# SCEDs

## Specific Consumer Exposure Determinants

May 10th, 2013
DUCC/Concawe

# ENES 4 Background document for the BREAK-OUT SESSION on SCEDs

**Based on the SCED DUCC/Concawe draft guidance document** v10

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## Foreword

This guidance is issued by the DUCC/Concawe SCEDs Task Force, which provided the project lead for the SCEDs-project.

The **SCEDs (Specific Consumer Exposure Determinants)** have been developed by **DUCC member associations**, which represent companies that use chemicals to formulate mixtures as finished products for end users, including consumers and professional users, and by **Concawe**, whose members sell formulated consumer products such as fuels and lubricants, as well as manufacture the petroleum substances used in such products. Participant DUCC members are A.I.S.E./FEA, CEPE and FEICA.

The final vision for the activity was to develop a comprehensive library of SCEDs that reflect the principle situations of use for consumer chemical products formulated by the involved sectors.

This document addresses the use of SCEDs by registrants in their chemical safety assessment (CSA) or by downstream users (in case they need to develop their own CSA), and assumes that the user has some expertise in using the ECETOC TRA tool as, at an initial stage, the SCEDs will need to be manually introduced in v3 of this tool.

The participating sector organizations, or each member association in the case of DUCC, retain the responsibility for the content of the SCEDs.

# 1. Introduction

## 1.1. Overview of an exposure assessment and risk characterization

In order to perform a consumer exposure assessment/estimation under REACH, the assessor will need to collect the following information:

- a minimum set of substance parameters
- use(s) description by means of the use descriptor system[1], in particular the Product Category (PC)
- conditions of use: operational conditions and risk management measures (OC/RMM)

The **exposure estimation** is then done using the above mentioned information as input parameters in the exposure assessment tool

The next step will be the **risk characterisation**, which consists of comparing the exposure estimation with the applicable DNEL. The assessor also needs to be in possession of the relevant DNELs – being up to him to define which values are appropriate, considering the relevant route and duration of exposure. This step will also be done "automatically" and "simultaneously" with the exposure assessment by the chosen tool.

If the risk characterisation ratio (RCR) is below 1, the assessment stops as safe use can be demonstrated. If the RCR is above 1, the exposure assessment needs to be further refined until the risk assessment passes.

The result of the exposure assessment demonstrating the safe use of a substance will be reflected in the exposure scenarios to be annexed to a Safety Data Sheet and in the substance Chemical Safety Report submitted by registrants. More information on Consumer Exposure Assessment can be found in chapter R15 of the ECHA guidance on IR/CSA.

## 1.2. The SCEDs and its relation to an exposure assessment

The **SCEDs (Specific Consumer Exposure Determinants)** are refined exposure determinants to be used as "information input" in a consumer exposure assessment.

In the context of Chesar[2], a determinant is a condition or measure driving the exposure of a substance to man or environment (e.g. the amount of substance used per day at a site, or local exhaust ventilation (LEV) installed at a work place); it can be quantitative or qualitative. In ECETOC TRA v3[3], as in some other assessment tools, the determinants relevant for a particular assessment are pre-defined and thus the assessor only needs to provide the appropriate values for his case. The SCEDs will constitute the values that the assessor needs to perform a refined consumer exposure estimate, using primarily Tier-1 exposure models, e.g. ECETOC TRA.



[1] http://echa.europa.eu/documents/10162/17224/information_requirements_r12_en.pdf
[2] Chesar manual part 6 version 1.0 2012-06-20
[3] http://www.ecetoc.org/tra

# 2. Incentives and benefits of the SCEDs Project

## 2.1. ECETOC TRA update (consumer module) and the development of the SCEDs

It has been recognized that one of the potential areas for improvement of the ECETOC TRA v2 was the fact that consumer predictions were too conservative to be routinely useful for many substance groups under REACH. The reason for this conservatism was twofold: the limited nature of its algorithms and the fact that many of its exposure determinants derive from worst case situations.

For this reason, the consumer module of ECETOC TRA v3 now offers the possibility to develop more realistic exposure predictions through the "Add Subcategories" tab. This tab gives the user flexibility to estimate consumer exposure for a specific product(s) of their choice, beyond the current subcategories described in the TRA, using expert judgment. This is done through the incorporation of more appropriate exposure determinant information, where available and justifiable. The information to be used in this refined assessment will be made available through the SCEDs - a series of factsheets containing habits and practices (or other similar) data for a range of consumer products. The use of the SCEDs will not change the underlying algorithms in the TRA v3; the SCEDs simply serve to provide an additional set of refined determinants that can be used in the existing algorithms.

These SCEDs data will also improve harmonization of exposure information communication and serve to support the targeted and efficient use of higher Tier consumer exposure models.

## 2.2. Expected benefits/improvements from using the SCEDs

Four main benefits have been identified:

1) More pragmatic exposure scenarios for downstream users

   The SCEDs will significantly improve the defaults used in the exposure algorithms, leading to more realistic predictions of consumer exposure, while still being conservative? This will benefit both registrants and downstream users (DU), who are more likely to receive an exposure scenario that covers their uses and does not contain unduly restrictive risk management measures (e.g. an unrealistic small amount of product for consumer use or too small percentage in the formulation or changes to packaging design). In general, it will avoid the need for unnecessary communication of risk management measures or operational conditions within affected supply chains.

2) More certainty on safe use

   By using the SCEDs it is also more likely that the risk assessor can demonstrate safe use, i.e. RCR<1.

3) Easiness of Chemical Safety Assessment (CSA)

Particularly in the case of a DU CSA, the DU can obtain more refined exposure estimates without having to use more complex, higher tier models. This becomes even more relevant for SMEs with limited technical expertise.

4) Standardisation and harmonisation of communication in the supply chain

The SCEDs will also serve to standardize and harmonize the communication of information for the safe use in the supply chain, resulting in efficiency gains in supplier/DU dialogue.

## 3. Principles underpinning SCEDs

1. The application of the information (exposure determinants) within a SCED 'fact sheet' should be consistent with the process described in ChR15 of the ECHA guidance on IR/CSA i.e. the information applicable to a Tier 1 model (such as the ECETOC TRA) will first be applied to determine the nature of any exposure/risk. If exposures/risks are considered inappropriate, the process will then proceed to include additional exposure determinants until 'safe use' can be concluded.
2. SCEDs should cover all relevant routes of exposure for the use. Where a route of exposure is not considered relevant, then the SCED must include a clear (and ideally quantitative) justification for this. In some cases, 'common sense' is applied (e.g. exposure by oral route in non-accidental circumstances may not be applicable to some product types e.g. car refueling with gasoline).
3. SCEDs are developed by trade groups/associations. They represent a consensus view of that group on how the products that group represents are/should be used for the EU setting.
4. After having developed the SCED, Ideally the group is expected to communicate and apply its contents when developing consumer CSAs under REACH.
5. SCEDs should ideally be available for most situations where consumer exposures to chemicals are commonly encountered and need to be assessed. However, it is for each industry sector to decide to develop SCEDs for their sector.
6. The format and content of the SCED uses the template described in Appendix F of ECETOC Technical Report 114. Appendix F not only describes determinants necessary to run the ECETOC TRA, but also those critical for other consumer models. E.g. CONSEXPO, EGRET.
7. The minimum content of the SCED addresses exposure determinants for the ECETOC TRAv3 consumer module although the SCED may be extended to incorporate other exposure determinants. When this is the case, such determinants should be clearly distinguished within the SCED.
8. Each data point within the SCED should be substantiated/verified by reference to suitable 'open access' information sources that, ideally, have been published and peer reviewed. Preferably these will also refer to European data sources and/or be already utilized in regulatory processes (within the EU or beyond e.g. EPA, IPCS). SCEDs are designed so that the scenario as a whole represents a conservative representation of exposure. Each individual parameter of a SCED is not necessarily a worst case value. Rather, relationships between dependent factors (room size and use amount for a DIY product, for example) are considered so that the resulting scenario represents a conservative, yet realistic, exposure estimate when calculated with the ECETOC TRA v3 tool.

9. Where habits and practices significantly vary across European countries/regions, then the SCED will reflect those areas with the highest uses/exposure conditions. Following on from this, if habits and practices information indicate that use frequencies are less than daily, then these should be noted and applied consistent with point #1 above.
10. When a SCED is developed, the trade group should regularly review its content to ensure it remains accurate and current. Implicit in the review is the need to identify and close any information deficiencies e.g. data points based on expert judgment or which may be associated with significant uncertainties.
11. DUCC is willing to make the SCEDs available in a publicly accessible SCED library.
12. In order to ensure that all SCEDs provide the necessary assurance and confidence across stakeholders, then as new SCEDs are developed, these will initially be distinguished in the SCED library from those that have undergone review by stakeholders.

# 4. Development of SCEDs

Prior to REACH, many sector associations had developed or undertaken various activities that related to consumer exposure estimation, such as the tables of habits and practices describing the relevant consumer uses in their sector. These activities were, by their nature, *ad hoc*. The SCEDs project aims to place all these activities into a common format that covers the key exposure determinants necessary for reliably estimating consumer exposure. This also has the benefit that sectors are able to readily identify any gaps or shortfalls in their understandings of consumer use and to target efforts to further underpin understandings.

The information resulting from the above mentioned activities, as well as data from published literature and higher Tier exposure models have been used to populate the SCEDs.

At the final stage of the process, the SCEDs were tested in ECETOC TRA v.3 to confirm their functionality and the exposure calculated showed that the estimates were indeed more refined.

# 5. Description of the SCEDs

## 5.1. Information contained in a SCED factsheet

Each SCED factsheet consists of a table with a list of descriptors and determinants:

The following **exposure descriptors or determinants** have been assessed as relevant for the consumer exposure estimation. Normally, the determinants provided within a SCED can be used directly in the "Add Subcategories" tab of the Consumer TRA to refine exposure estimation (referred to as "Standard TRA"). However, some exposure descriptors or determinants are written in **blue font** – these are the ones that cannot be directly entered into tool. However, these determinants can still be used in the TRA algorithms by writing out the TRA equations manually (this is referred to as the "Extended TRA"). The determinants in blue can also be used in other higher tier consumer exposure tools, as appropriate.

| **Use descriptor or determinant:**<br>**Explanations of a SCED** | | **Relevance in ECETOC TRA v3**[4]<br>*To be further checked* |
|---|---|---|
| Use Description<br>Title of the use, generic description: e.g. ES short title | | |
| **Product/Article Use Category** | The product category (PC) describes in which types of chemical products (substances as such or in mixtures) the substance is finally contained when it is supplied, in this case to consumers.<br>The article category (AC) describes the type of article into which the substance has eventually been processed. | Standard TRA , Extended TRA, other tools |
| **PC/AC Subcategory** | If one of the product or article sub-categories used as entries to the ECETOC TRA is more suitable than a product category it shall be stated here. | Standard TRA, Extended TRA, other tools |
| **Product Ingredient Fraction (by weight)** | Concentration of the substance in the product, based on product-specific information. This should be adjusted on a case by case basis.<br>Note to SCED author:<br>- if value remains unchanged, state: "Unchanged from TRA default value".<br>- if value is changed, provide references/justification. | Standard TRA,<br>Extended TRA, other tools |
| **Frequency of Use (events/day , and for an infrequently used product also provide days/year)** | Number of times per day that a product is used, based on product-specific information.<br>Note to SCED author:<br>- if value remains unchanged, state: "Unchanged from TRA default value".<br>- if value is changed, provide references/justification. | Standard TRA, Extended TRA, other tools |
| **Relevant Route(s) of Exposure** | Consumer exposure estimation needs to consider three separate exposure routes: inhalation, dermal and oral exposure. Indication of which of these route is (are) relevant for the use of the product.<br>Note to SCED author:<br>- if routes of exposure differ from TRA defaults, state, e.g. "X exposure not considered relevant for this use" and provide justification. | Standard TRA, Extended TRA, other tools |
| **Product Characteristics / Properties** | In case there is a characteristic/property than can/will affect the value of some of the exposure determinants (e.g. volatility) it shall be stated here. Such physchem-based considerations may be relevant for certain sector, e.g. for the use of fuels of varying volatility.<br>Note to SCED author: | Extended TRA |

[4] This column specifies if the determinant or descriptor is relevant for (i) a standard TRA exposure calculation, (ii) an 'extended' TRA exposure calculation, (iii) other consumer exposure assessment tools. E.g. ConsExpo.

| | | |
|---|---|---|
| | Insert narrative that enables the relationship between the determinants and the Product Characteristics / Properties to be ascertained e.g. volatile liquid having a Pa of 1K Pa. | |
| **Dermal Specific Parameters** | | |
| **Skin Contact Area** | This is the skin area (in $cm^2$) which is exposed to the product. This value can be selected from a drop down list.<br><br>Note to SCED author:<br>- If value remains unchanged, state: "Unchanged from TRA default value".<br>- If value is changed, provide references/justification. | Standard TRA<br>Extended TRA,<br>other tools |
| **Skin Transfer Factor** | This is the fraction (>0 to 1) of the substance transferred from the product to the skin. If the user has relevant, specific information or knowledge on the pattern of transfer, he can enter transfer fraction values to refine the exposure estimate. If no data is available, a conservative estimate of 100% is assumed.<br><br>Note to SCED author:<br>- If value remains unchanged, state: "Unchanged from TRA default value".<br>- If value is changed, provide references/justification. | Standard TRA,<br>Extended TRA |
| **Inhalation Specific Parameters** | Note, when providing inhalation parameters, any relationships between amount used, exposure time and room volume should be maintained (e.g., for a wall coating the amount used should match the wall area of the room size- default is 20 m3). Specifying relationships (i.e., coverage per product mass) is helpful for scaling. | |
| **Amount of Product used per application** | Amount used, in g, based on product-specific information.<br><br>Note to SCED author:<br>- If value remains unchanged, state: "Unchanged from TRA default value".<br>- If value is changed, provide references/justification. | Standard TRA,<br>Extended TRA,<br>other tools |
| **Exposure Time** | Duration of the exposure, in hr., based on product-specific information and consumer habits.<br>Note to SCED author:<br>- If value remains unchanged, state: "Unchanged from TRA default value".<br>- If value is changed, provide references/justification. | Standard TRA,<br>Extended TRA,<br>other tools |
| **Inhalation rate** | In $m^3$/hr.<br>Note to SCED author:<br>- default values for children/adults for standard rates can be obtained from ConsExpo 4.1.<br>- if value remains unchanged, state: "Unchanged from TRA default value".<br>- if value is changed, provide references/justification. | Standard TRA,<br>Extended TRA,<br>other tools |

<table>
<tr><td>Room Volume</td><td>Room volume, in $m^3$.<br>Note to SCED author:<br>- if value remains unchanged, state: “Unchanged from TRA default value”.<br>- if value is changed, provide references/justification.</td><td>Extended TRA, other tools</td></tr>
<tr><td>Is product use outdoors only?</td><td>Information on whether the use occurs only outdoors.</td><td>Extended TRA, other tools</td></tr>
<tr><td>Ventilation specified or likely due to properties (i.e., odor, etc.)- if so what type – (open window, fan)</td><td>Ventilation rate (number of air changes per hour).<br><table><tr><th colspan="3">Inhalation Specific Parameters</th></tr><tr><td>Amount of product used per application (g)</td><td>37500</td><td>Based on 50 litres and density of 750 g/l</td></tr><tr><td>Exposure Time (hr)</td><td>0.05</td><td>3 minutes, 97$^{th}$% value from Vainiotalo et al, 1999</td></tr><tr><td>Is product used outdoors only?</td><td>Outdoor use</td><td></td></tr><tr><td>Room Volume ($m^3$)</td><td>100</td><td>$100m^3$ used as default volume (consistent with Stoffenmanager)</td></tr><tr><td>Ventilation specified or likely due to properties (i.e. odour, etc.) – if so what type – (open window, fan)</td><td>0.6</td><td>Outdoor air exchange rate considered to equivalent to value cited by RIVM for garages (0.6x)</td></tr><tr><td>Inhalation factor (fraction of total amount handles lost to air)</td><td>0.2%</td><td>Evaporative losses during refuelling expected to be <<1% based on mass balances</td></tr></table>Note to SCED author:<br>- if value remains unchanged, state: “Unchanged from TRA default value”.<br>- if value is changed, provide references/justification.</td><td>Extended TRA, other tools</td></tr>
<tr><td>Inhalation Transfer Factor</td><td>Fraction (>0 to 1) of the substance transferred from the product into the air. If the user has relevant, specific information or knowledge on the pattern of transfer, he can enter transfer fraction values to refine the exposure estimate (by varying the ‘effective’ amount of substance handled). If no data is available, a conservative estimate of 100% is assumed.<br>Only likely to be applicable to certain types of products (PCs). 100% default. If value is changed: include references of study, etc.</td><td>Standard TRA, Extended TRA, other tools</td></tr>
<tr><td colspan="2">Oral Specific Parameters</td><td></td></tr>
<tr><td>Volume Ingested</td><td>In $cm^3$.</td><td>Standard TRA, Extended TRA</td></tr>
<tr><td>Oral Transfer Factor</td><td>Fraction (>0 to 1) of the substance transferred from the product to the mouth, after mouthing of a product. If the user has relevant, specific information or knowledge on the pattern of transfer, he can enter transfer fraction values to refine the exposure estimate. If no data is available, a conservative estimate of 100% is assumed.</td><td>Standard TRA,<br>Extended TRA, other tools</td></tr>
<tr><td>Sector/organization with responsibility for the sheet</td><td>Indication of the industry sector association responsible for the SCED, the contact person and their email address.</td><td>Not applicable</td></tr>
</table>

The **justifications** will include the reference to any published data that support the choice of the value for each exposure descriptor or determinant, e.g. sector industry data, scientific publication or report.

In a completed SCED, the first column refers to the exposure descriptor or determinant, the second column specifies the value to be used directly in ECETOC TRA v.3 and the third column includes a reference/justification for the chosen value.

## 5.2. Specific comments

When creating SCEDs and using them in ECETOC TRA v3, the user should stick to the human data provided in the "defaults 2" tab (for example, bodyweights, surface areas assigned to different parts of the body, thickness of layer, etc.) Although surface areas have already been assigned, the user has the option to choose a different part of the body, if defendable.

If an alternative room volume and breathing rate is proposed in the SCED, it is worth using the RIVM dataset to maintain consistency across sectors (the RIVM data were originally used to populate much of the TRA.

## 5.3. Appropriate DNELs to be used with SCEDs

In most risk characterizations involving exposure estimates based on SCEDs chronic DNELs are to be used. These values are compared to time-weighted average exposure concentrations, in line with ConsExpo methodology.
Exceptions are those substances which are classified for their acute systemic toxicity. They require derivation of an acute DNEL and comparison of this value with the peak exposure.

## 5.4. Boundaries

The SCEDs are primarily designed to be used in ECETOC v3 and will, for this reason, be subject to the tool's underlying science, assumptions, and limitations. For more information please refer to the ECETOC Technical Reports No. 93 and 114. The SCED information is also capable of being applied in other REACH consumer models such as CONSEXPO and the ESIG (European Solvents Industry Group) EGRET tool.