Addendum to TR114 : Technical Basis for the TRA v3.1

Technical Report No. 124

EUROPEAN CENTRE FOR ECOTOXICOLOGY AND TOXICOLOGY OF CHEMICALS

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Environmental Exposure Assessment of Ionisable Organic Compounds

CONTENTS

BACKGROUND

ECETOC Technical Report 114 (ECETOC, 2012) Appendix F described the broad concept of the Specific Consumer Exposure Determinant (SCED). Following the release of version 3 of the TRA in 2012, various industry sectors have begun to develop SCEDs for their products. However, during the development of SCEDs, it has become apparent how conservative the current TRA algorithms are in their treatment of uses that are only carried out infrequently.

It must be remembered that version 3 adopts the algorithms contained in ChR15 of the REACH Technical Guidance (ECHA, 2010). But these assume that consumer uses of a substance are daily. This is clearly not the case with all consumer products.

At the same time, groups compiling SCEDs were not always clear on the meaning that ECETOC ascribes to the 'transfer factors' applied in the base algorithms.

This Addendum to Report TR114 sets out how infrequent uses of consumer products can now be evaluated in the TRA (as an enhancement contained in version 3.1) together with an extended clarification of the use of the term 'transfer factor'. It also provides further explanation of the basis behind the "Outdoor" and "Indoor" options which version 3.1 of the tool provides when conducting an inhalation exposure assessment for consumers.

This Addendum also clarifies the conditions under which the updated SpERCs should be incorporated when undertaking a TRA-based environmental exposure assessment.

1. INFREQUENT USES

Version 3.1 of the TRA differentiates infrequent consumer uses by placing them into one of four categories as shown in figure 1.

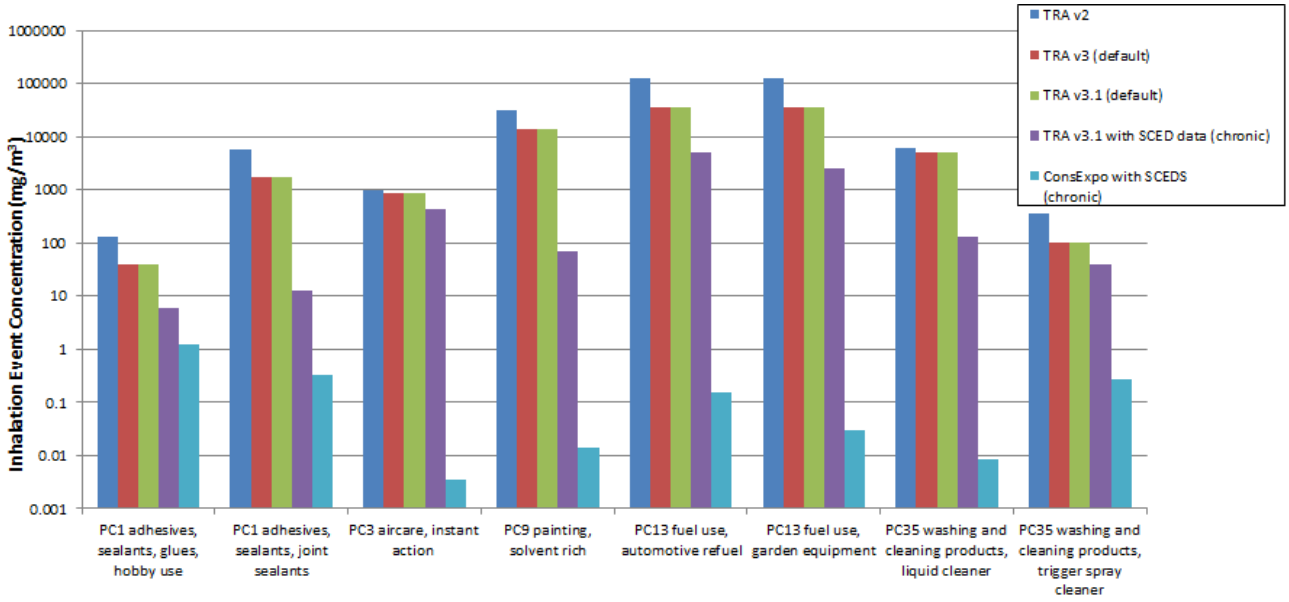
Figure 1: Categories for infrequent consumer use

Frequency of Use	Definition	Proposed TRA Multiplier	Rationale for Multiplier
Frequent	Event occurs at least once a week.	1	Equates to daily use
Occasional	Event occurs between once a week and once a month.	0.2 (5x)	Exposure reduction factor reflects the fact that average exposures are expected to be at least one order less than daily exposures
Infrequent	Event occurs between once a month and once every 6 months.	0.04 (25x)	Exposure reduction factor reflects the fact that average exposures are typically expected to be at least 50 fold less than daily exposures
Very Infrequent	Event occurs no more than once in 6 months.	0.01 (100x)	Exposure reduction factor reflects the fact that average exposures are expected to be at least two orders less than daily exposures

Because the TRA is a Tier 1 tool, any approach for integrating frequency of use information needs to remain consistent with the principles and processes outlined in ChR15 of the REACH Technical Guidance (ECHA, 2010). Accordingly, the categorisation of substance/product use frequency allows the conservatism to be maintained whilst at the same time ensuring that the exposure estimate better reflects reality. In the case of very short term and infrequent exposures, the multiplier is applied to the event exposure as calculated by the TRA. If the number of events per day is one or less, the TRA uses a value of one. If the number of events per day is higher than one, then the actual value is applied (2, 3, or any other as appropriate).

An analysis of the impact of the changes (TRA 3.1 versus TRA 3) for different product uses types (PCs) is shown below in figure 2.

Figure 2: analysis of the impact of the changes (TRA 3.1 versus TRA 3) for different product uses types (PCs)



It can be seen that there is no difference between v3 and v3.1 in the default/base case (i.e. for the default exposure determinants contained within the TRA). The differences only become apparent when SCED data are introduced (using the 'Add Subcategories' tab in the TRA). In all cases, predicted exposures remain much higher than those suggested by Tier 2 (such as CONSEXPO).

2. WHAT IS THE TRA TRANSFER FACTOR?

The transfer factor (TF) mentioned in Appendix F of TR107 for the ECETOC TRA consumer module refers to a coefficient used to describe the difference between the amount of the product/substance being handled (in the event) and the actual amount of material available for exposure during the event i.e. it describes the proportion of the material handled that is likely to be available for exposure (for either the dermal, inhalation and/or oral routes). The TF described by ECETOC must be distinguished from the transfer factor that is referred to in some other areas of risk assessment. For example, the dermal TF has been (inappropriately) described (Kissel, 2011) as referring to the amount of material that is absorbed through the skin and into the body. In this respect, the use of the TF by the TRA is a misnomer: in reality the TRA uses an 'exposure availability factor' i.e. one that distinguishes (within the context of the TRA algorithms) the difference between the amount of product used and the amount that is actually available as an exposure source (and which will also likely vary by exposure route). It is important to remember that the TRA always assumes 100% skin absorption of substances under consideration.

The factor will also vary with the type of use and product characteristics. For example, the factor could change across different scenarios e.g. fuelling a car with a gas or liquid is likely to have different exposure consequences for the inhalation, dermal and oral routes. Within the TRA, the factor is generally assumed to be '1' (100% release) unless otherwise stated (for example, within the SCED, where a supporting rationale would also need to be provided

The following specific comments apply to the transfer factors for the inhalation, dermal and oral routes:

Inhalation transfer factor

The inhalation transfer factor (ITF, >0 to 1) represents the fraction of the substance or product that is released to air during a consumer use. For example, a factor of 0.05 would be applied in a case where 5% of a substance/product is released to air i.e. the ITF generally applies to scenarios where all of the product being handled is not released into the air during the use event, such as is the case for the solid components of paints or when a car is being filled with fuel. In the absence of data to the contrary, a conservative default of 100% is assumed.

Dermal transfer factor

For dermal exposures, the ECETOC TRA applies an algorithm that uses skin surface area; product concentration and the thickness of the product layer to calculate dermal loading. Consistent with Prud'homme et al (2006), the layer thickness is set at 0.1 mm (0.01 cm), based on data that relate to direct handling of liquid products. However, for many uses, dermal exposures which cover the whole area of skin to a uniform (and conservative) thickness are unlikely, for example where exposure is indirect. The DTF is therefore applied to adjust the loading to a level that is more representative of that experienced in the actual scenario (which is a function of the actual exposed skin area and likely product thickness).

Within the context of the TRA, the dermal transfer factor (DTF, >0 to 1) therefore represents the fraction of the theoretical worst case dose that is most appropriate for that scenario. For example, a DTF of 0.05 would reflect the circumstances of the scenario determined that only 5% of the theoretical worst case was

available for exposure. For example, dermal exposure when fuelling a car results from a consumer holding the handle of the fuel pump filling nozzle. But resulting dermal exposure does not occur via contact with a single uniform layer of fuel. Rather, because the exposure event is one where the contact is indirect, then the affected skin area is not uniform. Clearly, justification of this parameter can be difficult. But simulation experiments (both quantitative and qualitative) enable it to be described.

In this sense the DTF may not be the most accurate description; rather, the fraction represents a form of dermal exposure availability factor**.** It should also be emphasized that the DTF does not refer to or account for the amount of material that might then be subsequently absorbed through the skin and into the body (and which the TRA conservatively assumes to be 100%).

Oral transfer factor

Oral transfer factor (OTF, >0 to 1) represents the fraction of the substance of interest that is likely to be ingested from a product or article during an exposure event. (ECETOC, 2009 and ECETOC, 2012). This would be the case, for example, if a child was to suck clothing and an assessment was being made of the exposure to cleaning product residues when some, but not all, the residue could be expected to be released. For example, if only 5% of the product is transferred and available for ingestion, the OTF is 0.05. As a conservative estimate, 100% is assumed as a default for those scenarios where ingestion is considered a likely exposure route.

3. "INDOOR" OR "OUTDOOR" OPTIONS FOR INHALATION EXPOSURE ASSESSMENT

Version 3.1 of the TRA defines either an indoor or an outdoor scenario when considering consumer exposure. For an indoor scenario, 20m^3 is used as a default room volume and 0.6 as its default air exchange rate. Both defaults are based on RIVM General Fact Sheet values for unspecified rooms (Bremer et al, 2006). For an outdoor scenario, 100 m^3 is used as a default room volume and 2.5 as its default air exchange rate. The room volume of 100m^3 for an outdoor scenario is a conservative estimate deducted for near field exposure from Stoffenmanager model (Marquart et al, 2008). The air exchange rate of 2.5 is based on the air exchange rate for a room with window open provided by the RIVM General Fact Sheet (Bremer et al, 2006).

4. SPERCS

In ECETOC TRA 3.1 the SpERCs of AISE, FEICA, etc. were changed according to revisions made by these sector organisations. These SpERCs carry new version numbers. For more information on these SpERCs please refer to the web-pages of the respective sector organisations.

More information about spERCs can also be found in the Cefic SpERC Guidance Document (http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/SPERCs-Specific-Envirnonmental-Release-Classes.pdf)

ABBREVIATIONS

AISE	Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien (International Association for Soaps, Detergents and Maintenance Products)
ConsExpo	Consumer Exposure and Uptake Models
DTF	Dermal transfer factor
FEICA	Fédération Européenne des Industries de Colles et Adhésifs (Association of European Adhesive and Sealant Industry)
ITF	Inhalation transfer factor
OTF	Oral transfer factor
PC	Product use type (category)
REACH	Registration, Evaluation, Authorisation and restriction of CHemicals
SCED	Specific Consumer Exposure Determinant
SpERCs	Specific Environmental Release Classes
TF	Transfer Factor
TGD	Technical Guidance Document
TRA	Targeted risk assessment

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