAL EXPOSURE

This document provides a brief guidance on possible refinements of ECETOC TRA predictions of dermal exposure, based on the work done in this project. The description of the guidance will be brief and, where relevant, reference will be made to other parts of this document for more details (i.e. where relevant data can be found for conducting a dermal exposure assessment).

5.1 POSSIBLE REFINEMENTS OF ECETOC TRA CONSUMER DERMAL EXPOSURE MODEL OUTCOMES

Based on the experiments and evaluations as performed within the DRESS project, a number of possible improvements with regard to the ECETOC TRA consumer dermal exposure model can be suggested. Several types of improvement / refinements can be considered:

1. Modify a default value for a parameter that is already included in the ECETOC TRA model
2. Use of a specific value for a parameter that is already included in the ECETOC TRA model in case the default value is not sufficiently representative for the specific article type
3. Modify the ECETOC TRA model by adding additional parameters or modifying existing approaches

The suggestions for improvements of the dermal exposure assessment for consumers, based on the findings of the DRESS project and structured according to the types indicated above, are presented below.

5.1.1 OPTION 1: MODIFY A DEFAULT VALUE FOR A PARAMETER THAT IS ALREADY INCLUDED IN THE ECETOC TRA MODEL

The information on relevant parameters, studied in this project, did not lead to the conclusion that existing default values need to be modified. A (partial) exception is the default for body weight for adults.
Based on the 25th percentile of a wealth of measured data for the European population, it could be considered to raise the default body weight for adults to 65 kg and to add gender-specific defaults (60 kg for women and 70 kg for men).

5.1.2 OPTION 2: USE OF A SPECIFIC VALUE INSTEAD OF THE DEFAULT VALUE

For a number of parameters that are part of the ECETOC TRA consumer dermal exposure model it is recommended to use specific values instead of the default value(s) that are given in the model:

a. *Product ingredient* (fraction of substance in the article); use a specific value, unless this is not possible (see 3.1)
b. *Frequency of use*; consider the specific values for some articles, e.g.:
    i. Some clothing articles (see 3.3.2)

   ii. Several printed paper articles (see 3.3.3)

   The *Frequency of use* values recommended should not be used automatically in the calculations to lower the long term exposure level, because averaging over weeks, months or a year is not a generally accepted approach in human risk assessment of chemical substances. It can, however, be used to indicate, either via calculation of long term exposure level or qualitatively, that average exposure levels over a long period are much lower than exposure levels on a day of exposure. This indication can influence the decision on whether there is concern for risks due to chronic effects.

c. *Density*
   i. PVC flooring material (see 3.5.1)
   ii. Textiles (see 3.5.2)
   iii. Printed paper articles (see 3.5.3)

d. Whenever possible, use a specific value for the *Transfer factor* in case such a specific value is available for a combination of substance and article type (see 3.6).

e. *Contact area* (see 3.2)

f. *Body weight* (see 3.7)

5.1.3 OPTION 3: MODIFY THE ECETOC TRA MODEL BY ADDING ADDITIONAL PARAMETERS OR MODIFYING EXISTING APPROACHES

Next to modification of values of parameters it is also possible to modify the model by adding parameters or modify the ECETOC approaches for assessed release from articles (based on the thickness of layer concept), by alternative approaches.

5.1.3.1 ACCOUNT FOR ADDITIONAL PARAMETERS

A number of potentially relevant additional parameters have been studied. It was found that a simple addition of one or two parameters would not be a relevant option. However, the use of some form of combination of the parameters *duration of exposure* and *surface area of article in contact with skin*. It is suggested to differentiate between two approaches:

1. Constant contact during prolonged time
2. Many short duration contacts

In the first approach, the *duration of exposure* can be included via a 'duration factor'. In the second approach the *surface area of article in contact with skin* plays a role and this parameter may be estimated using an equation including the *number of contacts*.

See 4.1.1, 4.1.2, 4.1.3 and 4.1.4 for more information on these parameters and for descriptions on how these parameters can be used in an improved model. It should be noted that there is currently a lack of underpinned parameter values to follow these approaches. However, it gives direction towards further needs (involving human observational studies).

5.1.3.2 MODIFY THE APPROACH USED IN ECETOC TRA

A tiered approach has been suggested as modification to estimate the release of substances from the article ('ASRA'):

1. Mass balance-based release (see 4.2.1)
2. Simplified diffusion model-based release (see 4.2.2)
3. Sweat extraction-based release (see 4.2.3)

When using these alternative approaches for ASRA approach, some of the factors of TRA equation, i.e. the factors for assessing ASRA in TRA (TL, D, PI and 1000) should be replaced.

The TRA equation is (see Equation 1) :

DE = (PI * CA * TF * TL * D * 1000) / BW

Consequently, the modified equation for assessing dermal exposure DE becomes:

DE = ASRA*CA*TF/BW

With ASRA: *amount of substance released from the article per unit of area during an exposure event (g/cm²).*
Options to assess ASRA are explained in chapter 4.2

On top of this alternative approach for ASRA, additional factors (reduction factors related to washing, cleaning, accounting for number of contact, surface area of contacted article) might be used to assess dermal exposure .

6 CASE STUDIES

6.1 INTRODUCTION AND GENERAL APPROACH

In this chapter, potential refinements of ECETOC TRA dermal exposure equations and alternative strategies to assess dermal exposure to substances in consumer articles are demonstrated in three case studies, namely:

- Textiles (garments)
- Printed paper
- PVC flooring

These 3 article categories were selected since experimental data and consumer surveys performed within the DRESS project have generated data to demonstrate the potential refinements and alternative approaches.

The general strategy to perform a case study is according to the procedure explained in chapter 5, as illustrated in Figure 3:

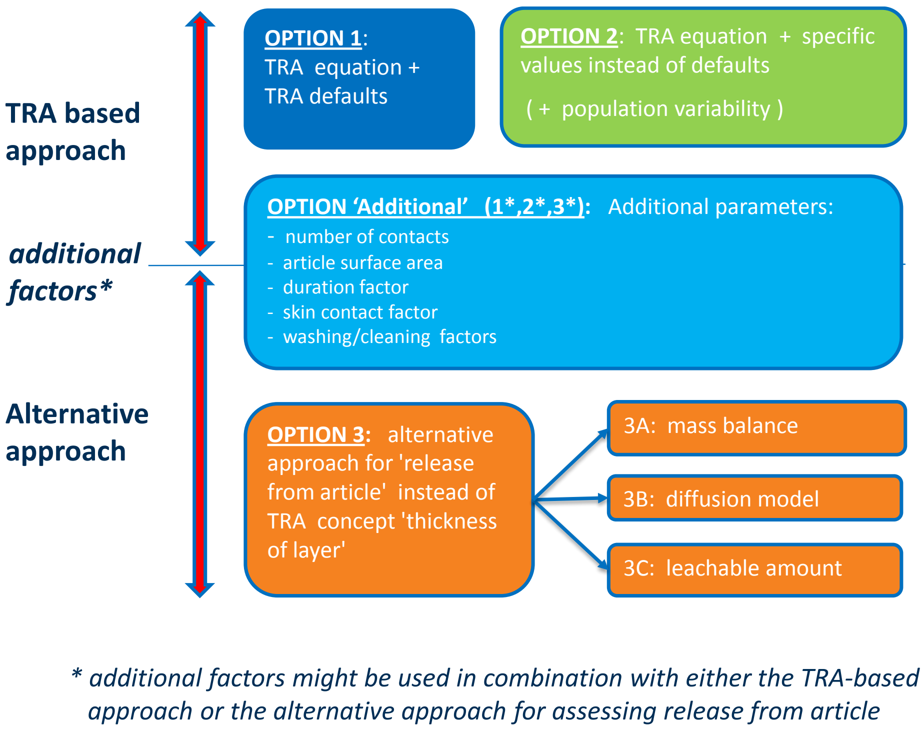


Figure 3: strategy for case studies, following guidance developed in previous chapters

Each case study will be run using the different relevant options (from OPTION 1 to OPTION 3). In a first stage (OPTION 1), case studies are run using ECETOC TRA as it is (using TRA equations and its

defaults). As a first type of refinement (Option 2), case studies are run using TRA equation avoiding the use of default values whenever possible; whenever possible defaults are replaced by more specific parameter values (albeit including population variability or not) – also for parameter for which the ECETOC TRA model as such does not allow deviations from defaults.
In a next steps (Option Additional; annotated with *), additional factors not accounted for in ECETOC TRA (such as skin contact factor, washing/cleaning factors) may be introduced, by multiplying these factors with the ECETOC TRA outcome (either the default TRA – option 1: (option 1*); or with the TRA using specific values (option 2*).
In a next (parallel) approach, one may replace part of the ECETOC equation (namely the joint action of the factors predicting release from substances; i.e. thickness of layer, density, product ingredient) by three other methods (mass balance approach, diffusion model and/or leachable amount approach) (resp. Option 3A$^{(*)}$,Option 3B$^{(*)}$; Option 3C$^{(*)}$.

Obviously, the possibility to use Option 1$^{(*)}$, Option 2$^{(*)}$ or Option 3$^{(*)}$ depend on 1) data availability and 2) on relevance of refinements for some scenario's. For example for (1), there might not always be data available to perform the diffusion based approach (Option 3B), or the leachable amount approach (Option 3C).
For (2), for example, accounting for number of contacts and (new) surface area of the article is relevant for articles where the nature of contact exist of very frequent, repeated contacts with subsequent contact with new parts of the article compared to the previous contact (e.g. contact with printed paper), while this not relevant for articles with one long prolonged contact (e.g. textiles).

The overall aim of the case studies is to demonstrate to what extent estimates for dermal exposure to substances in consumer articles based on the refinements or alternative approaches differ from the default ECETOC TRA approach. It should be emphasises there is up till now no golden standard to compare how much each of the approaches is closest to reality. Whenever possible, independent data from literature will be used to verify the outcomes of the various approaches.

The reporting of case studies (data inputs and assumptions) are facilitated by using a template (e.g. see Table 11) , based on the existing template of Appendix F of Ecetoc Technical Report 114 on ECETOC TRA v3 (ECETOC, 2012), with extensions of fields for additional dermal exposure parameters.

6.2 CASE STUDY 1: TEXTILES

Two case studies for the article group of textiles were performed. The first case study (DMF in polyester T-shirt) was selected because of demonstrating the use of experimental data gathered within the DRESS project. The second case study (dioxins in T-shirt) was selected to demonstrate the guidance for cases where not all information is readily available from testing; since this will be the case in many situations beyond this project. Dermal exposure to dioxins released from T-shirts was selected for the second case study because of the availability of an independent validation study ("PCDD/Fs in textiles: transfer from clothing to human skin: Klasmeier et al, 1999)

6.2.1 CASE STUDY 1A: DMF IN POLYESTER T-SHIRT

Exposure scenario : wearing polyester T-shirt in everyday life.

Coverage of exposure scenario: 7 % of the EU population uses polyester as main fabric for T-shirts; for another 20 % of the population, the main fabric for T-shirts is a mix of cotton and polyester (from ISPSOS; 2014)

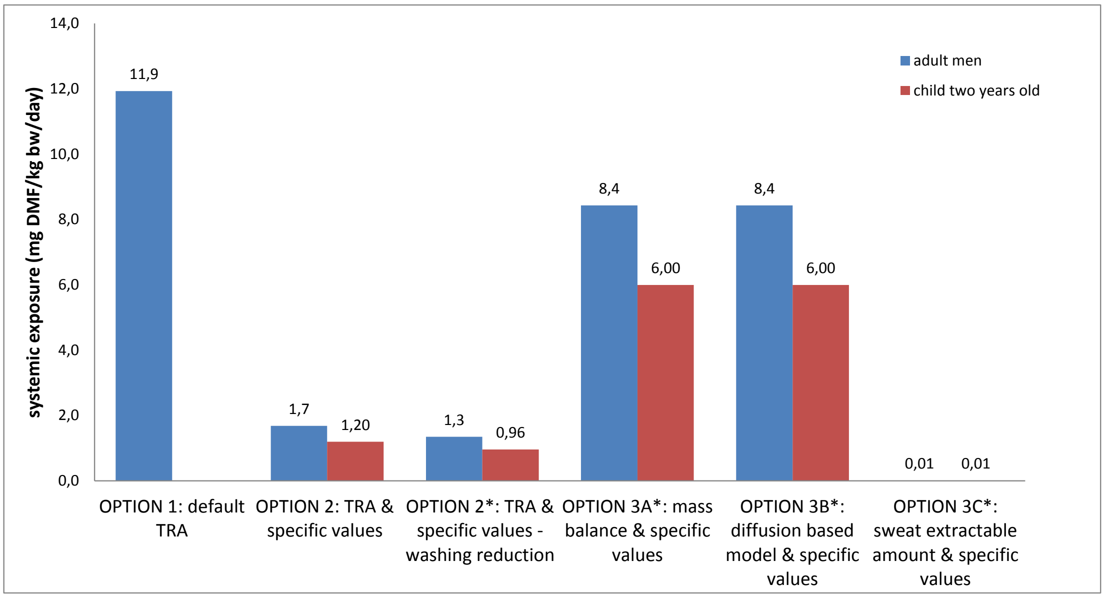
Chemical selected: DMF (dimethylformamide) is used as a solvent in the production process of synthetic textiles (and artificial leather), normally, there should be no traces left in the end product.

Case study parameter values: see Table 11.

Case study: results and discussion

The predictions for dermal DMF exposure due to wearing of a polyester T-shirt (in which DMF is used in manufacturing process) according to the default TRA method, and refinement of TRA parameters, additional parameters and alternative approaches is given in Figure 4.

Figure 4: dermal exposure (systemic dose) to DMF due to wearing of polyester T-shirt – calculations according to different strategies: default TRA, refinement of TRA parameters, additional parameters and alternative approaches



The default TRA approach (Option 1) results in the highest predicted value among all approaches (11.9 mg DMF/kg bw). Note that this 'default TRA approach' is based on all TRA defaults, except the value of product ingredient; 0.5 %), since the TRA model allows user-specific input for the latter parameter. Obviously, the predictions would be much higher (238 mg DMF/kg bw) when relying on the TRA default of 0.1 g/g for PI.

The predicted exposure drops about 7-fold (from 11.9 to 1.7 mg DMF/kg bw) when replacing defaults for ECETOC TRA parameters by scenario - specific values for CA, FQ, D or BW (OPTION 2). The largest impact (5-fold) of ECETOC TRA parameter refinement in this case is due to adjustment of the value for Density, i.e. from 1 g/cm^3 to 0.2 g/cm^3 for textile. There is an additional effect of adjustments of 1) CA from default value for clothing (14315 cm^2) to a CA corresponding to surface area for trunk and arms (10957 cm^2), which is a relevant match for a long-sleeved T-shirt, and 2) an adjustment of BW from 60 to 65 kg (25th percentile for adult men in EU). Since there were no specific TF for textiles/DMF, no deviations from the default value of 1 for TF were made. The specific (default) value for FQ for textile – polyester T-shirt (gathered from IPSOS survey) was the same as the ECETOC TRA default value of 1 for FQ textile.

The ECETOC TRA model considers adults as relevant population group for textiles. When expanding the calculations to a group of young children in the EU (e.g. 2 years old children) – the exposure (expressed as dose per kg bw) is slightly lower for 2-years old children compared to adults. Differences in predictions for adults versus children rely in differences in both CA and BW.

Accounting for influence of exposure reduction due to removal of DMF by washing clothing before first use further reduces the predicted exposure to 1.3 mg DMF/kg bw. The washing reduction factor (0.8) is additionally multiplied with the 'specific' ECETOC TRA outcome (OPTION 2*). By lack of specific DMF reduction factors due to washing, the washing reduction factor (0.8) is based on smallest reduction in release upon washing from other substances we found in literature (permetrin in clothing used). Washing clothing before first use is a common practice in 40 % of the EU population.

Consideration of other additional parameters such as the number of contacts between skin and textile and the surface of the article is not relevant for textile since the nature of contact between skin and textile is one long contact between skin and textile.

A skin contact factor of 1 (thus not modifying the outcome) was selected since a T-shirt could be worn as stretch T-shirt. For garments with looser contact, a smaller skin contact factor could be considered.

Above described calculations reflect predicted outcomes based on the TRA equation, including parameter refinement and extension with other parameters Thus, all above calculations (including refinements) rely on the concept that DMF present in the '*thickness of layer'* (TL) (for the case of textile: 0.01 cm) is released from the article to the skin. By lack of options to refine the parameter value for TL, predictions were made using alternative approaches for release from article (OPTION 3).
For options 3A, 3B and 3C a duration of contact of 16 hours between skin and T-shirt is used.

The first – most conservative (Tier 0) – approach among OPTION 3 , i.e. based on the mass balance principle (Option 3A) – predicts exposure levels of 8.4 mg/kg bw (for adult men). This outcome is slightly lower than the ECETOC TRA outcome (Option 1), however higher than the refined 'specific TRA outcome (Option 2). The aspect of 'release from article', is slightly lower when using the mass balance principle (Option 3A), compared to the default TRA approach (Option 1); . However, this should be ascribed to the lower value for Density applied in Option 3A compared to Option 1, and not the TL concept. Actually Option 3A applies implicitly a TL of the full textile thickness (i.e. 0.05 cm), which is larger than the (assumed) TL of 0.01 cm in the case of textile.

The diffusion based model (Option 3B) resulted in this case in the same outcome as the mass balance approach (Option 3A). Actually, the mass balance model resulted in a predicted value which was slightly higher than the mass balance equation (0.06 mg/cm² versus 0.05 cm²); however, the diffusion based model is topped off at mass balance prediction outcomes.
The mass balance approach was based on experimental determined diffusion coefficient of DMF in polyester (in DRESS project, Annex 10).
The surprisingly high estimate for release of DMF from polyester textiles using the diffusion based model relies partly on the fact that 1) a simplified instead of full diffusion model was applied, and, 2) that diffusion is assumed to be the release limiting factor.
In fact, this assumes that once DMF is released from the article to the skin, DMF is immediately removed from the skin (e.g. by absorption) , so that the concentration at the skin-textile interface drops again to zero, so that diffusion keeps being the active force for releasing DMF from the textile to the skin. In practice, it is very likely that solubility of DMF and slow removal of DMF from the skin might be a limiting factor, so that diffusion and thus migration of DMF from textile to the skin will be lower compared to diffusion based predictions.
However, by lack of mechanistic or empirical model to account for these factors, it is yet not possible to include solubility and removal (by skin) into the diffusion based model.
These considerations of conservatisms of diffusion based predictions are especially relevant for long duration contacts such as textiles; in case of (repeated) short term contact, the duration of a short term contact will lower the released amount since duration is playing a role in Equation 5. For example, when considering a contact duration of 1 hour instead of 16h for textile, the released amount would have been 0.015 mg/cm² (instead of 0.05 mg/cm² ; value of mass balance).

The third alternative to predict release of DMF from textile (Option 3C) is based on experimental testing of DMF release from textile in artificial sweat This resulted in predicted exposure of 0.01

mg DMF/kg day. This value is 1000 fold lower than the predictions based on the other approaches (OPTIONS 1, 2, 3A-3B).
On the one hand, this value might be surprisingly lower than via other approaches. However, when comparing with sweat extractable fractions of other compounds (e.g. textile dyes and auxiliaries 0.1 – 2 % extractable amounts; Krätze and Platzek, 2004); the predicted outcome seems to be in realistic ranges.
Whereas predictions according to other approaches (OPTIONS 1, 2, 3A-3B) can be more or less performed without experimental testing, experimental testing is required when performing predictions based on Option 3C.

No experimental data on skin loading of DMF were available in literature. Thus, an independent validation of the predictions is not possible

<u>Conclusion</u>

This case study demonstrated that the ECETOC TRA default approach resulted in predictions for dermal exposure to DMF which are about 1000 fold higher than when using an approach based on experimental testing of sweat extractable fractions of DMF from textile. The latter approach, leading the lowest (most realistic?) predictions, requires unavoidably experimental testing.
When wishing to avoid experimental testing, one can refine the ECETOC TRA outcome by replacing TRA defaults by specific values for most values of the TRA equation (except for the 'tickness of layer' parameter). In the current case study, these adjustments led to predictions which are about 7 –fold lower than the default TRA approach. However, when keeping the TRA approach and only refining parameter values, one still relies on the (not validated) assumption that release of substances from textile is limited to the outer 0,01 cm layer of the textile.
Replacing this concept of the thickness of layer by the based diffusion model, leads to a more physically based underpinned approach; however, prediction levels based on the diffusion based model are not drastically lower than ECETOC TRA default approaches; probably because in reality diffusion is not the limiting factor for release of DMF from textile to skin. A next step in improvement of our understanding and prediction of dermal exposure could involve the expansion of the diffusion based model by additional considerations of solubility in the skin lipid layer or sweat removal from the textile or skin.

Table 11: parameter values and justification for case study dermal exposure to DMF in polyester T-shirt.

Exposure determinant	**Value (TRA default)** (Use in option 1)	**Specific value** (use in option 2/ 3)	**Justification for specific value**
Article and article use description			
Relevant exposure process	Direct contact between skin and textile during wearing a T-shirt	idem	
Article category	AC 5		Fabrics, textiles and apparel
Article subcategory	AC 5		Subcategory in ECTOC TRA: clothing all kind of materials
Article characteristics	Polyester T-shirt		
Initial concentration/ fraction of substance in the total article	Default 0,1 g/g User defined value: 0,005 g/g	0,005 g/g	Measured conc in PU coated polyester (from WP 3.2 report). Note that DMF should be found in end product
Density of article	1 g/cm³	0,2 g/cm³	See 3.5.2
Frequency of uses	1 event per day	1 event per day	Frequency of T-shirt use from consumer survey and frequency of polyester fibres (see 3.3.2))
History of aging	New- non washed T-shirt	Idem	washing clothing before first use is respresentative for 40 % of EU population (default set at 75th Perc. Population)
Thickness of article**	Not considered in TRA	0,05 cm	Measured in WP 3.2 (thickness of article plays role in option 3A)
Duration of use (exposure event)**	Not considered in TRA	16 hours/day	Assumption (see 4.1.3.2)
Anthropometic parameters			
Body weight	60 kg (only adults considered for textiles in TRA)	65 kg (adults) 13.3 kg (2 years old child)	From WP 4 (see 3.7)
Skin contact area (cm²)	whole body except feet, hands, head: 14315 cm²	Truncks + arms : 10957 cm²	Trunck + arms SA for adult mean Europe (3.2.2)
Physico-chemical parameters of the substance			
Chemical identity	N',N'-dimethylformamide (DMF) CAS nr 68-12-2		

Exposure determinant	**Value (TRA default)** (Use in option 1)	**Specific value** (use in option 2/ 3)	**Justification for specific value**
Molecular weight*	73,09 g/mol		
Other dermal exposure relevant parameters			
Thickness of contact layer	0.01 cm	Not relevant	
Transfer factor	1	1	Default (75th perc TF = 1) (see 3.6.1) used since no data available for TF of DMF for textile
Leachable amount**	Not considered in TRA	0.06 µg/cm²	From experimental work (WP 3.2); release at 24 h extractions of (wors case proxy for 16 h exposure duration)
Diffusion coefficient**	Not considered in TRA	$3.1\ 10^{-12}$ m²/s	Value from experimental work (WP 3.2): see also Annex 10
Skin contact factor*	Not considered in TRA	1	Worst case value for stretch T-shirt
(new) article surface in contact with skin*	Not considered in TRA	Not relevant for textile	
Number of contacts per exposure event*	Not considered in TRA	Not relevant for textile	

used as additional factor (OPTION); as extension to ECETOC TRA equation, or alternative approaches

** not used in TRA, but needed for calculation of alternative approach for release of substance from article (OPTION 3A, 3B or 3C)

6.2.1 CASE STUDY 1B: DIOXINS IN POLYESTER T-SHIRT

Exposure scenario : wearing polyester T-shirt in everyday life.

Coverage of exposure scenario: 7 % of EU population uses polyester as main fabric for T-shirts; for another 20 % of the population, the main fabric for T-shirts is a mix of cotton and polyester (from ISPSOS; 2014)

Chemical selected:

dioxins in polyester T-shirt
mix of PCDD/Fs; mainly penta and hexa chlorinated dibenzofurans

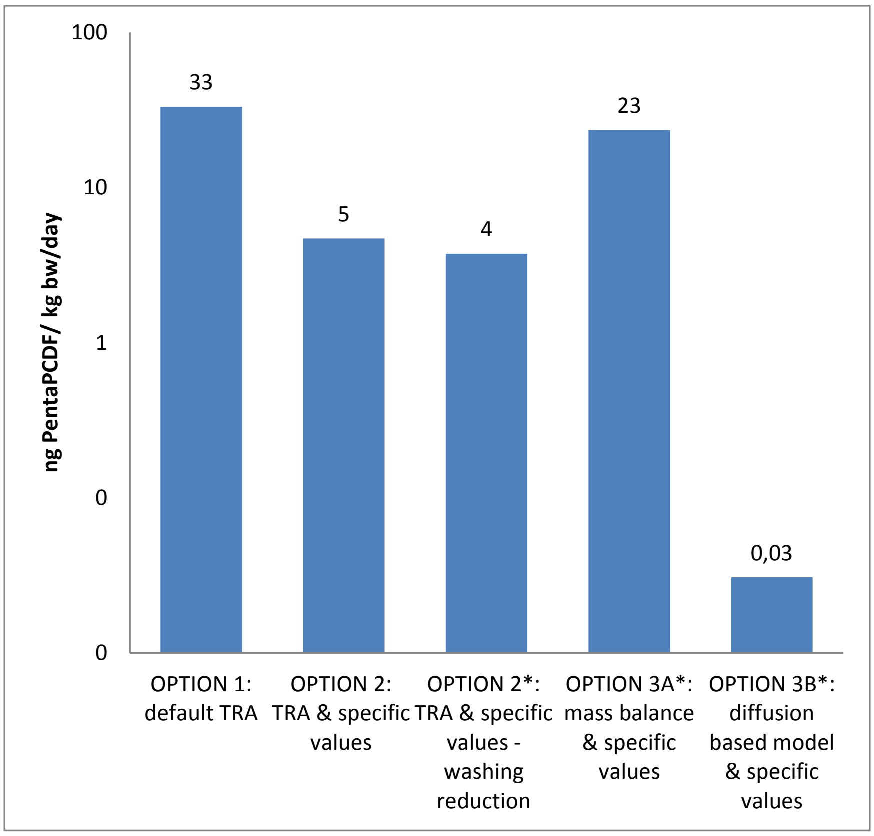
contamination level of dioxins in T-shirts used in this case study is not to be considered a presentative levels in the current EU market. The contamination levels are selected from a paper published in 1999, and reflect dioxin contaminated T-shirts purchased in stores (Klasmeister et al.1999).

Case study parameter values: see Table 12.

Case study: results and discussion

The predictions for dermal exposure to dioxins due to wearing a polyester T-shirt (according to the default TRA method, and refinement of TRA parameters, additional parameters and alternative approaches is given in Figure 5.

Figure 5: dermal exposure (systemic dose) to dioxins due to wearing of polyester T-shirt – calculations according to different strategies: default TRA, refinement of TRA parameters, additional parameters and alternative approaches



The differences between the default TRA approach (OPTION 1) and use of specific values (OPTION 2 and 2*) is very similar to the ones described in the case study of DMF exposure (see 6.2.1) and will not be repeated here.

By lack of experimental data for diffusion coefficients of PCDD/Fs in polyester fabrics, the value for Ddiff was estimated using the empirical model of Piringer (equation 6). No values for A'p and Tm were available for polyester. As a proxy, the values for A'p and Tm from Nylon 12 were applied. This resulted in an estimated diffusion coefficient of $3.74\ 10^{-18}$ m^2/s. It should be noted that the value of D is subjected to uncertainties 1) related to the use of parameter values for Nylon 12 as proxy for polyester ; and 2) the shape of the Piringer model (no uncertainty bands available).

Obviously, the diffusion based model resulted in remarkably lower predictions of dermal exposure compared to the TRA equation (in contrast to the findings in the previous textile cases study for DMF), and also compared to the mass balance based equation.

No data were available to run approach 3C (sweat extractable fraction).

The difference between the mass balance based equation and the diffusion based exposure is nearly 1000 fold. This ratio corresponds rather well with the findings of Klasmeier et al. (1999), reporting a < 0.1 % transfer of PCDFs from textile to skin in human volunteers wearing dioxins contaminated T-shirts. Klasmeier et al. (1999) explained the low transfer of PCDFs to skin to the strong binding between polyester fabrics and PCDFs.

In summary, although there are uncertainties about the exact value for the diffusion coefficient of dioxins in polyester, a comparison with literature data indicated a rather good match between diffusion model based released and dermal loading of dioxins in human volunteers wearing PCDD/F contaminated T-shirts , suggesting that diffusion of dioxins is the limiting factor in this case study, and resulting in more realistic predictions compared to the TRA approach (either the default approach or the approach using specific factors).

Table 12: parameter values and justification for case study dermal exposure to dioxins in polyester T-shirt

Exposure determinant	**Value (TRA default)** Use in option 1	**Specific value** (use in option 2/ 3)	**Justification for specific value**
Article and article use description			
Relevant exposure process	Direct contact between skin and textile during wearing a T-shirt	idem	
Article category	AC 5		Fabrics, textiles and apparel
Article subcategory	AC 5		Subcategory in ECTOC TRA: clothing all kind of materials
Article characteristics	Polyester T-shirt		
Initial concentration/ fraction of substance in the total article	Default 0,1 g/g User defined value: 1.39 10^{-8} g/g	1.39 10^{-8} g/g	Measured conc in dioxin contaminated T-shirts from purchased on the market in the ninetees (Klasmeister, 1999) (value is the sum of PCDD/Fs)
Density of article	1 g/cm³	0,2 g/cm³	See WP guidance (3.5.2)
Frequency of uses	1 event per day	1 event per day	Frequency of T-shirt use from consumer survey and frequency of polyester fibres (3.3.2)
History of aging	New- non washed T-shirt	Idem	washing clothing before first use is respresentative for 40 % of EU population (default set at 75th Perc. Population)
Thickness of article**	Not considered in TRA	0,05 cm	Measured in WP 3.2 (thickness of article plays role in option 3A)
Duration of use (exposure event)**	Not considered in TRA	16 hours/day	Assumption (see 4.1.3.2)
Anthropometic parameters			
Body weight	60 kg (only adults considered for textiles in TRA)	65 kg (adults) 13.3 kg (2 years old child)	See 3.7
Skin contact area (cm²)	whole body except feet, hands, head: 14315 cm²	Truncks + arms : 10957 cm²	Trunck + arms SA for adult mean Europe (3.2.2)
Physico-chemical parameters of the substance			
Chemical identity	Dioxins and furans (mix of PCDD/Fs)		Tetra, penta and heptachlorinated dibenzofurans were the dominant congeners

Exposure determinant	**Value (TRA default)** Use in option 1	**Specific value** (use in option 2/ 3)	**Justification for specific value**
			in polyester T-shirts
Molecular weight*	340 g/mol		Value for penta chlorinated dibenzofuran was used (as middle point estimate for tetra, penta and hepta)
Other dermal exposure relevant parameters			
Thickness of contact layer	0.01 cm	Not relevant	
Transfer factor	1	1	Default (75th perc TF = 1) (see 3.6.1) used since no data available for TF of dioxins for textile
Leachable amount**	Not considered in TRA	No data	
Diffusion coefficient**	Not considered in TRA	3.78 10^{-18} m^2/s	Estimated from Piringer model and values for A'p of 0.5 and Tm = 0 used based on data for Nylon 12 (by lack of data for polyester fibres)
Skin contact factor*	Not considered in TRA	1	Worst case value for stretch T-shirt
(new) article surface in contact with skin*	Not considered in TRA	Not relevant for textile	
Number of contacts per exposure event*	Not considered in TRA	Not relevant for textile	

used as additional factor (OPTION); as extension to ECETOC TRA equation, or alternative approaches

** not used in TRA, but needed for calculation of alternative approach for release of substance from article (OPTION 3A, 3B or 3C)

6.3 CASE STUDY 2: PRINTED PAPER

As a case study scenario, it was decided to use the article category that was also included in the experimental part of the project, to be able to use the dedicated values for this type of article based on the results of these experiments. Thus, the scenario can be described as follows: Printing one page of standard A4 paper at home with an inkjet printer, one side fully covered by black ink (with 2.1% Disperse blue 360 (DB360) as substance in this ink). Further details, as well as the input parameters and assumptions taken into account when performing this case study, are presented in Table 16.

When taking into account either the default values from ECETOC TRA (Option 1) or the values as derived specifically for the article subcategory ‘printed paper’ within the article category ‘paper articles’(AC 8), the estimated dermal exposure decreases from 0.7147 mg/kg/day to 0.00001 mg/kg/day (see Table 13). The lower dermal exposure estimate in case of Option 2 is mostly caused by a much lower product ingredient fraction (PI) and transfer factor (TF).

Table 13: Inputs and results for printed paper case study based on option 1 and 2 from Guidance document

TRA Parameters	TRA (option 1)	Specific values (option 2)	
	Value	**Value**	**Remarks**
Input parameters			
PI (g/g)	0.1	0.0009	g/g DB360 on one A4 (one-sided printed)
TL (cm)	0.001	0.001	Keep TRA default
D (g/cm³)	1	0.78	New default for printed paper, from literature search
CF	1000	1000	
TF	1	0.009	Based on transfer experiments with printed paper
CA (cm²)	428.8	214.4	Fingers one hand
FQ (event/Day)	1	0.5	P75, based on consumer survey
BW (kg)	60	65	New default for adults (men and women)
Exposure outcome			
Release from article (mg/cm²)	0.1	0.000702	
Local exposure (release x TF) (mg/cm²)	0.1	6.32E-06	
Dermal load per body (local exposure x CA) (mg/body)	42.88	0.001355	
Dermal exposure (mg/kg/day)	0.7147	0.000010	~71,000-fold lower estimated exposure in case of specific values

Within option 1* and 2*, some additional factors are proposed to be taken into account when estimating exposure. Within this approach, the number of contacts, surface area in contact with the skin, duration of contact, and removal by washing are proposed as additional factors. As is presented in the Guidance document, in case of consumers handling printed paper at home, it is assumed as an exposure scenario with many short duration contacts, in which the surface area is used as a proxy for total intensity of the contact with the article surface (taking into account duration and number of contacts). Removal by washing is not considered applicable for this scenario, and is thus left out. In this case, instead of the 'standard' ECETOC TRA equation (dermal exposure = (PI x CA x FQ x TL x D x TF x 1000) / BW) and alternative equation is proposed (dermal exposure = (PI * TF * TL * D * SA * 1000) / BW). When using either the ECETOC TRA default values or the values as derived specifically for the article subcategory 'printed paper', the estimated dermal exposure is respectively 0.8040 mg/kg/day (option 1*) and 0.000047mg/kg/day (option 2*) (see Table 14). In case of this printed paper scenario, using this alternative parameter as a proxy for total intensity of contact, thereby replacing CA and FQ in the exposure estimation, results relatively comparable results (although a bit higher). However, in case of a scenario in which the number of contacts would be much higher and with every contact a new part of the article surface would be contacted, the estimated dermal exposure would be much higher.

Within option 3, several alternatives for estimating the release of substance from the article are proposed. The estimated release is the highest in case of the mass balance approach (option 3A) (7.5 mg/cm² when taking into account the ECETOC TRA defaults, 0.053 mg/cm² when taking into account printed paper-specific values), followed by the leachable amount (option 3C) (0.027 mg/cm²) and the simplified diffusion model (option 3B (0.326 mg/cm² and 0.002 mg/cm²) (see Table 15). These alternative estimated releases can then be used in combination with either the default ECETOC TRA parameter values or the printed paper-specific values within either the 'standard' equation (#) or taking into account the additional parameters (##). The different combinations lead to estimated dermal exposures between 0.000034 mg/kg/day and 60.3 mg/kg/day (see Table 15)

In general, it can be concluded that in case of handling home printed paper being able to use specific values instead of the default values as proposed within the ECETOC TRA model for this scenario results in a 70,000-fold lower estimated dermal exposure in case the 'standard' equation is used, and a 17,000-fold lower estimated dermal exposure in case the equation with additional parameters is used. An exception is the approach with estimated release based on leachable amount, since for this approach no specific values are used.

Table 14: Inputs and results printed paper case study based on option 1 and 2 from Guidance document in combination with additional factors (Option 1 and 2*)*

(TRA) Parameters	TRA (1) +	Specific values (option 2) + additional factors	
	Value	**Value**	**Remarks**
Input parameters			
PI (g/g)	0.1	0.0009	g/g DB360 on one A4 (one-sided printed)
TL (cm)	0.001	0.001	Keep TRA default
D (g/cm³)	1	0.78	New default for printed paper, from literature search
CF	1000	1000	
TF	1	0.009	Based on transfer experiments with printed paper
SA	482.4	482.4	Proxy for total intensity of contact *
BW (kg)	60	65	New default for adults (men and women)
Exposure outcome			

Release from article (mg/cm²)	0.001	6.318E-09	
Local exposure (=release x TF) (mg/cm²)	0.001	5.6862E-11	
Dermal exposure (mg/kg/day)	0.8040	0.000047	~17,000-fold lower estimated exposure in case of specific values

* Proxy for total intensity of contact, taking into account considerations with regard to number of contacts and duration of contacts

Table 15: Inputs and results based on alternatives for estimating 'release' in combination (Option 3 and 3)*

(TRA) Parameters	TRA (A)	Specific values (B)	
	Value	**Value**	**Remarks**
Input parameters			
PI (g/g)	0.1	0.0009	g/g DB360 on one A4 (one-sided printed)
D (g/cm³)	1	0.78	New default for printed paper, from literature search
TF	1	0.009	Based on transfer experiments with printed paper
CA (cm²)	428.8	214.4	Fingers one hand
FQ (event/day)	1	0.5	P75, based on consumer survey
SA	482.4	482.4	Proxy for total intensity of contact [1]
BW (kg)	60	65	New default for adults (men and women)
Estimated release from article (mg/cm²)			
Release - Mass balance approach	7.500	0.053	Based on PI, D, and thickness of article
Release -Diffusion model	0.326	0.002	Based on PI, D, estimated diffusion coefficient and 5 minutes/event
Release -Leachable amount	0.027	0.027	Based on experimental work
Exposure outcome			
DE (mg/kg/day) - Mass balance approach (#)	53.6000	0.000781	DE = release * TF * CA * FQ / BW [2]
DE (mg/kg/day) - Mass balance approach (##)	60.3000	0.003517	DE = release * TF * SA / BW [3]
DE (mg/kg/day) – Diffusion model (#)	2.3290	0.000034	DE = release * TF * CA * FQ / BW [2]
DE (mg/kg/day) – Diffusion model (##)	2.6201	0.000153	DE = release * TF * SA / BW [3]
DE (mg/kg/day) - Leachable amount (#)	0.1930	0.000401	DE = release * TF * CA * FQ / BW [4]
DE (mg/kg/day) - Leachable amount (##)	0.2171	0.001803	DE = release * TF * SA / BW [5]

[1] Proxy for total intensity of contact, taking into account considerations with regard to number of contacts and duration of contacts

[2] ~69,000-fold lower estimated exposure in case of specific values

[3] ~17,000-fold lower estimated exposure in case of specific values

[4] ~480-fold lower estimated exposure in case of specific values

[5] ~120-fold lower estimated exposure in case of specific values

Table 16: Exposure scenario for case study home printed paper

Exposure determinant	(Default) Model value	Specific value	Justification value
Article and article use description			
• Relevant exposure process	Direct contact between printed paper and skin		
• Article category	AC 8: Paper articles		
• Article subcategory	AC 8: Subcategory 'Printed paper'		
• Article characteristics	Home printed A4 paper, fully covered by black ink, printed with inkjet printer on one side of the paper		
• Initial concentration of fraction of substance in the total article (PI)	0.1 g/g	0.0009 g/g	By weighing of the paper before and after printing (WP 3.2) (0.224 g ink with 2.1% Disperse blue 360 / 5.2 g paper = 0.0047 g DB 360 / 5.2 g paper)
• Density of article (D)	1 g/cm^3	0.78 g/cm^3	WP4 (Guidance)
• Thickness of article	Not considered in TRA	0.075 cm	Estimated value (WP 3.2)
• Initial concentration of the substance in the article (mass/volume, in g/cm^3) (C_o)	Not considered in TRA		
• History - ageing	Freshly printed paper (worst case)		Most transfer directly after printing (WP 3.2)
• Frequency of use	1 event per day	0.5 event per day	WP4 (Guidance), based on ISPOS consumer data (P75 value, WP 3.1)
• Duration of contact per event • Duration of use per event (DF)	Not considered in TRA 8 hr (based in consumer inhalation model)	1-5 min. per event 0.01	WP4 (Guidance), based on ISPOS consumer data (reasonable worst case, WP 3.1) 5 min / 480 min = 0.01
Anthropometic parameters			
• Body weight (BW)	60 kg	65 kg	Adults in EU (see WP 4, Guidance)
• Skin contact area (cm^2)	428.8 cm^2 (inside hands / one hand / palm of hands)	214.4 cm^2	Fingers of one hand (ECETOC TRA v3.1)
Physico-chemical parameters of the substance			
• Chemical identity	Disperse Blue 360: CAS 70693-64-0 (Benzenamine,N,N-diethyl-3-methyl-4-[2-(5-nitro-2-thiazolyl)diazenyl]-)		
• Molecular weight	0 (??)		
Other parameters relevant for dermal exposure			

Exposure determinant	(Default) Model value	Specific value	Justification value
• Thickness layer (TL)	0.001 cm		
• Transfer factor (TF)	1	0.009	Based on transfer experiments with printed paper (WP 3.2), maximal measured transfer of 0.855% based on amount of ink used for printing
• Number of contacts (N_c)	Not considered in TRA	3	Expert judgement (assumed to be 3 contacts per piece of paper)
• Average surface area of article in contact with skin per contact (SA_c)	Not considered in TRA	214.4 cm²	Expert judgement (assumed to be the surface contact area)
• Surface area factor for new contact (SA_{new})	Not considered in TRA	0.75	Expert judgement (assumed that one replaces the fingers, but with a little overlap with the previous surface area
• Article surface in contact with skin (SA)	Not considered in TRA	482.4 cm²	Too little information from consumer survey (WP 3.1) to be able to derive a RWC. Based on method in WP 4 (Guidance) $SA = SAF_{new} * SA_c * N_c = 0.75 * 214.4 * 3 = 482.4$
• Leachable amount	Not considered in TRA	0.027 mg/cm²	From WP 3.2 (artificial sweat extractable amount during 24 h)
• Diffusion coefficient	Not considered in TRA	$1.77\ 10^{-12}$ m²/s	From WP 3.2 (based on methanol extraction)

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ANNEX 1: GENERAL PRINCIPLES FOR DERIVING DEFAULT VALUES IN THE SCOPE OF THE DRESS PROJECT

The approach as described below is a very general description of what and how defaults can be set. In the derivation of this description the actual availability of data within the DRESS project has not yet been taken into account. Some of the methods and options might therefore not be relevant. In the end, whether and how defaults are set is very much dependent on the availability of data.

Background

Defaults are (generic) values that are used when no specific input value for a parameter in a model is available, which can be replaced by more specific values, preferably based on actual information, or better estimates when available. The ECETOC TRA model (v3) contains several defaults to be used in dermal exposure assessment for consumers. The DRESS project has gathered information that, in some cases, can lead to an improvement of defaults for certain type of articles. However, such defaults should be chosen in a systematic way to ensure their appropriateness and acceptability.

Type of value to aim for

In general there are two options for the derivation of defaults:

1. Average or typical values
2. Reasonable worst case values

Exposure models used for regulatory risk assessment are generally required to be somewhat conservative. Conservatism is required to ensure that a model outcome is protective enough for the vast majority of situations it aims to cover, and thus models should at least implicitly account for uncertainties and variability. The use of only average values as defaults will not lead to a conservative estimate. Therefore, it is preferred to use default values that lead to conservative end results. However, the level of conservatism should not be too high, because otherwise models will predict unrealistic high exposure levels and too many situations will be considered 'at risk' unnecessarily.

Present exposure models often contain a combination of more or less reasonable worst case values as defaults and may also include some average values as defaults. The disadvantage of using only typical values as defaults is that a final exposure estimate will also represent a typical or average value, although in regulatory risk assessments the requirement is to estimate reasonable worst case exposure levels. However, if you use only reasonable worst case defaults, the end result may be a very worst case exposure estimate, since by adding worst case assumptions the probability that the exposure estimated exposure level will represent an exposure value that is assumed to occur in practice can be very low (exposure estimated at the very high end of the underlying true exposure distribution).

Therefore, the RIVM has chosen to use 75th or 25th percentiles of a parameter distribution (depending on whether high or low percentiles lead to higher exposure levels) for separate defaults in their consumer exposure model (ConsExpo), taking into account that the end-result of combining several defaults in and exposure model might then be a 99th percentile of the exposure distribution (Bremmer *et al.*, 2006). Similarly, EFSA recommends using 95th percentile intake levels of the highest contributing separate food categories in combination with average intakes for other food categories, in order to reach a 97.5t^{h} percentile overall dietary intake (EFSA, 2011).
However, aiming for a 99th percentile as exposure estimate might be considered as very conservative. Guidance document R.15 (ECHA, 2012) only mentions the need to estimate exposure for a reasonable worst case situation, but does not indicate what percentile of an exposure

distribution would be considered reasonable worst case. The documentation on the ECETOC TRA tool also does not indicate the percentile that is considered to be reasonable worst case for consumer exposure estimates. The document TR 107 from Version 2 of the tool (ECETOC, 2009) indicates in the definition section a reasonable / realistic worst case exposure value to be usually the 90th or 95th percentile of a data set of measured values. The document TR 114 from Version 3 (ECETOC, 2012) indicates that in case of worker exposure: "…TRA is intended to reflect the 75th percentile value of the 8 hour value." These remarks do not suggest that in case of consumer exposure the intention would be to estimate the 99th percentile of the exposure distribution, although no specific indication is provided either.
In practice, the existing models are used by most users without any specific consideration of what level of conservatism is reached. There is also no real knowledge on the relation between the choice of values for parameters and the real conservatism of the estimates. The knowledge on real exposure levels for consumers is much too limited to enable the derivation of such relations. Therefore, an approach that can be expected to lead to an exposure value representative of a percentile in the order of the 90th to 99th percentile should be acceptable.

The defaults in ConsExpo tend to be (close to) the 75th or 25th percentiles of measured. For example, Bremmer *et al.* (2006) have derived 25th percentiles of 74.2 kg for weight of men and 60.7 kg for women. Although the report describes defaults of 74 and 61 kg, in practice the values of 70 and 60 kg are used in the model.

Since ECETOC TRA intends to present reasonable worst case exposure estimates as a Tier 1 assessment, the goal when deriving improved defaults should be to lead to such reasonable worst case estimates. It is therefore suggested to adhere to the approach that was also used by RIVM for the ConsExpo defaults:

- Use (an estimate of) the 25th percentile of the distribution for parameters where lower values lead to higher exposure levels;
- Use (an estimate of) the 75th percentile of the distribution for parameters where higher values lead to higher exposure levels.

How to derive defaults

Defaults can be set at different levels of aggregation. For instance, in case of body weight a default can be set for adults, for adult men or adult women and for children of different ages. Similarly, a default can be set for a broad product or article group or for more specific subproducts or subsets of articles. This is for example the case in ECETOC TRA v3, where there are estimates for 'sentinel products/articles' that cover a broad group and for specific (sub)products or subsets of articles within such a group. For example, there are defaults for the group "AC8: Paper articles", but also separate defaults for the subgroups: "Diapers", "Sanitary towels", "Tissues, paper towels, wet tissues, toilet paper" and "Printed paper (papers, magazines, books)".

For defaults to be useful in practice, it is preferable to have defaults at both a high level of aggregation as well as at a lower level of aggregation. The possibility to set defaults at a certain level of aggregation depends on the availability of data and on the knowledge (or expert judgment) with regard to differences between subpopulations or subcategories of articles within the total population or category. For pragmatic reasons, in this document both populations and categories will be called 'group' and both subpopulations and subcategories will be called 'subgroup'. If there is insufficient data to divide groups into potentially relevant subgroups, only defaults for the overall group can be set. If there is only data on one or a few subgroups, it may not be possible to set a default for the group as a whole. However, if it is known, or assumed, that the subgroups studied

are the ‘worst case’ subgroups within the overall group, the data on the subgroups may still be used to set a default for the overall group.
A default for an overall group should be conservative enough that it covers all subgroups, also the ones representing more worst case scenarios. Therefore, a default for an overall group tends to be more conservative than the defaults of most subgroups.

For the setting of defaults within the DRESS project the following approach is suggested for all parameters:

1. Consider whether subgroups are expected to exist that (are assumed to) have significantly different values for that particular parameter; for example, will the contact area of skin contact with the product be different for adults or children?
    a. This should be done based on available knowledge, e.g. the information gathered into the database at WP1 and WP2, in combination with expert judgment resulting from an understanding of exposure processes and differences between subgroups in such processes

    →If this is not the case, set one default for that parameter to cover the group as a whole at once
2. If there are potentially relevant subgroups, check whether the available data/information gathered in this project, such as literature gathered in the early parts of the project and information from migration and transfer factors as well as use patterns in WP3, allows separation into subgroups with regard to default setting:
    a. Are subgroups indicated in the data set (e.g. is there a probable difference between newspapers and magazines within the group printed paper)?
    b. Is sufficient data per subgroup available to set a default for each subgroup?

    → If the answers to questions a. and b. are positive, set defaults based on the available data by choosing the 25th or 75th percentile
3. If there are not sufficient data points for a subgroup, do not set a default for this subgroup
4. If subgroups are not indicated, of course no defaults for subgroups can be set
5. Check whether the complete set of subgroups for which sufficient data/information is available can be assumed to cover the overall group in a sufficient way, including potential worst case subgroups
6. If this is the case, use the default from the most worst case subgroup as default for the overall group as well
7. If no default could be derived for the worst case, do not set a default for the overall group
    a. In case a worst case subgroup is not represented or underrepresented in the data or information, it might be considered, on a case by case basis, to use the defaults from the next worst case subgroup for which there <u>is</u> sufficient information, multiplied by a certain safety factor; this is probably only possible when there is a reasonable indication of the general differences in default values within the subgroups that can support this kind of extrapolation.

The aim is to set defaults on the basis of the 25th or 75th percentile of a parameter distribution. These values can be derived in different ways. One option is to derive this value directly from the dataset. This is only reasonably possible with sufficiently large datasets. The smaller the dataset, the larger the uncertainty around such a value, specifically if the distribution is skewed (e.g. log-normal). Generally, a dataset of 20 or more values could be considered sufficient, although this depends very much on the variation within the data.[16] When there is limited variation within the data, and there is no reason to assume that the variation in real life is much larger, a smaller dataset (e.g. 10 or more data points) might be sufficient. If there is a very large variation, 20 data points might not yet be sufficient for setting a proper default. If the general shape of the distribution of the data is known, it is often considered better to derive the percentile by first calculating the descriptive statistics of the distribution (e.g. mean and standard deviation in case of a normal distribution or geometric mean and geometric standard deviation in case of a lognormal distribution) and calculate the relevant percentile on the basis of these descriptive statistics. This procedure is somewhat less uncertain, because the direct derivation of e.g. the 20th observation of 25 data points actually only uses information from a few data points (*i.e.* the 19th to 21st), while the distribution calculated based on descriptive statistics makes use of information on the total dataset. The decision what number of data points will be sufficient needs to be made on a case-by-case basis, because this depends very much on the expected variability in the (sub)group, the variability in the dataset, in how far the dataset is considered to be representative for the relevant (sub)group, the uncertainty in the data gathering methods and the perceived uncertainty in knowledge regarding the earlier mentioned values, such as variability and representativeness.

The X^{th} percentile of a normal distribution is calculated as:

$$X^{th} = \mu + Z_X * \sigma \qquad [1]$$

Where X^{th} = the value of the X^{th} percentile
μ = the average of the distribution
Z_X = the Z-value from the standard normal distribution for the desired percentile
Σ = the standard deviation of the distribution.

In Excel, the X^{th} percentile is calculated as: X^{th} = Norm.INV(probability;μ;σ)

Similarly the X^{th} percentile of a lognormal distribution is calculated as:

$$X^{th} = exp(ln(GM) + Z_X*(ln(GSD))) \qquad [2]$$

Where X^{th} = the value of the X^{th} percentile
GM = the geometric mean (or the exponent of the μ of the logarithms of the values)
GM = exp(μ_logarithms)
Z_X = the Z-value from the standard normal distribution for the desired percentile
GSD = the geometric standard deviation (or the exponent of the σ f the logarithms of the values)
GSD = exp(σ_logarithms)

In Excel the X^{th} percentile of a lognormal distribution is calculated as X^{th} = Lognorm.INV(probability;ln(GM);ln(GSD))

Therefore the following approach is suggested for derivation of percentiles of a parameter distribution:

- Assess how representative the data is for a whole group or a subgroup

[16] REACH Guidance document R.14 contains a table of numbers of measurements for worker exposure that could be considered sufficient in various situations with regard to variability and uncertainty.

   - If data is considered representative for a whole group, it may be used as a basis for the group
   - If data is considered representative for a subgroup, it may be used as a basis for that subgroup and potentially also for the whole group (if the subgroup is considered to be the worst-case subgroup_
   - If the data is not considered sufficiently representative for a specific group or subgroup, it may be necessary to account for lack of representativeness by adding a safety factor when deriving a default value
   - For example:
     - The 'group' to be considered is 'low volatility liquids with a vapour pressure below 10 Pa'
     - Only data on liquids with a vapour pressure between 5 and 10 Pa are available
     - Is this representative for the whole group? No, because there are liquids with much lower vapour pressures that might be of interest and the vapour pressure might be a relevant factor
     - Is the dataset representative of a subgroup? Yes (possibly, depending on other factors) representative for substances with a vapour pressure of 5-10 Pa
     - Is this the worst-case subgroup? Probably not, because higher vapour pressure leads to more evaporation and lower availability for skin contact
     - Can the data be used for deriving defaults for the whole originally intended group? This depends on other available information. If there is information that gives some indication about potential difference in effect of very low vapour pressures compared to those of 5-10 Pa, a 'safety factor' could be used to estimate the default for the whole group, albeit with a larger uncertainty
- When raw data are available and the general shape of the distribution is known or can be assumed, calculate the descriptive statistics of that distribution and then calculate the required percentile based on these descriptive statistics
- When only descriptive statistics of a distribution are known (e.g. from literature), calculate the relevant percentile based on these statistics
   - In this case we have to assume that the correct distribution was presented by the authors
- When raw data are available, but there is no proper indication of the correct distribution, set a value at the higher or lower end of the distribution, either directly from the data (e.g. the 75th percentile of 20 data points is the 15th value), or, when the dataset is very strangely distributed, by choosing the value somewhere towards the lower or higher end of the distribution 'a vue' to take into account the available knowledge.
   - This would for instance be necessary when there are lumps of data with large gaps in between. Such a situation may or may not suggest that this data actually represents two different scenarios. If that is expected, the data cannot be used as one dataset.
   - This type of process would lead to a value that is not the maximum/minimum, but fits somewhere between the maximum/minimum and the central tendency of the distribution, but closer to the maximum/minimum than to the central tendency. This is a largely arbitrary process that should be avoided as much as possible.
- When only the minimum, average and maximum of a distribution are available (e.g. from literature), the default could be set at either the minimum or maximum. However, if there is a very large variation in the data, this approach is probably not very representative, and it should be considered not to use the dataset.

- When there is a small dataset available (e.g. less than 20 data points), the minimum or maximum can be used for setting a default. However, when the dataset is very small (e.g. less than 10 data points) and the variation is considerable, it may be better not to set a default based on this data.
  - These values are not based on statistical evaluation, but on expert judgment.
  - In the REACH Guidance R.14 (ECHA, 2012) for worker exposure assessment the minimum number of worker exposure values to be used for drawing conclusions is mentioned to be 6-12.
- Describe the uncertainty in the derived default values
  - The uncertainty can only be described qualitatively. The argumentation for the conclusions on the uncertainty should be presented.
    - The uncertainty is very low if the values are based on a large set of data that can be considered representative for the real population of data
    - The uncertainty increases if the representativeness is less certain (e.g. if data are from just a few subsets of articles or from just a small subset of the EU population)
    - The uncertainty also increases if the dataset is small (e.g. less than 20 or even less than 10 data points per parameter)
    - The uncertainty also increases if the variation in the data is very high or if there is no knowledge on the type of distribution of the data
    - The uncertainty is very high if the default has to be based on literature data that only presents very minimal context and some summary statistics
- If there are different datasets (from literature) on the same subject, the method of combining the datasets depends very much on the available detail in the datasets.
  - A method that can be used for sets with only summary statistics is to plot the descriptors of the set (e.g. minimum, median, 90^{th} percentile, maximum, depending on what is available) on a separate line in a graph in which the value of the parameter is on the x-axes and the datasets are on the y-axes. In this way (with appropriate settings for the x-axes) it is easier to estimate ‘a vue’ where the overall reasonable worst case value is
  - If one of the datasets is much larger and at least as representative for the relevant (sub)group as the other datasets, the estimation can be based on the largest dataset. However, the values of the other datasets can be used to check whether they provide a similar picture and suggest that the largest dataset is indeed representative
  - If raw data points for different sets are available, they can be combined into one set.
    - When the sets have similar numbers of data points, a simple combination is possible
    - When the sets have large differences in number of data points a weighting method may be needed to give more weight to larger sets
- Very poor datasets, e.g. sets that can simply not be considered representative for certain (sub)groups or very small datasets or sets without any relevant description of context, can only be used to verify whether the data in such sets appear to agree with defaults that already exist or with newly made defaults based on other datasets. They should not be used as the sole source of a new default value.

It is also possible that there is a combination available of some measured data and some data from literature. In those cases it would be preferable to only rely on the available measured data, but

one has to decide whether this measured dataset is large enough and sufficiently representative of the group to be used for setting a default. If this is not the case, it may be required to pool the two sets of information, especially when there is reason to assume that the data from literature might be (slightly) outdated. Ideally, the data from literature would consist of the original single data points, which would allow such pooling and actual statistical calculations of 25^{th} or 75^{th} percentile can be done.
When the literature does not provide single data points, but only summarized data (e.g. parameters of a distribution), the measured data can be used to modify the values from the literature either up- or downward on the basis of expert judgment. In this case, it is necessary to report the considerations taken into account during this judgment as detailed as possible, since these is no other generally accepted scientific approach available.

It is not per se necessary to derive a totally new default for a parameter and a (sub)group for which a default already exists, even if good datasets are available. If it is considered that new data are representative for a certain (sub)group for which a default already exists, the next step is to check whether the new data can be expected to lead to a substantial change in the default. If a preliminary analysis of the new data suggests that the new default would probably be (very) close to the existing default, it can be decided to use the new data only to better justify the existing value. However, if the old default is purely based on assumptions, without support of real data, it may be better to modify the default to allow a better linkage between available knowledge and default value.

Reporting

The following type of information needs to be reported:

- A brief description of the dataset (summary statistics)
- If there are subgroups expected in the data, and why
- Whether separate defaults are set for the total group and/or subgroups, and why/why not
- What the methods for deriving the defaults were
- What the argumentation is when expert judgment is used
- The applicability domain of the defaults
- What the uncertainty of the defaults is

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ANNEX 2: SUMMARY OF THE RESULTS OF THE CONSUMER SURVEY ON PARAMETERS FOR DERMAL EXPOSURE – FREQUENCY OF USE

PVC flooring

In the consumer survey, the number of homes with PVC flooring was determined to range from 20% to 63% over different countries with an average of 42%. Only 3% to 14% of the respondents in different countries use PVC flooring as their only type of flooring, the remainder of the respondents who indicated that they have some PVC flooring actually have a mixture of flooring materials in their home.
PVC flooring can be totally or partially covered by rugs, mats or carpets. Between 19 and 42% of respondents with at least some PVC flooring indicated that the full surface area was somehow covered, while 23 to 46% indicated that less than 25% of the surface area was covered. The percentage covered may differ from room to room.

Based on this data, it is clear that PVC flooring is quite common and that potential exposure to substances from PVC flooring is not exceptional and should be assessed.

The fact that there is PVC flooring in a home cannot in itself be considered to be an 'event' relevant for dermal contact. However, direct skin contact with PVC flooring would be an 'event'. For adults, the most logical form of skin contact with PVC flooring is walking barefoot in the home. This may occur mostly in summer and the consumer survey therefore focused on summer. Table A2-1 shows the average percentage of respondents that have PVC flooring that indicates a certain frequency of spending time barefoot in their home in summer.

Table A2- 1: Frequency of being barefoot in their home in summer of respondents with PVC flooring (time spent sleeping excluded)

Subpopulation	Most of the times	Sometimes	Rarely	Never
Adults	26%	33%	26%	15%
Children 12 years or younger	32%	41%	18%	9%

Women were found to be more likely than men to spend time barefoot in their home (63 versus 53%). There are also differences observed between the countries, with 'most of the times' and 'sometimes' together being reported by 46% in Spain up to 68% in Czech republic.

Textiles

In the consumer survey, questions were asked relating to the frequency of wearing certain clothing items. Underwear, socks, trousers and T-shirts are worn 'often' by more than 50% of the respondents, while less than 20% of the respondents wears tights/stockings or nightgowns 'often'. Of course, some items, such as bras and tights/stockings, were considered 'not applicable' by a large percentage of (male) respondents. Looking at women only and items considered to be more relevant for women, more than 25% 'often' wears nightgowns and tights/stockings, while more than 75% often wears bras.
Cotton is the most used fabric material for most clothing items, followed by a mix of cotton and polyester. Silk, wool and viscose material is used for most items in less than 10% of the cases, except for jumpers that are almost in 50% of the cases made from wool.

The frequency of use was also inquired about specifically for the relevant items. Table A2-2 shows the results, separated in wearing during summer or the rest of the year and answered by all who ever where such items.

Table A2-2: Frequency of wearing clothing items during summer and the rest of the year (for those wearing such items)

Clothing item	Frequency of wearing in summer (% of respondents)				Frequency of wearing rest of the year (% of respondents)			
	Daily	Weekly	Monthly	Less / DK*	Daily	Weekly	Monthly	Less / DK*
Underwear	81	14	2	3	88	8	1	3
Bras	73	20	2	5	82	12	2	4
Socks	43	33	6	18	79	15	2	4
Nightgowns	40	32	8	20	41	30	9	20
Pyjamas	38	27	9	27	57	26	5	12
Cotton T-shirts with prints	31	54	6	9	27	52	8	13
Vests/tank tops	25	36	10	29	39	36	10	15
Trousers (not cotton)	23	53	13	11	36	46	8	11
Cotton T-shirts without prints	20	52	8	19	17	47	10	26
Cotton trousers	17	50	13	20	33	43	9	15
Shirts	14	51	13	16	18	49	19	14
Tights/stockings	12	24	13	50	30	36	10	16
Jumpers	5	32	19	44	24	58	10	8

* DK = don't know

Based on these results, the frequency of use should be set at the highest frequency that is indicated by at least 25% of the respondents in either the summer period or the rest of the year, because longer periods of high frequency, even if not throughout the year, should conservatively be considered relevant for the whole year. Table A2-2 indicates the suggested reasonable worst case frequency of use for clothing items for the full population based on these results.

Printed paper articles

The frequency of use was studied for several subtypes of printed paper articles in the consumer survey. Table A2-3 presents the frequency of reading or handling several types of printed paper articles according to the consumer survey.

Table A2-3: Frequency of reading or handling printed paper items

Printed paper item	Frequency of reading or handling (% of respondents)					
Newspapers, books, magazines and brochures/catalogues	Daily			Weekly	Monthly	Less / DK*
Newspapers	28			39	11	22
Books	23			33	17	27
Magazines	6			43	26	25
Brochures / catalogues	4			40	27	27
Paper receipts	Daily			Weekly	Less than once a week	
Goods and services purchased in everyday life	29			37	14	
Clothing and accessories	16			19	65	
Goods and services purchased occasionally [a)]	14			11	74	
Paper currency	> 10 times/day	2-9 times/day	once/ day	Weekly	Less than once a week	
Paper currency bills	5	36	17	32	11	
Home printed paper or photographs	Daily			Weekly	Monthly	Less/ DK*

Printed paper item	Frequency of reading or handling (% of respondents)			
Print documents at home printer	8	37	24	31
Make photocopies	3	21	27	49
Contact with home printed paper (prints, photocopies)	34	35	31	
Print photographs	1	6	15	78
Contact with home printed photographs	17	23	60	

[a] Examples are white goods, furniture and jewelry

* DK = don’t know

For some of the articles a differentiation can be made between different subpopulations. Table A2-4 presents the frequency of reading newspapers or books daily and handling some printed paper items daily for several subpopulations

Table A2- 4: Frequency of reading newspapers or books daily per subpopulation

Item	Country (% of respondents)[a]						Gender (%)		Age (%)		
	SE	DE	UK	ES	PL	CZ	Men	Women	55+	35-54	18-34
Newspaper	47	36	30	27	17	13	--	--	46	22	12
Books	23	23	33	26	21	15	18	29	30	22	17
Paper receipts	39	39	43	58	49	66	--	--	--	--	--
Paper currency bills	24	70	40	68	70	66	--	--	--	--	--
Handling home printed paper	27	42	24	39	32	38	--	--	--	--	--

[a] SE = Sweden, DE = Germany, UK = United Kingdom, ES = Spain, PL = Poland, CZ = Czech republic

Based on the results presented above reasonable worst case estimates for frequency of use can be made for the full population. These reasonable worst case estimates are presented in Table A2-5.

Table A2- 5: Reasonable worst case estimates of frequency of use of printed paper articles for the full population studied

Item	Reasonable worst case frequency of use [a]	Remarks regarding subpopulations or subcategories
Newspapers	Daily	• Poland and Czech republic: weekly • Age < 55 years: ‘weekly’
Books	Weekly	• UK and Spain: daily • Women: daily • Ages 55+: daily
Magazines	Weekly	
Brochures, catalogues	Weekly	
Paper receipts	Daily	• Weekly for clothing and accessories and for goods purchases occasionally
Paper currency bills	Daily; 2-9 times/day	• Weekly for Sweden
Home printed documents or photocopies – fresh [b]	Weekly	
Home printed documents or photocopies – older [c]	Daily	
Home printed photographs - fresh [b]	Less than monthly	
Home printed photographs – older [c]	Weekly	

[a] Reasonable worst case frequency of use: the highest frequency of use that is (cumulatively) indicated by at least 25% of the respondents

[b)] Home printed documents, photocopies or photographs – fresh: contact with freshly printed paper printed by the respondent
[c)] Home printed documents, photocopies or photographs – older: contact with home printed paper not necessarily printed (that day) by the respondent

ANNEX 3: SUMMARY OF RESULTS OF EXPERIMENTS TO DETERMINE TRANSFER FACTORS

Table A3-1: Transfer factors for substances relevant for PVC flooring, textiles and printed paper from glass and aluminum plates (Clausen et al., 2014)

Substance [a)]	Relevant for	From material	Type of wiping	Transfer factor [b)] Median	75th perc.
DEHP	PVC flooring	Aluminum	Dry	0.24	0.29
			Artificial sweat	0.29	0.44
		Glass	Dry	0.57	0.75
			Artificial sweat	0.77	1.08
DINCH	PVC flooring	Aluminum	Dry	0.36	0.44
			Artificial sweat	0.27	0.32
		Glass	Dry	0.28	0.42
			Artificial sweat	0.43	0.47
Disperse Blue 360	Inkjet ink	Aluminum	Dry	0.41	0.45
			Artificial sweat	0.28	0.38
		Glass	Dry	0.40	0.45
			Artificial sweat	0.34	0.39

a) DEHP = diethyl hexyl phthalate, CAS No. 117-81-7, DINCH = Diisononyl cyclohexane-1,2-dicarboxylat, CAS No. 166412-78-8, Disperse Blue 360 = 5-nitro-2-(2-methyl-4-(diethylamino)phenylazo)thiazole (no CAS No.)
b) These are the transfer factors corrected for the blanks

Table A3-2: Factors for combination of emission and transfer for substances from actual article materials (PVC flooring and printed paper) based on performed transfer experiments (wiping with dry cotton and cotton with artificial sweat)

Substance [a)]	Material		Relative transfer (%) based on full thickness of article [b)] N	Median	75th perc.	Relative transfer (%) based on upper 10 µm of the article [c)] N	Median	75th perc.
DEHP	Blue PVC	Dry cotton	3	0.000875	0.001122	3	0.1750	0.2245
		Artificial sweat	3	0.002281	0.002755	3	0.4561	0.5510
DEHP	Red PVC	Dry cotton	3	0.001343	0.003091	3	0.6715	1.5453
		Artificial sweat	3	0.000566	0.001218	3	0.2830	0.6090
DnBP	Red PVC	Dry cotton	3	0.000070	0.001202	3	0.0879	1.5155
		Artificial sweat	3	0.000032	0.000033	3	0.0403	0.0416
DiBP	Red PVC	Dry cotton	3	0.000656	0.003857	3	0.1301	0.7645
		Artificial sweat	3	0.000460	0.000506	3	0.0912	0.1004
DINCH	White PVC	Dry cotton	3	0.000864	0.001380	3	0.1555	0.2484
		Artificial sweat	3	0.000210	0.000296	3	0.0379	0.0534
DB 360	Printed paper	Dry cotton	12	0.002867	0.004951	12	0.2150	0.3713
		Artificial sweat	12	0.003386	0.006496	12	0.2540	0.4872

a) DEHP = diethyl hexyl phthalate, CAS No. 117-81-7; DiBP = Diisobutyl phthalate, CAS No. 84-69-5; DnBP = Dii-n-butyl phthalate, CAS No. 84-74-2; DINCH = Diisononyl cyclohexane-1,2-dicarboxylat, CAS No. 166412-78-8; DB 360 = Disperse Blue 360 = 5-nitro-2-(2-methyl-4-(diethylamino)phenylazo)thiazole (no CAS No.)
b) These are the transfer factors, where relevant corrected for the blanks, based on the total amount in the article with the volume equal to the wiped surface area * the thickness of the article
c) These are the transfer factors, where relevant corrected for the blanks, based on the total amount in the upper 10 µm layer of the article with the volume equal to the wiped surface area * 10 µm
d) Median below limit of detection

ANNEX 4: ARE BODY WEIGHT AND/OR BODY HEIGHT DISTRIBUTED NORMALLY?

Aim of the research:
The aim of this research is to investigate whether based on the available data gathered from sources mentioned under the chapter on physiological parameters, it can be assumed that bodyweight and/or bodyheight are normally distributed. If so, distributions can be calculated from the mean and standard deviation.

Approach and conclusions:
By means of the "Pearson second skewness coefficient", it can be investigated whether data are normally distributed.
Pearson 2nd skewness coefficient (Sk_2):

$$Sk_2 = 3\frac{(\bar{x} - m)}{s}$$

where $\bar{x}$ = the mean, m = the median and s = the standard deviation.

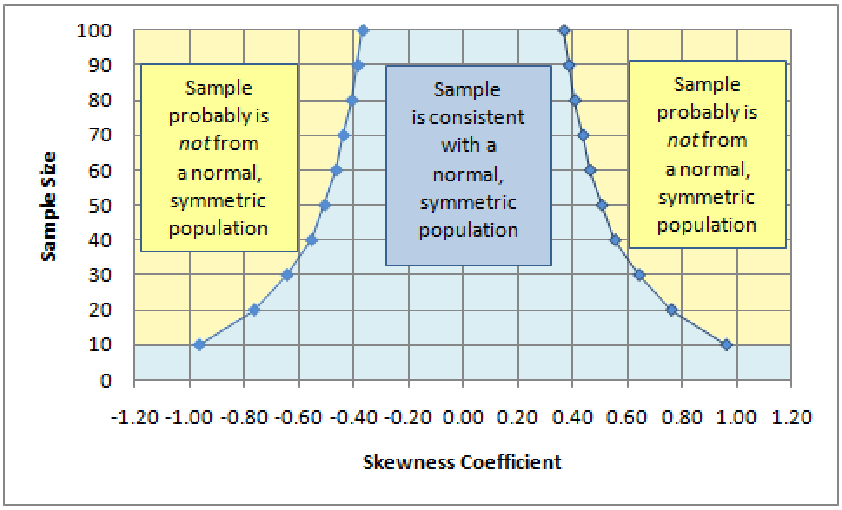
Pearson 2nd skewness coefficient is a skewness measure that directly compares the mean and median. It is easy to calculate and interpret and needs only three summary statistics (the sample mean, median and standard deviation). As such, Sk_2 is the only way to measure skewness when the original sample data are not available. It lies between -3 and +3, it is zero for symmetric distributions, it is unaffected by scale shift, and it reveals either left- or right-skewness equally well. Doane & Seward created tables of critical values to determine if the distribution is skewed or not (Doane and Seward, 2011).

Table 4. 90% expected range for Pearson 2 skewness coefficient Sk_2.

n	*Lower Limit*	*Upper Limit*	*n*	*Lower Limit*	*Upper Limit*
10	–0.963	+0.963	60	–0.463	+0.463
20	–0.762	+0.762	70	–0.437	+0.437
30	–0.643	+0.643	80	–0.407	+0.407
40	–0.554	+0.554	90	–0.385	+0.385
50	–0.506	+0.506	100	–0.367	+0.367

Note: If your sample is from a normal population, the skewness coefficient Sk_2 would fall within the stated range 90 percent of the time. Values of Sk_2 outside this range suggest non-normal skewness.

Only sample sizes up to 100 were displayed because the diagram narrows sharply and labeling becomes difficult.



Source: Doane & Seward, 2011

Application of the skewness coefficient to the data collected on body weight and body height:

- Bodyweight
  - Number of studies : N = 1173
  - Of the 1173 available studies, 564 studies reported the mean, the standard deviation and the median (50^{th} percentile)
    - Range Sk_2 = [-1.5; 11.538]
    - Normaly distributed or not?

Sample size	Criteria	Number of normally distributed studies
≤ 100	According to the table of Doane & Seward	24/42
>100	[-0.35; +0.35]	164/306
Not known	[-1; +1] [-0.35; +0.35]	190/216 64/216

So, for the studies with reported samples size, about have of the data on bodyweight are normally distributed. In the cases where N is unknown, the acceptance of normality strongly depends on the applied criteria (190/216 for criteria N ≤ 100 ; 64/216 for criteria N > 100).

Hence it is not warranted to assume that all studies on bodyweight are normally distributed. The available data are therefore not used to calculate distributions from mean values, or to calculate mean values from distributions.

- Bodyheight
  - N = 992
  - Of the 992 available studies, 267 reported the mean, standard deviation and medean value.
    - Range Sk_2 = [-1.375; 2.956]
    - Normally distributed or not?

Sample size	Criteria	Number of normally distributed studies
≤ 100	According to the table of Doane & Seward	0/42
>100	[-0.35; +0.35]	21/126
Not known	[-1; +1] [-0.35; +0.35]	35/99 20/99

So, regarding the studies with reported samples size, only a small fraction has a normally distributed body length. In the cases where N is unknown, the application of the least stringent criteria, only for approximately $1/3^{th}$ of the studies normal distribution is accepted (35/99).

Hence it is impossible to assume that all studies on bodyheight are normally distributed. The available data are therefore not used to calculate distributions from mean values, or to calculate mean values from distributions.

ANNEX 5: CALCULATION OF BSA USING DIFFERENT FORMULAS

In all commonly used exposure assessment guidances, the surface area is calculated from the average values for body weight and body height. Some widely used equations are listed in . As an example the BSA calculated with the different formulas and the mean European body weight (72.9 kg) and body height (169.7 cm) is presented in Table A5-1.

Table A5- 1: Equations used for the calculation of the whole body surface area (BSA). H=body height, W=body weight

Exposure assessment guidance	Formula for whole body surface area	Used in	BSA for W= 72.9 kg and H= 169.7 cm
McKone und Daniels (1991)	$\frac{4 * W + 7}{W + 90}$	AUH 1995	1,83 m²
Dubois and Dubois [17]	$71.84\ H^{0.725} W^{0.425}$	Tikuisis (2001) Tan (2001)	1,84 m²
Mosteller [18]	$\left(\frac{H * W}{3600}\right)^{0.5}$	INTERA-KMS (CEFIC-LRI project)	1,85 m²
REACH guidance R15	$0.0239\ H^{0.417} * W^{0.517}$	REACH Current report	1,87 m²
Gehan and George [19] (1970)	$0.02350\ H^{0.42246} W^{0.51456}$	Bremmer 2006, ECETOC TRA, US EPA 2011 2FUN (EU-FP6)	1,87 m²

Table 5-1 shows that the equations that are used in REACH guidance R.15 and the exposure factors handbook (US-EPA, 2011) result in the highest BSA values (1.87 m²). However, the difference with other methods is very small, maximum 0,04 m², which is below the standard deviation of measured values (Table A5- 1).

In a pilot project, Tan et al. (2011) determined body surface area using 3D whole body scans, and compared the measured surface area to several formulae in order to investigate the accuracy of calculating BSA (Tan *et al.*, 2001). The results showed that the Dubois and Dubois formula was the best estimator, with an average and maximum difference of about 1% and 3.5% respectively. Tikuisis et al. (2001) also used body scans to measure total body surface area of children and adults. The measured BSA values were compared with predictions of various equations. Deviations with the formulae of Dubois and Dubois, Gehan and George, and Mosteller were -0.32%, 0.02% and 0.54% respectively. The authors concluded that the predictions with the equations they used closely agreed with the measured BSA, but with a bias for increasing body size (Tikuisis et al., 2001). Tan (2001) did not use the Gehan and George formula for comparison with measured data.

[17] Dubois, D., Dubois, EF., (1916). A formula to estimate the approximate surface area if height and weight be known. Arch Intern Med 17:863-871.
[18] Mosteller RD. Simplified calculation of body-surface area. N Engl J Med 1987;317:1098
[19] Gehan E., George, GL. (1970). Estimation of human body surface area from height and weight. Cancer Chemother Rep 54(4):225-235

ANNEX 6: PROPORTION SURFACE AREA BODY PARTS/WHOLE BODY SURFACE

The surface area of separate body parts can also be calculated as a percentage of the total body surface area.
The German Ausschuss für UmweltHygiene (AUH) advises to use the 50th percentile because it relates more to realistic scenarios (AUH, 2000).
Mostly one of two sets of percentages is used in risk assessment guidances:

- Consexpo fact sheet (Bremmer 2006), used by Consexpo, LRI-NTERA-KMS, ECETOC TRAv3, RIVM report 'How to address children's exposure"
- US-EPA exposure factors handbook used in REACH guidance R.15 (US-EPA, 1997) and EU-FP6 project 2FUN (US-EPA 2011 for adults, and 2008 for children).

REACH Guidance Table R.15-13 presents the values of the exposure factors handbook of 1997 (US-EPA). This handbook was updated in 2011. The values in the 2011-version are higher, probably due to:

- another calculation method
- increased body weight compared to the body weight of 1997

The mean of various body part surfaces, for adult men and women, is given in Table R.15-13 of the REACH guidance. For females, it was assumed that the ratio of body part surfaces to total body surface is similar to that for men. For children, Boniol *et al*. (2008) illustrated differences in proportion by sex from around 10 years of age (Boniol *et al*., 2008). Tikuisis (2001) demonstrated significance sex difference by calculating the ratio (R) of SA/volume of various body segments in women and men. The R-value for head+neck, trunk, feet, arms and hands showed significant differences between men and women.
Boniol *et al*. (2008) applied measured data for 87 body parts of 2050 children and teenagers from the United States, to a computer human model (MAN3D) to calculate the proportion of the skin surface area of 13 body parts relative to total surface area. In comparison with previously published studies, Boniol illustrated that the proportion of arms and trunk is underestimated and of head and legs overestimated. The underestimation of the proportion of the arms was confirmed for female but not for male adults, from measurements performed by Tikuisis (2001) by means of body scans of 12 men and 12 women. The percentages of the arms of females is 2.1% higher than the recommended values of the exposure factors handbook (US-EPA, 2011). The proportion of the legs of females is 2.6% higher than the recommended values of the exposure factors handbook (US-EPA, 2011). For the arms and legs of men the differences in the proportions measured by Tikuisis (2001) and the proportions of of the exposure factors handbook, are within the standard deviation of the measurements of Tikuisis (2001). The proportion of the hands and feet of adults are comparable (hands) to and lower (up to 1% for female feet) than the values of the exposure factors handbook.
The exposure factor's handbook of US-EPA (2011) recommends to use the proportions published by Boniol *et al*. (2008) for children aged 2-18 years. Recommended proportions of body parts to the total skin surface area from US-EPA (2011), and the default values used by ConsExpo and ECETOC TRA are presented in Table A6-1. Values for other body parts can be found in ECETOC TRA and US-EPA 2011. The Exposure factors handbook (US-EPA, 2011) gives more narrow age-categories and hence more specific age-related surface area values than Bremmer (2006).
The quality factor for the body parts surface area of children and adults in Bremmer (2006) is 3, meaning that the number and quality of the data is satisfactory, and that the parameter value is usable as default value. The quality score for toddlers is low, namely 2, meaning that the parameter value is based on single data source supplemented with personal judgement (Bremmer, 2006).

Table A6- 1: Mean proportion (%) of total skin surface area by body part for children (male and female combined) and adults

Body part	Age (years)								Ref.
	1	2	3-5	6-10	11-15	16-20	21+ (male)	21+ (female)	
Head (face)	16.5	8.4	8.0	6.1	4.6	4.1	6.6	6.2	1
	16.9				9.8 (9-14 y)		6.4	6.7	2
Head + neck							8.01	8.64	4
Trunk + neck	35.5	41.0	41.2	39.6	39.6	41.2	40.1	35.4	1
	34.3				33.15 (9-14 y)		36.4	34.8	2
Trunk							24.28	23.23	4
Head + trunk + neck	52	49.4	49.2	35.7	44.2	45.3	46.7	41.6	1
	51.2				42.95 (9-14 y)		42.8	41.5	2
							32.29	31.87	4
Arms[b]	13.0	14.4	14.0	14.0	14.3	14.6	15.2	12.8	1
	12.6				13.9 (9-14 y)		14.3	13.8	2
							15.8	14.93	4
Hands[c]	5.7	4.7	4.9	4.7	4.5	4.5	5.2	4.8	1
	5.3				5.7 (9-14 y)		4.9	4.9	2
	5.3 (child)						4.9 (adult)		3
							4.95	4.62	4
Legs[a]	23.1	25.3	25.7	28.8	30.4	29.5	33.1	32.3	1
	23.8				30 (9-14 y)		31.5	32.9	2
							33.42	34.89	4
Feet	6.3	6.3	6.4	6.8	6.6	6.1	6.7	6.9	1
	7.1				7.4 (9-14 y)		6.5		3
							6.16	5.92	4
Five finger tips	0.2 (child)					0.20 (adult)			

[a] sum of thighs and legs, [b] sum of upper and lower arms (Boniol, 2008); [c] two hands inside and palms;
References (Ref.): 1= Exposure factors handbook (US-EPA 2011); 2= Bremmer (2006) and ConsExpo (25[thP] values); 3 = ECETOC TRA; 4 = Tikuisis *et al.*, 2001

Annex 7: European body weight measurement campaigns and their geographical distribution

A wealth of measured body weight data of European people are available in the literature . The body weights are reported as mean and/or distribution of a large set of individual measurements. Most of the measurements for children and adults are reported for males and females separately. The number of measurements for males and females is about the same. The European countries for which data on body weights were found are listed per geographical region in Table A7-1. To explore regional differences, these countries are classified under Northern (N), Western (W), Eastern (E) or Southern (S) Europe according to the United Nations Geoscheme. The number of countries with measured data is highest in N-Europe (9) and lowest in S-Europe (2). W-Europe is represented by five countries and E-Europe by four countries with measured data. Although S-Europe is represented by only two countries, Italy has the highest number of measurements of all the countries that reported numbers of measurements. The number of measurements is not necessarily equal to the number of individuals. It is very probable that in certain monitoring campaigns the same persons have been measured at different ages. For example the same babies may have been measured from month to month within national programs of baby health care.

An overview of the countries of which measured data are taken into account in this report, their geographical classification and the number of measurements per country is presented in Table A7-1.

Table A7- 1: Geographical classification of the countries with measured data on body weight, and the number of measurements per country

Geographical region	Country	Total number of measurements	Number of measurements for children and teenagers	Number of measurements for adults (20+)
Northern Europe	Denmark	not reported	not reported	0
	Estonia	1329	98	1231
	Finland	>3220	>284	2936
	Iceland	not reported	not reported	0
	Ireland	2738	0	2738
	Latvia	1991	210	1781
	Lithuania	>1849	not reported	1849
	Sweden	>13655	>4120	>9535
	United Kingdom	>1707	>1707	0
Western Europe	Belgium	not reported	not reported	not reported
	France	not reported	not reported	not reported
	Germany	>75777	65286	>10491
	Netherlands	>13537	not reported	>13537
	Switzerland	19237	4165	15072
Eastern Europe	Bulgaria	43171	33776	9395
	Czech Republic	9641	7165	2476
	Hungary	>15771	not reported	15771
	Slovakia	7165	7165	0
Southern Europe	Croatia	11546	11546	0
	Italy	>140011	>28126	111885

From those cases, where the distribution, the mean and the standard deviation was reported, it can be shown that a normal distribution of body weights cannot be assumed (see Annex 4 for details). Therefore, calculation of the mean from the distribution was not warranted for those studies where a distribution but not a mean value was reported. Nor could the 50th percentile be set equal to the mean. So we only used the mean reported values from the consulted literature sources.

ANNEX 8: GENDER SPECIFIC EUROPEAN BODY WEIGHT VALUES FOR CHILDREN (SOURCE: FP6, 2-FUN PROJECT)

In the 2-Fun project of the 6th framework program of the European Commission, the mean values of children's bodyweight in the Expofacts database were explored. It was concluded that little differences exist between countries. As an example the bodyweight for females and males >2 - <21 years are presented in Figure A8- 1 and Figure A8- 2. It can be expected and seen in these two figures, that body weight of boys is higher than the body weight of girls of the same age category.

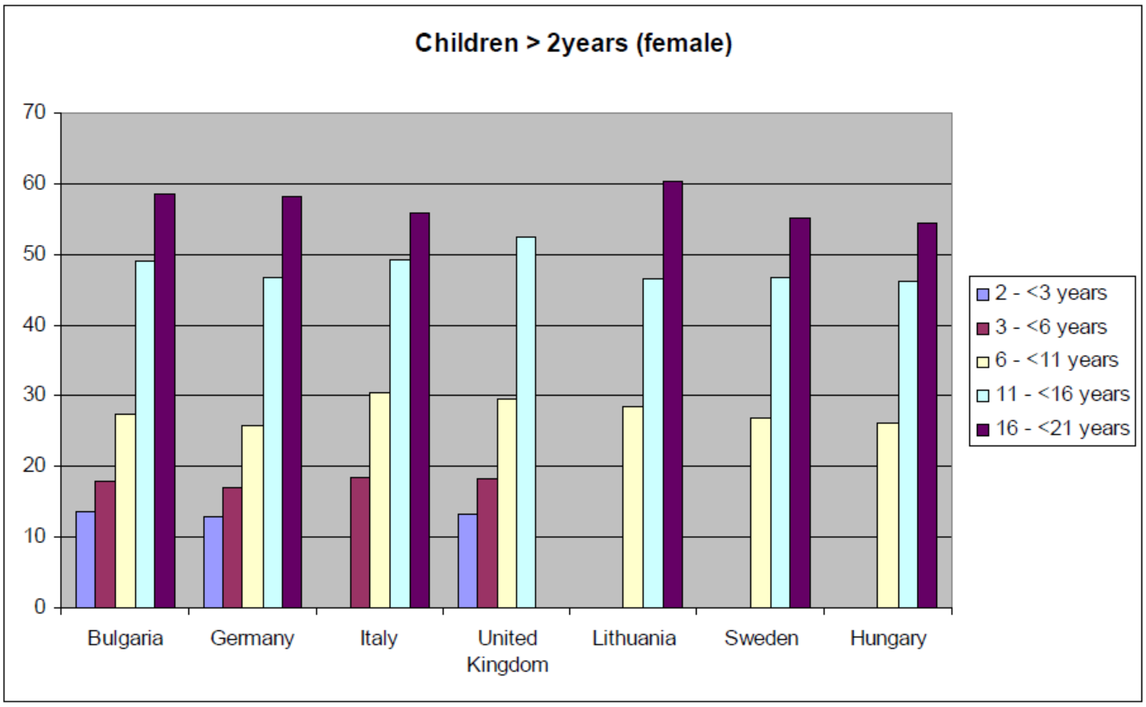


Figure A8- 1: Mean male body weight (kg) for different age categories > 2 -21 years in different European countries (Source 2-FUN).

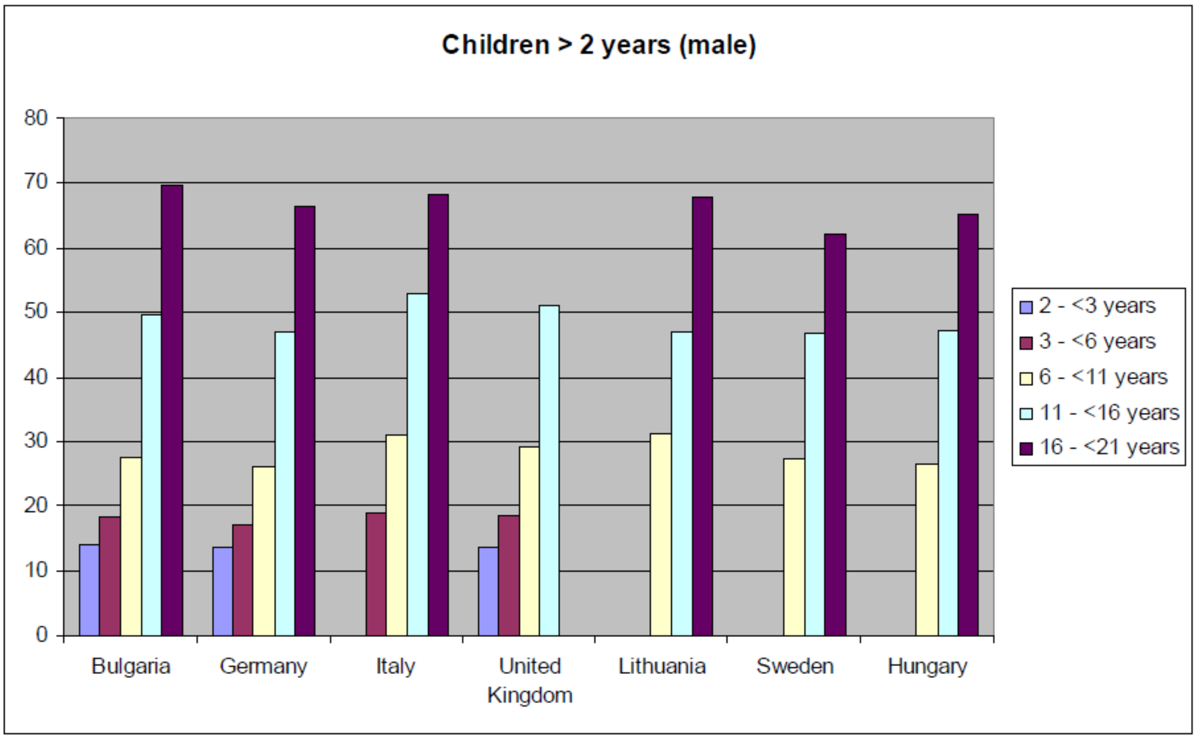


Figure A8- 2: Mean female body weight (kg) for different age categories > 2-<21 years in different European countries (Source: 2-FUN).

ANNEX 9: MEASURED WHOLE BODY SURFACE AREA OF ADULTS AND CHILDREN

Little measured data on body surface area are available (Table A9-1). Mean measured values of 1.8 m² and 1.79 m² for adult females and 2.03 and 2.06 m² for adult males are reported in Expofacts and Bremmer (2006) respectively. In Sweden the BSA of a large number of children and adults has been measured in 2010 (Table A9-1), the mean measured values for Swedish women and men are 1.8 and 2.06 m² respectively.
In a pilot project, Tan *et al.* (2011) determined the BSA of 5 females and 5 male adults and one 8-year old boy, using 3D whole body scans (Tan *et al.*, 2001). Tikuisis *et al.* (2001) also used body scans to measure total BSA of children and adults. An overview of measured BSA values for children and adults is given in Table A9-1.

Table A9- 1: Measured mean BSA for adults and children (m²)

Gender	Age (years)	BSA (SD)	Country	Number of measurements	Year of measurements	Reference
Male	3 - 6	0,76 (0,07)	Sweden	881	2010	Expofacts
	8	1,16	the Netherlands	1	-	Tan *et al.,* 2011
	9 - 11	1,27 (0,15)	Sweden	1180	2010	Expofacts
	16 - 84	2,03 (0,18)	Sweden	2703	2005	Expofacts
	18 - 64	2,030 (0,193)	North America	395	2000	Tikuisis *et al.,* 2001
	22 - 50	1,56 - 2,02	the Netherlands??	5	-	Tan et al., 2011
	24-77	2,06 (0,17)	Sweden	1693	2001 - 2004	Expofacts
	25 - 58	2,11 (0,242)	North America	12	2000	Tikuisis *et al.,* 2001
	adult	2,03 (0,17)	the Netherlands	6094	1995 - 1997	RIVM, 1999 (cited in Bremmer, 2006)
Female	3 - 6	0,75 (0,07)	Sweden	841	2010	Expofacts
	9 - 11	1,25 (0,15)	Sweden	1217	2010	Expofacts
	16 - 84	1,77 (0,18)	Sweden	3199	2005	Expofacts
	19 - 63	1,734 (0,193)	North America	246	2000	Tikuisis *et al.,* 2001
	21 - 50	1,67 - 2,13	the Netherlands	5	-	Tan *et al.,* 2011
	24-76	1,8 (0,17)	Sweden	1908	2001 - 2004	Expofacts
	33 - 53	1,802 (0,312)	United States of America	12	2000	Tikuisis *et al.,* 2001
	adult	1,79 (0,17)	the Netherlands	7443	1995 - 1997	RIVM, 1999 (cited in Bremmer, 2006)

ANNEX 10: OVERVIEW OF LITERATURE DATA WITH DIFFUSION COEFFICIENTS

In this annex, an overview is given of diffusion coefficients of materials and substances measured within the DRESS project (table A10-1), additional data from literature (table A10-2), and parameter values to estimate diffusion coefficients based on the model published by Holmgren (2012) (table A10 – 3 and A10-4).

Table A10-1: summary of diffusion coefficients experimentally determined in the DRESS project (Clausen et al. 2014)

Article/Substance pair	D (m2/s)	95%Conf
PVC flooring (Blue Tarkett Eminent) DEHP	6.6E-13	3.6E-13
PVC flooring (Green PVC China) DEHP	2.0E-12	5.7E-13
PVC flooring (Red PVC China) DEHP	1.3E-11	3.1E-12
PVC flooring (Red PVC China) DnBP	2.0E-12	6.1E-13
PVC flooring (Red PVC China) DiBP	1.3E-11	3.2E-12
PVC (White) DINCH	1.6E-11	7.8E-12
Polyester, PVC coated DEHP	3.0E-12	5.4E-13
Cotton, PVC coated DEHP	7.5E-12	2.3E-12
70% viscose + 30% PP, PVC coated DEHP	7.5E-12	1.4E-12
Polyester, PVC coated DiNP	1.1E-12	1.4E-13
Cotton, PVC coated DiNP	4.5E-12	6.1E-13
70% viscose + 30% PP, PVC coated DiNP	4.5E-12	1.7E-12
Polyester, PU(1) coated DMF	3.1E-12	1.9E-12
Cotton, PU(1) coated DMF	6.7E-12	6.5E-12
Polyester, PU(2) coated DMF	2.8E-11	7.9E-12
Cotton, PU(2) coated DMF	7.2E-12	8.7E-12
Polyester, PU(2) coated DMA	-	
Cotton, PU(2) coated DMA	-	
Inkjet printed paper Disp Blue 360	1.8E-12	2.1E-13

Table A10-2: Overview of diffusion coefficients obtained from literature of substances and materials that are relevant for consumer product exposures (Delmaar et al., 2013)

Table 3
Overview of diffusion coefficients obtained from literature of substances and materials that are relevant for consumer product exposures.

Substance	Matrix/product	D (m^2/s)	Molweight (g/mol)	Study
Toluene	Carpet backing	4.31×10^{-11}	92.14	Bodalal et al. (2000)
Nonane	Carpet backing	2.83×10^{-11}	128.26	
	Vinyl floor tile	1.48×10^{-11}		
Decane	Carpet backing	5.42×10^{-12}	142.29	
	Plywood	1.28×10^{-11}		
	Vinyl floor tile	2.09×10^{-12}		
Undecane	Carpet backing	2.79×10^{-12}	156.31	
	Vinyl floor tile	8.55×10^{-13}		
Cyclohexane	Plywood	1.55×10^{-10}	84	
Ethylbenzene	Plywood	4.04×10^{-11}	116.25	
	Vinyl floor tile	1.6×10^{-11}		
Water	Vinyl flooring	$3.6 \pm 1.1 \times 10^{-12}$	18	Cox et al. (2001)
n-Butanol	Vinyl flooring	$6.7 \pm 0.4 \times 10^{-13}$	74	
Toluene	Vinyl flooring	$6.9 \pm 1.2 \times 10^{-13}$	92	
Phenol	Vinyl flooring	$1.2 \pm 0.1 \times 10^{-13}$	94	
n-Decane	Vinyl flooring	$4.5 \pm 1.1 \times 10^{-13}$	142	
n-Dodecane	Vinyl flooring	$3.4 \pm 0.2 \times 10^{-13}$	170	
n-Tetradecane	Vinyl flooring	$1.2 \pm 0.1 \times 10^{-13}$	198	
n-Pentadecane	Vinyl flooring	$6.7 \pm 1.1 \times 10^{-14}$	212	
Hexanal	Oriented strand board	$1.8 \pm 0.2 \times 10^{-12}$	100.16	Yuan et al. (2007)
Styrene	Polysterene foam	$6.2 \pm 0.4 \times 10^{-12}$	104.15	
TVOC	Particle board	7.7×10^{-11}		Yang et al. (2001)
Hexanal	Particle board	7.7×10^{-11}	100.16	
α-Pinene	Particle board	12×10^{-11}	136.24	
Ethyl acetate	Brick	2.42×10^{-9}	88.11	Zhang and Niu (2004)
	Concrete	4.33×10^{-11}		
	Gypsum board	1.27×10^{-8}		
	Carpet	1.03×10^{-8}		
	Wall paper	2.78×10^{-12}		
n-Octane	Brick	1.40×10^{-9}	114.23	
	Concrete	1.69×10^{-11}		
	Gypsum board	1.20×10^{-8}		
	Carpet	3.56×10^{-8}		
	Wall paper	4.17×10^{-12}		
Styrene	Carpet	$3.6–4.1 \times 10^{-12}$	104.15	Little et al. (1994)
	Carpet	3.1×10^{-12}		
4-Ethenylcyclohexane	Carpet 1	5.2×10^{-12}	110.2	
	Carpet	$2.1 1 \times 10^{-12}$		
Methane	Polyethylene	1.9×10^{-11}	16	Piringer (2008)
Methane	Polyethylene	3.0×10^{-11}	16	
Ethane	Polyethylene	4.8×10^{-12}	30	
Ehtane	Polyethylene	5.4×10^{-12}	30	
Methanol	Polyethylene	4.8×10^{-12}	32	
Propane	Polyethylene	5.2×10^{-12}	44	
n-Pentane	Polyethylene	8.0×10^{-13}	72	
Benzene	Polyethylene	1.1×10^{-12}	78	
Benzene	Polyethylene	4.0×10^{-13}	78	
n-Hexane	Polyethylene	1.1×10^{-12}	86	
n-Hexane	Polyethylene	8.4×10^{-13}	86	
Phenole	Polyethylene	4.5×10^{-13}	94	
Heptanol	Polyethylene	5.3×10^{-13}	116	
2,3-Benzopyrole	Polyethylene	5.5×10^{-13}	117	
2-Phenyl–ethyl-alcohol	Polyethylene	4.3×10^{-13}	122	
3-Octene-2-one	Polyethylene	7.3×10^{-13}	126	
n-Octanal	Polyethylene	2.3×10^{-13}	128	
4-Isopropyl-toluene	Polyethylene	5.4×10^{-13}	134	
Limonene	Polyethylene	4.3×10^{-13}	136	
3-Phenyl-1-propanol	Polyethylene	2.8×10^{-13}	136	
n-Nonanal	Polyethylene	1.8×10^{-13}	142	
7-Methyl-chinoline	Polyethylene	4.3×10^{-13}	143	
2,3,5,6-Tetramethyl-phenol	Polyethylene	1.6×10^{-13}	150	
Dimethyl-benzyl-carbinol	Polyethylene	7.5×10^{-14}	150	
3,7-Dimethyl-6-octene-1-al	Polyethylene	1.0×10^{-13}	154	
n-Decanal	Polyethylene	1.4×10^{-13}	156	
3,7-Dimethyl-octene-3-ol	Polyethylene	1.6×10^{-13}	158	
Diphenyl-oxide	Polyethylene	3.7×10^{-13}	170	
n-Dodecane	Polyethylene	2.6×10^{-13}	170	
Dimethyl-phthalate	Polyethylene	1.9×10^{-13}	194	
n-Tetradecane	Polyethylene	1.9×10^{-13}	198	
Tetradecanol	Polyethylene	8.2×10^{-14}	214	
2,6-Di-tert-butyl-4-methyl-phenol	Polyethylene	4.8×10^{-14}	220	
Cedrylacetate	Polyethylene	4.1×10^{-14}	264	
Eicosane	Polyethylene	6.3×10^{-14}	282	
Docosane	Polyethylene	3.5×10^{-14}	310	

Table 3 (*continued*)

Substance	Matrix/product	D (m^2/s)	Molweight (g/mol)	Study
Timuvin 326	Polyethylene	2.0×10^{-14}	315.8	
2-Hydroxy-4-ethandiol methyl-thioacetic acid ester	Polyethylene	0.9×10^{-14}	346	
Methyl-tricosanate	Polyethylene	1.5×10^{-14}	368	
Methyl-octacosanate	Polyethylene	0.3×10^{-14}	438	
Didodecyl-3-3-thio-dipropionate	Polyethylene	0.2×10^{-14}	514	
3-(3,5-Di-tert-butyl-4-hydroxy phenyl)-propionate	Polyethylene	0.11×10^{-14}	531	

Table A10-3: Input parameters for empirical model for prediction of diffusion coefficients (Begley et al., 2005)

Polymer	A'p	τ_m
LDPE	*11.5*	*0*
LLDPE	*11.5*	*0*
HDPE	*14.5*	*1577*
PP (homo and random)	*13.1*	*1577*
Nylon 12	*0.5*	*0*
PP (rubber)	*11.5*	*0*
PS	*0*	*0*
HIPS	*1*	*0*
PET	*6*	*1577*
PBT	*6.5*	*1577*
PEN	*5*	*1577*

Table A10- 4: Input parameters for empirical model for prediction of diffusion coefficients (A'p and τ_m values) from Holmgren et al. 2012

Polymer	A'p	τ_m	Sdev
PVC	14.5	1577	1.07
PVC rigid	1	1577	2.45
PP	6.5		1.27
EP	8		1.31
EP	13	1577	1.31
EVA	11		0.29
EVA	15	1577	0.29
PVDC	1		3.64
PVDC	6	1577	3.64
EVOH	7		1.67
EVOH	12	1577	1.67
PMMA	-8.5		3.05
PMMA	-3.5	1577	3.05
PA	2		1.7
PA	7	1577	1.7
PET	-1	1577	3.6
PS	-1.5		3.05
PU	8		1.61
PU	13.5	1577	1.75
Epoxy acrylic	-1.3	0	1.24
Epoxy acrylic	3.1	1577	1.24
CR Neoprene	11.7		0.9
CR Neoprene	16.7	1577	1.12
SBR	12.8		1.13
SBR	17.8	1577	1.14
EPDM	13		1.19
EPDM	18	1577	1.43
Rubber	13		1.03
Rubber	18	1577	1.22
ABS	2		0.5
ABS	7	1577	0.66
HDPE	13.5	1577	0.64
LDPE	9.7		0.53
LLDPE	8.7		0.83
Paper	9		1.07
Paper	14	1577	1.07
POM	6.5		1.02
POM	12	1577	1.02
PU/PS	9		1.79
PU/PS	14	1577	1.9
PTT	3.9		0.45
PTT	8	1577	0.33
EDP	3		0.1
EDP	7	1577	0.27
PET	5.4	1577	1.58
Nylon 12	0.5		0.25
PC	-3.4		3.37
PC	0.6	1577	3.47
Phenolic resin	3.9		0.25
Phenolic resin	8.4	1577	0.25