Addendum to ECETOC Targeted Risk Assessment Report No. 93

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SUMMARY

The ECETOC targeted risk assessment (TRA) Task Force reported in 2004 (Technical Report No. 93), and launched the supporting web-based TRA tool shortly after. Since 2004, almost 1000 users have registered with ECETOC to gain an access to the tool and benefit from its abilities. As part of the process for maintaining the integrity and relevance of the TRA approach, ECETOC has also held a series of meetings and events with experts from member companies and regulatory authorities with the aim of identifying what further modifications may be either necessary or beneficial.

The TRA Task Force was re-convened in 2006 to review the current basis for the approach and make recommendations for further improvements. The Task Force's interim recommendations for how a future version of the TRA might be structured were delivered to the Scientific Committee in 2007 and were subsequently scoped in terms of the work effort required to integrate them into an updated version of the TRA tool. The new version is based on an Excel format and will be available to download from the ECETOC TRA website. At the same time, the value of the TRA was recognised under the European Commission's REACH RIP 3.2 stakeholder review activity on the development of chemical safety assessments. Specifically, the TRA was seen to be the preferred approach for evaluating worker health risks (at the Tier 1 level) and having the potential for also being adopted for evaluating consumer health risks. At the same time, the Task Force recognised the need to develop a more workable and pragmatic approach to environmental risk assessment using the principles laid down within the EUSES (European Union system for the evaluation of substances) model.

Since the summer of 2007, ECETOC has continued its dialogue with stakeholders and notably the Commission / European Chemicals Agency (ECHA). Many of the ideas outlined in the August 2007 Scoping Document are now incorporated into the planned ECHA CSA/CSR tool (Chesar). Furthermore, as the specification for the CSA/CSR tool foresees integrating the use of several elements of the TRA exposure estimation models, the TRA Task Force has worked to develop improved exposure estimation models for workers, consumers and the environment that continue to carry forward the principles that were pioneered in the original TRA web tool whilst accommodating many helpful suggestions from the stakeholder process. This report describes the current structure of the revised TRA approach (for workers, consumers and the environment), details the nature of the changes from the original TRA and describes the process of justification/verification where such changes are substantive.

1. GENERAL

1.1 Background to the current TRA activity

ECETOC first proposed its ideas for an integrated framework for evaluating the health and environmental risks of chemicals in 2003. Essentially, this advocated an efficient and reliable basis by which chemicals product risk assessment could be progressed by manufacturers and suppliers through a tiered and targeted approach. The intention was in particular to develop generic, conservative Tier 1 risk assessment approaches that allowed to quickly identify exposure situations that lead to no risk and only progress with more sophisticated higher tier approaches that need more detailed information in cases where the Tier 1 assessments highlighted a possible risk. The key ideas contained in the ECETOC targeted risk assessment (TRA) approach were subsequently established in a web-based tool derived from ECETOC Technical Report 93 in 2004. The web-version of the tool served to not only demonstrate the integrity of the approach, but also show that a reliable basis for Tier 1 risk assessment (and its documentation and communication) could be developed in a manner which made it accessible to users without scientific background knowledge of chemical risk assessment methodologies. Furthermore, the tool was structured in a manner that supported users with help screens and provide outputs that maintain the overall transparency of the work processes.

Since 2004, many hundreds of users have registered with ECETOC to use the tool. Throughout this period, ECETOC has maintained a dialogue with users and offered a feedback and enquiries function which has enabled it to identify areas where either the underpinning science and/or utility of the tool could be further improved. At a more formal level, the TRA was extensively reviewed as part of the REACH Implementation Project (RIP) 3.2 activity through which the Technical Guidance Documents (TGD) for Chemical Safety Assessment (CSA) under REACH (EC, 2006) have been developed and where the utility of the approach as an effective Tier 1 tool was confirmed by the recommendation that the TRA be used as the preferred screening approach for both workers and consumers. In parallel with the RIP activity, ECETOC has continued to promote and test the value of key concepts contained within the original TRA at scientific symposia and workshops.

In response to these developments, ECETOC re-activated the TRA Task Force in late 2006 with the aim of implementing a full review of the TRA in the light of the above and making available a fully revised version.

1.2 Status of TRA under REACH

The TRA has been extensively reviewed as part of the REACH Implementation Project (RIP) 3.2 activity through which the REACH Information Requirements and Chemical Safety Assessment

Technical Guidance Document (IR&CSA TGD) has been developed. RIP 3.2 considered the TRA as an effective Tier 1 tool for evaluating worker exposures and identified its potential for use with consumer exposures (subject to further refinement of the TRA). However, the original approach for evaluating environmental risks was not considered sufficient to be useful under REACH.

The TRA Task Force has therefore responded to this analysis in three ways:

- ***Workers***: To further improve the scope and accuracy of the TRA exposure estimates, as well as offering the ability to evaluate the effect of a wider range of relevant exposure determinants. Where possible, ECETOC has sought the counsel of stakeholders to ensure the content remains consistent with version 1.
- ***Consumers***: To work with the European Chemicals Agency (ECHA) and EU Member States (notably The Netherlands National Institute for Public Health and the Environment [RIVM] and the German Federal Institute for Risk Assessment [BfR]) to identify a basis that would lead to fully revised TRA exposure estimates but would continue to offer users the ability to evaluate the effect of a wider range of relevant exposure determinants.
- ***Environment***: To provide TRA exposure estimates meeting the requirements of REACH, a completely new assessment approach was conceived in order to implement the emission estimation put forward in the REACH Guidance and to employ the algorithms of the EU Technical Guidance Document for estimating environmental exposure concentrations. ECHA was in constant discussion during the development process.

1.3 Main differences between version 1 and version 2

The new version of the TRA significantly differs from the earlier version. The primary reason for this is the European Chemical Agency's intention to develop a CSA/CSR tool (CSAT) that embraces many of the features of the original TRA but which would continue to make use of the TRA exposure estimation models. The consequence of this is that version 2 of the TRA primarily focuses on an improved basis of the exposure assessments for workers, consumers and the environment. This means that the TRA no longer sustains the ability to undertake and target risk assessment. However, the TRA continues to maintain the original version's key features of usability across all groups; integrity and transparency of the supporting science; and provision of output reports that are capable of incorporation in the process for Exposure Scenario development throughout the Chemical Safety Assessment. Unlike the original web-version of the TRA, the new version is based upon an Excel format. Offering the TRA in Excel addresses the key concerns of many users regarding issues of data security that are often associated with a web-hosted version. The key technical features of version 2 are summarised in sections 1.3.1 to 1.3.4.

1.3.1 Workers

The structure of the worker exposure predictions has been wholly revised. TRA version 2 will enable worker exposures to be predicted across the range of REACH Process Categories (PROC), with an ability to differentiate between the exposures that might be anticipated under circumstances of industrial and professional use. The process of exposure prediction will align with the requirements of the IR&CSA TGD i.e. it will provide an initial prediction of exposure that is then capable of further modification (iteration) based upon the ability to account for a restricted range of operational conditions (duration of exposure, physico-chemical properties of substances, concentration of a substance in preparations) and risk management measures (i.e. presence of different forms of exposure control, the role of different forms of respiratory protection). As with the previous version of the TRA, the ability of users to iterate will remain limited and the nature of all changes will be displayed as an output file that demonstrates the necessary transparency expected by the TGD.

1.3.2 Consumers

The structure and content of the consumer exposure models has undergone extensive discussion and revision. The bases of the algorithms used to model exposures are largely retained, but have at the same time been revised to address a wider range of consumer uses consistent with the product use categories (PCs) that must be evaluated under REACH. The transparency of the tool has also been improved significantly; for each product use category a rationale is available that justifies the basis of the default values and assumptions. As a consequence, in several instances the predicted exposures vary significantly from those proposed within the original TRA.

1.3.3 Environment

With the TRA version 2, ECETOC has developed a completely new ECETOC TRA ENV as a completely new tool for environmental assessments under REACH. It fully replaces the module of the TRA version 1, which, according to the discussions in the REACH Implementation Projects (RIPs), does not meet the requirements set out under REACH. The newly developed environmental assessment of the TRA version 2 combines the novel element of the REACH guidance (i.e. the Environmental Release Classes) with the algorithms of the EU Technical Guidance Document (EC, 2003) for the estimation of environmental exposure concentrations. The process of environmental exposure prediction will align with the requirements of the IR&CSA TGD i.e. it will provide an initial prediction of exposure. Additional information on substance properties, emission circumstances and on risk management measures can be introduced to iterate the assessment. The output produced by the environmental assessment module will document all parameters employed in the environmental assessment, thereby ensuring the transparency expected by the TGD.

1.3.4 User interface and database

All three parts, the worker exposure assessment, the consumer exposure assessment and the environmental exposure assessment are incorporated into an integrated tool with a common user interface and a common database. The user interface allows a user to perform assessments of a single substance for different settings (e.g. different processes, consumer articles and environmental release classes). The data entered into the user interface can be stored in an Excel table, the database, and be processed. The database can store several substances and multiple scenarios. The user interface also enables a batch processing for several substances, which are stored in the database. Nevertheless, the three parts, worker, consumer and environment, can still be used separately.

1.4 Future of the web tool

The original web-based version of the TRA was made freely accessible by ECETOC on a secure server (https://www.ecetoc-tra.org). The web-based version was intended to ensure the TRA was accessible to a wide body of users. With the advent of the ECHA CSA Tool, the functionality of much of the TRA will become available on an EU-supported software platform. Because of this, ECETOC will no longer support the web-based version of the TRA and it will be withdrawn.

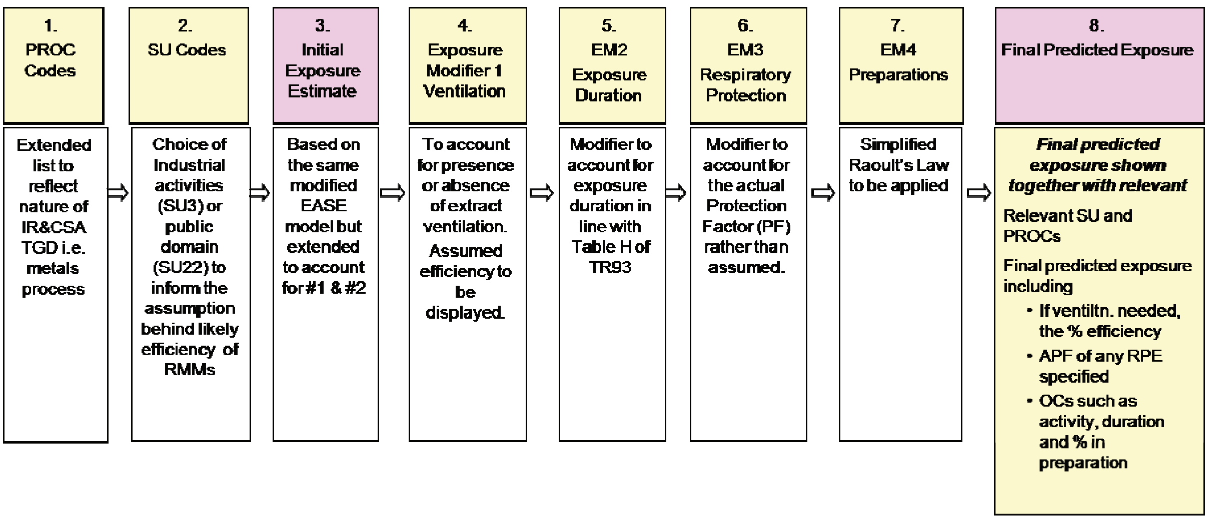
However, ECETOC also recognises that those wishing to undertake chemicals risk assessment often also need access to tools that are not entirely web-based. For this reason the Excel-based version will be made available on request. Users wishing to obtain a copy will need to register their details with ECETOC and will then be sent an email informing them of how this can be downloaded, together with the technical documentation and user instructions that have been developed to support version 2.

2. WORKER UPDATE

2.1 Changes from version 1 of the TRA

The workflows of the worker part of the ECETOC TRA have now been substantially revised. The 'workplace exposure scenario' which was originally used within ECETOC Technical Report No. 93 (ECETOC, 2004) to describe the various circumstances under which chemical exposure was likely to occur has been incorporated into the REACH Use Descriptor system (Chapter R12 of the Information Requirements and Chemical Safety Assessment Technical Guidance Document [IR&CSA TGD]). These have now been re-named Process Categories (or PROCs). The revised process for exposure estimation within the TRA now incorporates the changes resulting from the increase in the number of PROCs and from a series of recommendations made as a consequence of the consultation exercise that ECETOC undertook with stakeholders subsequent to the posting of the TRA web tool in 2004. These changes, while still retaining the core philosophy of the 2004 version, have resulted in the need to restructure the workflows within the tool. The exposure prediction remains based upon EASE (HSE, 2003) (see Figure 1). However, by restricting the nature of exposure predictions to any PROC, it has been possible to refine the estimates such that they exhibit an improved accuracy (in terms of the tendency of EASE to both under- and over-predict certain exposures). Moreover, by restructuring the workflows, it is now possible to further improve the sensitivity of the exposure predictions, accounting for the area of use (industrial and professional users), as well as an increased number of options relating to Operational Conditions (OCs) and Risk Management Measures (RMMs).

Figure 1: Structure for predicting worker exposures based on modified EASE estimates



2.1.1 Process categories

The structure of the TRA has been re-aligned to reflect the numerical order of the PROCs as laid down in R12 of the IR&CSA TGD (version 1.1, May 2008). This has resulted in a need to both re-title the earlier ECETOC exposure categories, and review the underlining basis for the exposure predictions within each PROC. Table 1 summarises the relationship between the structure of the revised TRA and its previous basis, together with the underlying definitions of each PROC. Those PROCs, which are additions to the original TRA categories, are identified in blue. However, in addition to the PROCs listed in section R12 of the IR&CSA TGD, one new category (PROC 8b) has also been identified by ECETOC that characterises the differences associated between dedicated and non-dedicated materials handling facilities in order to enable the TRA to offer a sufficiently accurate discrimination across PROCs. This is highlighted in grey.

One reason why the original TRA did not originally extend to the 10 new PROCs was the inherent inability of EASE to reliably predict exposures under the conditions of uses described by many of these PROCS, e.g. exposures to process fumes. Therefore, in order to ensure that the integrity of the exposure predictions within the new PROCs is consistent with those within the earlier version, ECETOC has worked with relevant sector associations and companies to either identify suitable models that might be used to predict exposure or, alternatively use point estimates based upon representative industry data (according to the approach of Tielemans *et al*, 1998 or those outlined in Chapter R14 of the REACH IR&CSA TGD). The intent remains ensuring that the predictions remain suitably conservative whilst at the same time reflecting the reality of current exposures in those areas of use. In addition to the 10 new categories, the updated version introduces a subcategorisation of PROC 8 (transfer of chemicals from/to vessels/large containers at non-dedicated facilities) to account for the fact that many of these activities are undertaken at dedicated facilities where the nature of exposures can reasonably be expected to be lower then those at non-dedicated facilities, but where no other PROC appears directly suitable to accommodate such a distinction.

Table 1: Relationship between the TRA v1 exposure scenarios and TRA v2 process categories

REACH Process Categories		TRA Worker Exposure Scenario (2004)	
PROC 1	Use in closed process, no likelihood of exposure	TRA 1	Use in a closed process with no likelihood of exposure
PROC 2	Use in closed, continuous process with occasional controlled exposure	TRA 2	Use in closed process with occasional controlled exposures e.g. during sampling
PROC 3	Use in closed batch process (synthesis or formulation)	TRA 3	Use in a closed batch process i.e. where only limited opportunity for breaching arises e.g. sampling
PROC 4	Use in batch and other process (synthesis) where opportunity for exposure arises	TRA 4	Use in a batch or other process (including related process stages e.g. filtration, drying) where opportunities for exposure arise e.g. sampling, dis/charging of materials
PROC 5	Mixing or blending in batch processes (multistage and/or significant contact)	TRA 5	Use in a batch process including chemical reactions and/or the formulation by mixing, blending or calendaring of liquid and solid-based products
PROC 6	Calendaring operations	-	No direct equivalent in 2004 TRA.
PROC 7	Industrial spraying	TRA 6	Spraying of the substance or preparations containing the substance in industrial applications e.g. coatings
PROC 8	Transfer of chemicals from/to vessels/large containers at non dedicated facilities	TRA 7	Dis/charging the substance (or preparations containing the substance) to/from vessels
PROC 8b	Transfer of chemicals from/to vessels/ large containers at dedicated facilities	-	
PROC 9	Transfer of chemicals into small containers (dedicated filling line)	TRA 8	Filling containers with the substance or its preparations (including weighing)
PROC 10	Roller application or brushing	TRA 9	Roller application or brushing of adhesives and other surface coatings
PROC 11	Non industrial spraying	-	Not directly addressed in 2004 TRA due to concern with limitations of EASE
PROC 12	Use of blow agents for foam production	TRA 10	Use as a blowing agent in the manufacture of foams, etc.
PROC 13	Treatment of articles by dipping and pouring	TRA 11	Use for coating/treatment of articles, etc. (including cleaning) by dipping or pouring
PROC 14	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	TRA 12	Production of products or articles from substance by compression, tabletting, extrusion or pelletisation
PROC 15	Use of laboratory reagents in small scale laboratories	TRA 13	Use as a laboratory reagent
PROC 16	Using material as fuel sources, limited exposure to unburned product to be expected	TRA 14	Use as a fuel
PROC 17	Lubrication at high energy conditions and in partly open process	TRA 15	Use as a lubricant (including metal working fluids)
PROC 18	Greasing at high energy conditions	-	TRA 15 was intended to also reflect such exposures
PROC 19	Hand-mixing with intimate contact (only PPE available)	-	No direct equivalent in 2004 TRA
PROC 20	Heat and pressure transfer fluids (closed systems) in dispersive use	-	Not directly addressed in 2004 TRA. Such exposures intended to be addressed under TRA 2

Table 1: Relationship between the TRA v1 exposure scenarios and TRA v2 process categories *(cont'd)*

REACH Process Categories			TRA Worker Exposure Scenario (2004)
PROC 21	Low energy manipulation of substances bound in materials and/or articles	-	No direct equivalent in 2004 TRA
PROC 22	Potentially closed operations with minerals at elevated temperature	-	No direct equivalent in 2004 TRA
PROC 23	Open processing and transfer of minerals	-	Not directly addressed in 2004 TRA. Such exposures intended to be addressed under TRA 8
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	-	Not directly addressed in 2004 TRA due to explicit limitations of EASE
PROC 25	Hot work operations with metals	-	Not directly addressed in 2004 TRA due to explicit limitations of EASE

2.1.2 Nature of user population

REACH introduces a Use Descriptor that characterises the Sector of Use (SU) of a substance. The SU can be expected to influence the nature of resultant workplace exposures predictions e.g. the confidence that professional users will be able to consistently manage exposures is lower and hence there is higher uncertainty in the exposure prediction. In its 2007 proposals for updating the TRA web tool (https://www.ecetoc-tra.org), ECETOC originally proposed to introduce the ability to relate all SUs (which amount to almost 40) to the PROCs that would normally be expected to be associated with any specific SU. However, while this is a comparatively straightforward concept, the effort required to re-programme the TRA to accommodate it is substantial. Instead, users are now able to make a broad distinction between whether a substance is used in an industrial and/or a professional setting. Industrial experience demonstrates that the nature of handling in non-industrial settings often gives rise to elevated exposures. This is reflected in the nature of the updated TRA predictions (see Appendix A) as well as the increased uncertainty associated with the likelihood that certain risk management systems will operate to equivalent standards to those in industrial settings (see Section 2.1.3 below): Figures in blue indicate an increase in the exposure estimate versus the EASE prediction. Figures in red indicate a decrease. These values, which have been discussed with the UK Health and Safety Executive, the owner of the EASE model, are intended to reflect those exposures that might typically be expected within any PROC i.e. they are intended to represent the typical upper boundary exposure arising from responsible use rather than those which might arise from misuse of a substance. In those cases where EASE is unable to predict exposure for the PROC (as is the case with PROCs nos. 20-25 for metals-based exposures), then predicted exposures have been derived from published sources. Appendix B contains further details of these.

The scheme as presented retains the original basis for distinguishing the propensity for fugacity based on a substance's volatility or dustiness (see ECETOC, 2004, Section 2.1.1 of TR 93). For volatile substances, this demands a consideration of volatility at the process/operating temperature. Therefore, where a substance is handled in similar applications but under different processing conditions (e.g. temperature), then the TRA will need to be applied several times in order to fully evaluate the range of possible exposures (and risks) associated with each use.

2.1.3 Presence of extract ventilation

While the original TRA allowed the user to determine whether local extract ventilation (LEV) was present or not, because the original TRA output was based on the (pre-set) EASE algorithms, it meant that the user was not directly aware of the assumed efficiency of the ventilation system. The revised version of the TRA provides a more transparent and realistic basis on which such choices can be determined. The new tool offers two levels of ventilation for those activities undertaken outdoors and those carried out inside. For operations undertaken in the open air, the predicted exposure is 70% of the indoor prediction (i.e. a reduction of 30%). This reduction reflects the increased dilution in the outdoor setting. However for outdoor activities, the ‘addition’ of LEV is not provided as an option, as the effectiveness of extraction ventilation in outdoor settings is notoriously dependent on local conditions and hence is inappropriate for incorporation into a screening tool. On the other hand, where the activity is undertaken indoors, then the user has a choice to evaluate whether this is performed with or without LEV. If LEV is chosen, then an assumed efficiency of between 75% and 97% applies dependant upon the particular PROC (and where the median value is ~85%). These values align with general guidance in this area (e.g. HSE, 2008). The efficiency also varies in most instances between industrial and non-industrial (professional) situations and is intended to reflect the differences in the level of control that is typically encountered across such sectors of use. In the case of those circumstances where control efficiencies exceed the default for the PROC e.g. the provision of laminar cross flow booths to manage inhalation and dermal exposures to high toxicity substances, then these must be defined by the user (and account for relevant regulatory and other guidance in this area).

Appendix A shows the basis of the choice of the ventilation efficiency for each PROC and SU, together with the assumed efficiency used within the corresponding EASE prediction and where these values have been modified: Figures in blue indicate an increase in the assumed efficiency versus the EASE value. Figures in red indicate a decrease. These values, which have been discussed with the UK Health and Safety Executive, the owner of the EASE model, are intended to reflect both increases and reductions in assumed efficiencies in-line with those that might typically be expected within any PROC i.e. they are intended to be reflective of typical practice rather than good/best practice.

2.1.4 Exposure duration

The correction factors that are intended to account for work shifts that are shorter than eight hours remain the same as those contained in Appendix H of TR 93 (ECETOC, 2004). The revised version of the TRA has not been adapted to include extended work regimens i.e. those fundamentally longer than a five-day, eight-hour work week. Where users consider that these are relevant for the Exposure Scenario under evaluation, then exposure modification algorithms other than those available within the TRA should be applied.

2.1.5 Respiratory protection

In-line with the sentiment contained in EU legislation that the application of personal protective equipment (PPE) should be the least preferred control option (EU, 1989), the original TRA did not include the ability to evaluate the impact of available respiratory protection. However, perhaps because this form of PPE is commonly encountered across industry, this was frequently identified as a shortcoming during the 2004-2006 TRA user/stakeholders consultation. The revised version of the TRA therefore includes the capability to account for the presence of commonly encountered forms of respiratory protective equipment (RPE).

Rather than using the protection values assigned by a manufacturer to marketed respiratory protective devices (often referred to as the Nominal Protection Factor, NPF), the effectiveness of RPE is evaluated within the revised TRA using the Actual Protection Factor (APF). The APF is a realistic measure of the protection offered in practice and is invariably significantly lower than the NPF and reflects the typical protection that is likely to be encountered within a (trained) working population during simulated working conditions. The general default within the TRA is that no RPE is used. However, when the RPE option is chosen, then two levels of APF are identified, reflecting APFs of 10x (90% exposure reduction) and 20x (95% exposure reduction). Adopting such an approach also ensures that the values used within the TRA align with the advice that is contained within commonly encountered regulatory schemes for workplace risk management e.g. UK COSHH essentials (HSE, 1999)[1], BAuA EMKG schemes (Easy-to-use workplace control scheme for hazardous substances) (BAuA, 2006)[2].

2.1.6 Preparations

The original TRA only addressed exposures to pure substances. However, in most workplaces, exposures to substances arise via the use of mixtures or preparations of substances. For this

[1] http://www.coshh-essentials.org.uk
[2] http://www.baua.de/nn_18306/en/Topics-from-A-to-Z/Hazardous-Substances/workplace-control-scheme.pdf

reason, the TRA has been revised to take into account the variable percentage of substance in product, where the product is a liquid.

Exposure to vapour models describes scenarios in which a compound evaporates from a surface (e.g. a vessel or painted wall) into the room air. The compound may comprise 100% of the product (default option), or be part of a mixture. Lower concentrations in a mixture generally lead to lower concentrations in the surrounding air. Higher tiered models e.g. ConsExpo, ChemSTEER, or WPEM use formulas in which the product amount is multiplied by the weight fraction of the compound in the total product. Therefore, as a first approximation the concentration of chemical in the room air is assumed to be directly proportional to the concentration in the mixture. This approach is scientifically covered by Raoult's and Dalton's laws. However, the use of the partial vapour pressure to calculate exposure to vapours resulting from a mixture is, in its simplest form, only valid within the restrictions of an 'ideal solution'. Therefore, in reality both false positive (the measured vapour pressure is lower than anticipated) and false negative (the measured vapour pressure is higher than anticipated) deviations from ideal behaviour are possible. To take these uncertainties into account the following conservative exposure modifying factors can be applied.

Table 2: Exposure modifiers for preparations

Percentage of substance in preparation	Exposure modifier (% reduction)
>25%	None (default)
5-25%	40
1-5%	80
<1	90

An alternative way to take account of reduced exposures to a substance in a mixture is to adjust the vapour pressure to reflect the partial vapour pressure for the component of interest. The resulting vapour pressure may result in moving the exposure estimate from one volatility band to a lower volatility band, e.g. high to medium, medium to low (see, for example, HSE, 2009). The means of recording this option is not captured within the ECETOC TRA tool, and should be explained in the text of the Chemical Safety Assessment supporting the evaluation.

2.1.7 Dermal exposures

While TR 93 identified a basis by which dermal exposures could be predicted (both as the applied exposure and absorbed dose), this aspect was not implemented within the web-based version of the TRA. Instead those exposure categories where dermal exposure was considered to represent a potential concern (and which are identified in Appendix Q of TR 93) were 'flagged' as part of the Tier 1 process in order that users of the TRA could determine (externally to the TRA process) the type of PPE considered most appropriate to manage dermal risks. However, as REACH requires that any Exposure Scenario is built around a quantitative assessment of risk, it is necessary for the TRA to include the ability to predict dermal exposures for each PROC.

Appendix C represents a revised version of the Appendix Q of TR 93. It exhibits the following characteristics:

- It extends the number of PROCs to align with those in Appendix A and Chapter R12 of the IR&CSA TGD.
- It no longer offers a qualitative differentiation between those scenarios/PROCs where dermal exposure is considered to be a potential concern or not. Instead, it offers quantitative exposure estimates for every scenario/PROC.
- It uses the EASE predictions of the applied external exposure to calculate systemic dose (assuming 100% absorption). To do this, the likely exposed skin contact area is identified (as a fixed value) commensurate with an expert view of what the nature of typical dermal contact might be for that circumstance of use.
- The EASE predictions have been reviewed in the light of available measured data such as those resulting from the RiskofDerm and related projects in order to ensure that they represent reasonable estimates of exposure. Where the EASE values have been modified, then figures in blue indicate an increase in the assumed exposure versus the EASE value. Figures in red indicate a decrease.
- In those cases where EASE is unable to predict exposure for the PROC (as is the case with PROCs nos. 20-25 for metals exposures), then predicted exposures have been derived from published sources. Appendix B contains further details of these.

It should be noted that, unlike EASE, the revised dermal TRA does not discriminate between dispersive and non-dispersive uses (which are considered as the equivalent to the industrial and professional uses described in the 'inhalation' portion of the model). Rather, the TRA predicts a single exposure for both population types. The rationale for this is essentially that there is little difference in the EASE estimates for both population groups (as shown in Appendix Q of TR 93) and that the situations where actual data are available do not appear to consistently show a marked difference between the dermal exposures of professional and industrial users for similar tasks. Therefore it would be misleading to make such a distinction within the tool.

Furthermore, the dermal exposure elements within the tool do not account for exposure duration, substance concentration (which is consistent with version 1), or the quantitative efficiency of dermal RMMs. As the influence of those parameters is strongly dependent on the substance properties, there is no scientific basis for a general algorithm that can systematically be applied to a Tier 1 tool. Dependent on the specific situation, however, 'simple' exposure modifiers may be applied (and which are discussed further in Appendix D), but as this may lead to a possible increase in uncertainty of the final exposure estimates if undertaken with appropriate knowledge, then these factors have not been formally incorporated into version 2 of the TRA.

2.1.8 Reference values

The principle focus of version 2 of the TRA lies with improving the exposure estimates. The TRA tool continues to include the ability to introduce a suitable exposure reference value (for both inhalation and dermal routes of exposure) against which the predicted exposures can be compared. The basis of this value is not defined and it is for the user to determine which value is most appropriate. For example, it could represent an existing regulatory occupational exposure limit (OEL) or an appropriate derived no effect level (DNEL) derived in the hazard assessment of the REACH Chemical Safety Assessment.

2.1.9 Presentation of the output

In order to align the revised TRA with the requirements of an exposure assessment for a CSA under REACH, the tool's outputs list all the relevant exposure determinants (from both OCs and RMMs) which are determined by the final exposure prediction for the relevant PROCs. These are shown in Table 3 and are structured in a manner consistent with Figure 1, i.e. an initial estimate of exposure is made based upon how and where a substance is used; upon which a limited set of pre-defined exposure reduction factors can then be applied (and those which have been applied are clearly indicated in the report output). These outputs then enable the user to explore whether the exposure predictions can be considered as safe in the context of REACH, or whether further iterations are indicated (and what these might need to embrace) in order to reduce the predicted exposures to acceptable levels.

2.1.10 Domain of application

TR 93 listed a series of conditions or circumstances where the worker portion of the TRA was not considered reliable and hence where it was not recommended to be applied. These largely stem from the inherent limitations of the model (EASE) used to derive the inhalation and dermal exposure estimates. In applying the revised TRA to an extended set of PROCs (and in particular PROCs 18-25), several of the previous limitations can now be considered to have been addressed. However, as the TRA continues to use EASE at its core, these restrictions as they relate to an inability to derive estimates of exposure for process fumes still apply.

Table 3: Output of revised TRA worker exposure model

Worker exposure report for substance demosub1 (CAS no. 01-02-03) – version 1.0 Low fugacity	**Exposure estimate (units ppm)**
Exposure scenario (formulation industrial) Procedure 5 – Mixing or blending in batch processes (multistage and/or significant contact) Industrial activity Initial exposure estimate	5
Exposure modifiers The activity takes place indoors Ventilation is not present	5
The maximum duration of the activity is >4 hours (default)	5
Respiratory protection is not used	5
Is this substance part of a mixture? Yes at >25% w/w Assessment factor applied is 1 The inhalative exposure estimate for this exposure scenario is	5 5 ppm
Dermal exposures may arise from this exposure scenario and assuming a maximal exposed skin area are estimated at	480 (sq cm) 0.07 mg/kg/day

3. CONSUMERS

3.1 Changes to version 1 of the TRA

Version 2 of the TRA for the 'Consumer' part is the result of a substantial revision of the previous version (TR 93). Despite these changes, the concepts and ideas behind the new TRA remain the same as those in TR 93 (ECETOC, 2004). It is a first tier (Tier 1) tool that aims to balance the need for both conservatism in the assumptions and generic applicability to a wide range of product categories to deliver reasonably plausible outcomes.

Changes in the TRA include minor changes in the details of the algorithms used to calculate exposure via the three routes of exposure considered, (dermal, inhalation and oral) as well as changes in the values of the parameters used in the algorithms. The list of product categories has also been revised and made fully compatible with the Product Categories and Article Categories that are listed as REACH Use Descriptors (IR&CAS TGD). Because of such changes the layout of the tool has also changed.

Although details of the revisions are shown below, it is pertinent to highlight that a number of important elements remain the same as the original version of the TRA. Specifically:

- The relevant exposure routes are selected for each product or article category (PC/AC).
- Exposure is estimated in systemic exposure units (mg/kg/d) per each relevant route (oral, dermal, inhalation).
- A substance bioavailability of 100% is considered for all routes of exposure.
- One simple algorithm for all categories is applied for each route of exposure.
- The values of the default parameters are fixed except for two key parameters per route of exposure.
- The estimation of systemic exposure from all routes can be added for each category.
- Estimations of exposure from different categories are not added up.

3.1.1 Product and Article Categories

3.1.1.1 Compatibility with PC and ACs use descriptors under REACH

Consumer uses are organised and classified according to the same list of categories as the previous version of the TRA. However the actual list of categories has been completely modified. The new list is identical to the list of 'Use Descriptors' proposed for REACH and described in chapter R12 of the Guidance on Information Requirements and Chemical Safety Assessment (ECHA, 2009, version 07.11.09). This full compatibility with the Use Descriptors maximises the utility of the TRA tool when used in the context of the development of REACH Chemical Safety Reports.

An immediate consequence of the above is that the new list of categories separates products from articles. All the different products and articles are classified in product categories (PC) and articles categories (AC) respectively, and each is assigned with a code number that is exactly the same as that in the REACH Use Descriptor (e.g. PC35 = Washing and cleaning products, or AC8 = Paper products). Consumer exposure to substances present in a number of the listed categories (PCs and ACs) is either not relevant (e.g. PC19 = Intermediates) or out of the scope of REACH (PC29 = Pharmaceuticals) and for that reason no consumer exposure assessment is undertaken by the TRA tool. However, to facilitate the flow of communication within the chemical industry supply chain, these categories are still listed in the user input section of the TRA tool and are identified with a letter 'n' (not relevant) next to the descriptor code. Appendix E-1 details the list of full PC and full AC used in the tool.

3.1.1.2 Sentinel products and product subcategories

The different product and article categories described above are purely based on the REACH Use Descriptors taxonomy and are not necessarily an accurate reflection of actual exposure characteristics. In other words, a given category may include several types of uses or subcategories with quite different exposure characteristics that translate into potentially different values of the default parameters and even differences in what might be considered relevant routes of exposure. To address this, many of the categories are subdivided into subcategories in an attempt to better display and differentiate the related exposure patterns. Version 2 of the TRA offers the possibility of estimating both the exposure associated with the broad categories and also the exposure specific to each and all of the subcategories. The exposure corresponding to a broad category can therefore be thought of as a sentinel of exposure for all of the subcategories within the broad category. Thus, if the estimated exposure for the broad category results in an acceptable risk assessment outcome when compared with the appropriate hazard reference value, then there is no need to continue estimating the exposure for the different subcategories. This approach places the underlying data supporting the TRA Product categories at an equivalent level to the Environmental Release Classes (ERCs). A full list of all the categories and subcategories is provided in Table E-1 of Appendix E-1.

3.1.2 Algorithms

As in the previous TRA version, one algorithm per exposure route (dermal, oral, inhalation) is used to calculate the exposure for all product and article categories. The three algorithms are straightforward and consistent with those proposed for Tier 1 consumer exposure assessment in chapter R15 of the "Guidance on information requirements and chemical safety assessment" (ECHA, 2009, version 07.11.09). Details for each algorithm are described below.

3.1.2.1 Details for dermal: Elimination of 'transfer to skin' and 'duration factors'

The algorithm used for calculating dermal exposure is shown below:

Parameter:	**P**roduct **I**ngredient (g/g)		**C**ontact **A**rea (cm²)		**F**re**Q**uency of use (events/day)		**T**hickness of **L**ayer (cm)		**D**ensity (g/cm³)		**C**onversion **F**actor (mg/g)		**B**ody **W**eight (kg)	**Exposure (mg/kg/d)**
Algorithm:	**(PI**	**x**	**CA**	**x**	**FQ**	**x**	**TL**	**x**	**D**	**x**	**1000)**	**/**	**BW**	

This is a simpler algorithm than that used in the previous TRA version. The two main differences are that it does not account for any duration factor and that it assumes 100% transfer of substance from the product or article to the skin without applying any transfer factor. These changes result in a substantial increase in the estimated values of exposure relative to the previous TRA version.

The values for two of the parameters in the algorithm can be chosen by the user. These parameters remain the fraction of substance in the product or article and the skin contact area (first two parameters in the algorithm above). The values for the other parameters remain fixed with defaults.

3.1.2.2 Details for inhalation: Introduction of vapour pressure for release from articles

The algorithm used for calculating inhalation exposure is shown below:

Parameter:	**P**roduct **I**ngredient (g/g)		**A**mount product used per application (g/event)		**F**re**Q**uency of use (events/day)		Fraction released to air[1] g/g)		**E**xposure **T**ime (h)		**I**nhalation **R**ate (m³/h)		Conversion Factor	Room **V**olume (m³)		**B**ody **W**eight (kg)	**Expo-sure** (mg/kg/d)	**Expo-sure** (mg/m³)
Algorithm:	**(PI**	**x**	**A**	**x**	**FQ**	**x**	**F**	**x**	**ET**	**x**	**IR**	**x**	**1000)**	**V**	**x**	**BW**		

The algorithm is essentially the same as that in the previous TRA version. The key difference is in the parameter describing the substance's transfer to air. In the previous TRA version, the value for that parameter was assigned to each product category based on an expert judgement of field data and the circumstances of use. In this version the value of the parameter is estimated based on the vapour pressure of the substance. Four bands (A to D) of vapour pressure values are considered. Each one is assigned a different value of fraction released to air. The values and the corresponding substance's vapour pressure are indicated in Table 4 below.

Table 4: Vapour pressure bands

DEFAULT VP (non-spray)			
CLASSES	Default Vapour Pressure Band (non-spray)	Default fraction released to air	
A	A: Vapour pressure ≥10 Pa	1	
B	B: Vapour pressure between 1 and 10 Pa	0.1	
C	C: Vapour pressure between 0.1 and 1 Pa	0.01	
D	D: Vapour pressure <0.1 Pa	0.001	
Vapour Pressure (Pa)			

Any substance with a vapour pressure higher than 10 Pa is assigned a transfer to air factor of 1, the substance is considered to be completely released into air instantly. This is of course a very conservative assumption.

It is important to note that the methodology described above is not used for spray products. In the case of spray products it is assumed that substances are released fully and instantly into the air. Again this is a very conservative assumption which translates into an exaggerated exposure estimate.

Version 2 of the TRA allows the inhalation exposure estimation to be expressed in both units of systemic exposure (mg/kg/day) and units of concentration of substance in air (mg/m^3) depending on the user's choice. This provides the necessary flexibility required by the form of hazard reference value (e.g. DNEL) that will be used for comparison in the risk characterisation phase.

Inhalation reference values in mg/m^3 can also be converted to mg/kg/day as follows:

$$IRV_{inh_2} = IRV_{inh_1} \times IR \times \frac{1}{BW}$$

where:

IRV_{inh2} : inhalation reference value [mg/kg/day]
IRV_{inh1} : inhalation reference value [mg/m^3]
IR : inhalation rate [m^3/day]
BW : body weight [kg]

Two of the values of the parameters in the algorithm can be defined by the user. These parameters are the fraction of substance in the product or article and the amount of product used per application (first two parameters in the algorithm above). The values for the remainder of the parameters are fixed with defaults.

3.1.2.3 Details for oral

The algorithm used for calculating oral exposure is shown below:

Parameter:	**P**roduct **I**ngredient (g/g)	**V**olume of product swallowed (cm^2)	Fre**Q**uency of use (events/day)	**D**ensity (g/cm^3)	**C**onversion **F**actor (mg/g)	**B**ody **W**eight (kg)	**Exposure (mg/kg/d)**
Algorithm:	**(PI x**	**V x**	**FQ x**	**D x**	**1000)**	**/ BW**	

Within the scope of products that are covered by REACH in the context of consumer exposure, the oral route is mostly an anomalous one. This is mainly because REACH does not deal with consumer assessment of food, food-related, and pharmaceutical products. This reduces the relevance of consumer oral exposure to accidental ingestions or special situations of foreseeable product misuse. Accidents are also out of the scope of REACH so the relevance of the oral route for consumers is in the realm of small children engaging in well known and common habits of mouthing. This is effectively limited to being mostly relevant for objects or articles and less so for products or preparations. The algorithm for consumer oral exposure is therefore meant to address mouthing by children. Because of this, the parameter referred to as ‘Volume of product swallowed’ (second parameter in the algorithm) is a calculated parameter obtained by multiplying the surface contact area of the mouthed article by the thickness of an imaginary surface layer of the article. In this context, it is assumed that 100% of the substance present in that surface layer is transferred and available for ingestion without considering any transfer factor. This invariably results in substantial overestimation of actual exposure values.

The values for two of the parameters in the algorithm can be chosen by the user. These parameters are the fraction of substance in the product or article and the volume of product swallowed (in reality, the contact area of the mouthed article). The values for the remainder of the parameters are fixed.

3.1.2.4 Algorithms for sentinel product

The algorithms used for calculation of exposure for the sentinel products (see section 3.1.1.2) are exactly the same as those described above. For the sentinel product/article, the exposure estimates for each route correspond to the highest exposure estimate of the individual product/article subcategories within the sentinel. Furthermore, depending on the default route of relevance (adult or child) for the product/article subcategory, total exposure for some sentinel products/articles may also include both adult and child exposures, resulting in conservative estimates. Child or adult exposure assumptions are determined by accounting for the differences in the body weight: A body weight of 10 kg corresponds to child exposures and a 60-kg body weight represents those of an adult.

3.1.3 Values of parameters

3.1.3.1 Fixed and changeable parameters

Consistent with the original TRA, the algorithms in version 2 of the TRA include parameters whose values are fixed by defaults and also parameters whose values can be selected by the user. For all three algorithms, the fraction of substance (ingredient) in product or article (PI) can be chosen by the user. In addition, the contact surface area, the 'mouthed' surface area, and the amount of product used are parameters whose values can be selected by the user for the dermal, oral, and inhalation routes of exposure (CA, A and V, respectively).

3.1.3.2 Default values (consistency with ConsExpo)

Default values associated with subcategories, such as amount of product used and exposure time, were obtained from the RIVM fact sheets for specific products (e.g. Paint Products Fact Sheet, RIVM report number 320104008/2007). However, for certain parameters such as frequency of use, 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). When product specific fact sheets were unavailable, values were derived using expert judgment. In these cases, the expert judgement reflects discussions during 2008-2009 within an ECHA consumer expert group comprised of representatives of ECHA, ECETOC, RIVM, BfR, INERIS and the Danish EPA. The supporting reference for each product category and subcategory are listed in Appendix E.

Within the Excel worksheet, the default values used to calculate exposure can be viewed for each subcategory in the Defaults tab. Pathway specific values are provided for the exposure routes considered relevant to the product. For example, for PC9a (coatings, paints, etc) below, the amount of product and exposure time are shown for the inhalation route and the thickness layer is shown for the dermal/oral route. It should be noted that only those exposure routes that are considered to constitute potentially significant exposures are 'flagged' i.e. oral exposures are confined to a few specific subcategories (e.g. finger paints).

Figure 2: Default parameters for estimating exposure in different product categories

Default Parameters for Estimating Exposure in Different Product Categories

		Dermal Exposure			Oral Exposure				Inhalation		Derm/Oral	All	
Descriptor	**Product Subcategory**	Body Part Considered	Adult **C**ontact **A**rea (cm²)	Child **C**ontact **A**rea (cm²)	**V**olume Prod Swallowed (cm³)	Body Part Considered	Adult **C**ontact **A**rea (cm²)	Child **C**ontact **A**rea (cm²)	**A**mount of prod for formula (g/event)	**E**xposure **T**ime (hr)	**T**hickness **L**ayer (cm)	**D**ensity (g/cm³)	**F**re**Q** of Use (events/day)
PC9a: Coatings, paints, thinners, removers	Waterborne latex wall paint	2: inside hands / one hand / palm of hands	428.8						3750	2.2	0.01	1	1
	Solvent rich, high solid, water borne paint	2: inside hands / one hand / palm of hands	428.8						1300	2.2	0.01	1	1
	Aerosol spray can								300	0.33			1
	Removers (paint-, glue-, wall paper-, sealant-remover)	3: hands	857.5						2000	4	0.01	1	1

3.1.3.3 Adult and children default values

Adult and child default values such as body weight and surface area were obtained from the RIVM fact sheets (RIVM Report 320104002/2006). For adults, surface areas for various body parts were based on both males and females, whereas body weight data were based on women. For children, both body weight and surface areas were based on a 1.5-year old child, respectively.

Population specific values for adults and children are summarised in the Defaults2 tab in the tool (see Appendix E-3). The specific default values used to calculate exposure for each of the product subcategories can be seen in the Defaults tab in the tool. The Defaults tab includes a justification for the routes of exposure considered relevant for each of the categories (see Appendix E-2).

A screenshot is shown below for ‘PC1: Adhesives, sealants’, which shows, for example, the adult surface area associated with the exposed body part (see columns N and O):

Figure 3: Default parameters for estimating exposure in different product categories

Default Parameters for Estimating Exposure in Different Product Categories

		Dermal Exposure			Oral Exposure				Inhalation		Derm/Oral	All	
Descriptor	**Product Subcategory**	Body Part Considered	Adult Contact Area (cm²)	Child Contact Area (cm²)	Volume Prod Swallowed (cm³)	Body Part Considered	Adult Contact Area (cm²)	Child Contact Area (cm²)	Amount of prod for formula (g/event)	Exposure Time (hr)	Thickness Layer (cm)	Density (g/cm³)	FreQ of Use (events/da
PC1:Adhesives, sealants	Glues, hobby use	1: fingertips	35,7						9	4	0,01	1	1
	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	3 hands	428,8						15000	6	0,01	1	1
	Glue from spray	1: fingertips	35,7						255	4	0,01	1	1
	Sealants	1: fingertips	35,7						390	4	0,01	1	1

3.2 Collaboration with RIVM and other stakeholders

The potential value of the consumer part of the previous version of the TRA was acknowledged in the RIP 3.2 stakeholder process. However, it was felt that a higher degree of consensus was desirable regarding the choice of default values. In response to this, ECHA worked with ECETOC to establish a peer view group to contribute to the development of the consumer part of the TRA. Initial contact between ECETOC, ECHA and with key stakeholders (RIVM, BfR, and INERIS) was made on 11th April 2008 in Helsinki, when ECHA formed an ad-hoc 'consumer exposure expert group' to discuss possible Tier 1 exposure estimation tools for use in developing exposure scenarios (including the ECETOC TRA and ConsExpo). This group then met again on 6th June 2008, followed by subsequent meetings on 7th November 2008, 1st July 2009, and 5th October 2009, in order to work on the consumer part of the TRA and make it acceptable for REACH. The Danish EPA was also included in the group after the first two meetings. The list of product categories has been modified and made fully compatible with the Product Categories and Article Categories that are listed as REACH Use Descriptors (IR&CAS TGD). The group refined and agreed on the algorithms used to estimate exposure from each of the three routes (dermal, oral, and inhalation). The group also worked on providing default values for each route of exposure and product/article category. RIVM acted as a key resource in the process, providing expertise and knowledge of use categories from ConsExpo plus scientific and conceptual ideas to aid the revision of the TRA and help to align the tool with REACH Product and Article categories. ECETOC acknowledges and thanks all the stakeholders and specially RIVM for their considerable input into this process.

3.3 Description of new layout

Unlike the web-version, the revised TRA is an Excel spreadsheet containing eight worksheets, each navigable via the tabs at the bottom of the tool. The first tab, User Input, is the only worksheet where entries are necessary or permitted. Entries can only be made in the cells shaded either green or grey. Green denotes parameters necessary for generating exposure estimates or risk characterisation ratios (RCRs). Grey cells are for those default values that can be over-ridden if the user has more use- or product- specific information. If no values are entered in the grey cells, the tool automatically assigns pre-selected default values from the Defaults tab.

Calculations and results for sentinel products/articles are contained in the second worksheet (Results by Sentinel Prod). Only products/articles selected in the User Input sheet are displayed and highlighted. In addition to exposure estimates and RCRs for individual pathways, a total exposure, which is the sum of dermal, oral, and inhalation exposures, is also calculated. Inhalation exposures are only added to the total exposure if the inhalation hazard reference value has been entered in units of mg/kg/day. Therefore, an inhalation reference value (e.g. the relevant DNEL) should also be entered in units of mg/kg/day to obtain an aggregated exposure even though the total exposure is compared to a worst-case reference value.

Figure 4: User input screen

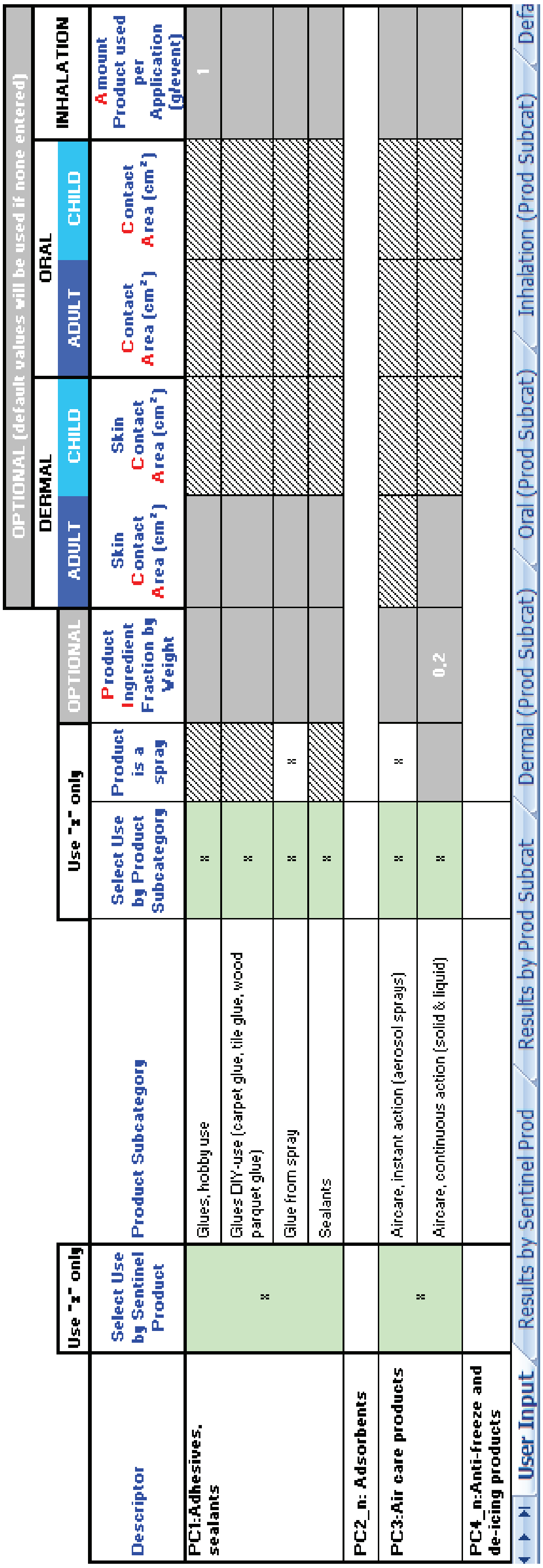


Figure 5: Summary of results for consumer product exposure (worst case for sentinel products)

Summary of Results for Consumer Product Exposure (Worst-Case for Sentinel Products)

CLICK TO UNHIDE DERMAL EXPOSURE PARAMETERS

CLICK TO HIDE INH EXPOSURE PARAMETERS

Descriptor[1]	DERMAL			ORAL			INHALATION				SUMMARY OF RESULTS FOR SENTINEL PRODUCTS	
	Worst-case Product Subcategory[2]	Dermal Exposure Estimate (mg/kg/day)	Dermal Risk Characterisation Ratio: Dermal Exposure / Dermal Ref Value	Worst-case Product Subcategory[2]	Oral Exposure Estimate (mg/kg/day)	Oral Risk Characterisation Ratio: Oral Exposure / Oral Ref Value	Worst-case Product Subcategory[2]	Inhalation Exposure Estimate (mg/kg/day)	Inhalation Exposure Estimate (mg/m³)	Inhalation Risk Characterisation Ratio: Inh Exposure / Inh Ref Value	Total Exposure[4] (mg/kg/day)	Risk Characterisation Ratio (Total Exposure / Worst-case Reference Value)
PC1:Adhesives, sealants	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	2,14E+01	2,1E+01				Glues DIY-use (carpet glue, tile glue, wood parquet glue)	3,08E+04	2,25E+05	1,1E+05	3,09E+04	6,2E+06
PC2_n: Adsorbents												
PC3:Air care products	Aircare, continuous action (solid & liquid)	1,19E-01	1,2E-01				Aircare, instant action (aerosol sprays)	5,71E+00	1,00E+03	5,0E+02	5,83E+00	1,2E+03

Input parameters used to estimate exposure and RCRs are hidden but can be viewed by selecting the corresponding buttons at the top of the page for a specific exposure pathway. If an exposure pathway is not relevant, no text appears in the 'worst-case product subcategory' column. Figure 5 above illustrates this for some of those Product Categories where oral exposures are not considered relevant. For inhalation exposures, the user must first enter a reference value in either mg/m³ or mg/kg/day in the User Input page before exposure values are calculated.

The third tab, 'Results by Prod Subcat', shows the results for product/article subcategories. Similar to sentinel products, inhalation exposures are included in the total exposure only if an inhalation reference value (in units of mg/kg/day) has been entered. However, unlike the 'Results by Sentinel Prod' worksheet, this sheet only summarises exposure estimates and RCRs. Input parameters and algorithms for estimating dermal, oral, and inhalation exposures are listed separately in tabs 4, 5, and 6, respectively.

The last two tabs (Defaults, Defaults2) list default parameters and assumptions used to estimate exposure. The Defaults sheet summarises pathway-specific parameters while Defaults2 summarises population-specific parameters. In the Defaults sheet, columns under the heading, 'Default Route of Relevance' show whether adult or child parameters are used for the route of relevance. For example, a 'y' under the adult column means 'yes' and exposure parameters are based on adult exposures. If an 'n' (no) appears under both the adult and child columns for the same exposure pathway, it means that pathway is not considered a significant pathway for that product/article subcategory.

3.4 Refinement of TRA consumer exposure estimates

As explained above, the new TRA is a tool for Tier 1 exposure assessment of chemicals used in consumer products and articles. It generates exaggerated exposure estimates that often largely exceed plausible levels. Simple reality checks can be applied to provide exposure estimations that are closer to plausible values. These could be considered as a form of some easy 'Tier 1.5' iteration of the exposure estimates made by the TRA tool. A number of such proposed refinements are discussed in Appendix F of this report. They mostly relate to possibilities for revising certain parameters if appropriate.

4. ENVIRONMENT

4.1 ECETOC TRA Tier 1 tool for REACH environmental exposure assessment

The environment module of the ECETOC (2004) web tool was conceived as a Tier 0 Screening Model for the environment. The discussions in the REACH Implementation Projects (RIPs) concluded that the Tier 0 Screening Model exposure assessments do not meet the requirements set out under REACH. In order to provide a toolbox meeting the REACH requirement for all exposure assessments (workers, consumers and environment), ECETOC decided to develop ECETOC TRA ENV as a new Tier 1 assessment tool which is aligned with the requirements for a REACH environmental exposure assessment.

4.2 REACH environmental exposure assessment

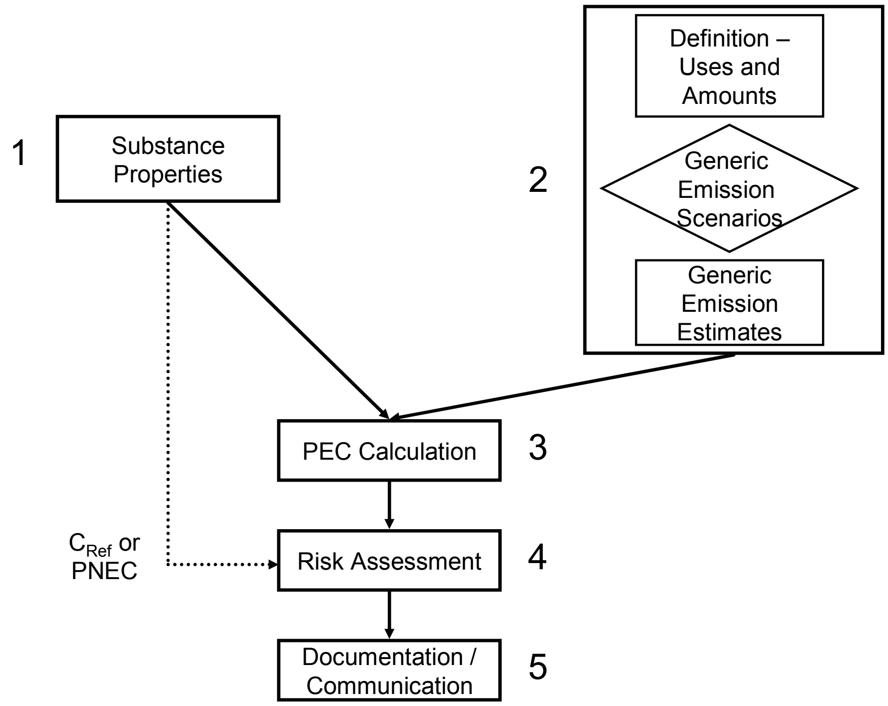
4.2.1 Background information

Chapter 16 of the IR&CSA TGD sets out the framework for environmental exposure assessment under REACH. This part of the guidance provides the algorithms used for calculating environmental concentrations once the emissions are known. It recommends the use of EUSES (European Union System for the Evaluation of Substances) version 2.1 (ECB, 2008a) as computer program. The EU TGD Excel Spreadsheet is mentioned as an alternative for computerised calculation of predicted environmental concentrations.

Chapter 16 of the IR&CSA TGD introduces the Environmental Release Classes (ERCs) as a novel approach to estimate emissions. The ERCs are limited in number and represent emission scenarios which are applicable to a wide variety of uses. As a result, the default emissions derived for these classes are conservative in nature and will frequently require review, and, where justifiable, refinement. Appendix G provides an overview of the ERCs.

Under REACH, exposure assessments are performed with the aim of specifying a set of conditions under which the risks of a substance are adequately controlled. This set of conditions is termed Exposure Scenario, reported in the Chemical Safety Report and communicated in the supply chain in the annex of the extended Safety Data Sheet (eSDS). In order to develop this set of conditions, predicted no effect concentrations (PNECs) are required. Under REACH PNECs are the products of the REACH hazard assessment. Adequate control of the environmental risk equates to PEC / PNEC ≤ 1, i.e. the predicted environmental concentration (PEC) will not exceed the concentration at which adverse effects are predicted (PNEC). The exposure assessment is an iterative process which allows for the refinement of the input data to define conditions under which PEC / PNEC ≤ 1. Scheme 1 outlines how the definition of substance properties and characteristics of the emission estimation deliver the input information required for exposure assessment (PEC calculation) which then feeds into the risk assessment.

Scheme 1: Generic environmental exposure assessment for calculation of PEC



4.2.2 Calculation of predicted environmental concentrations (PECs)

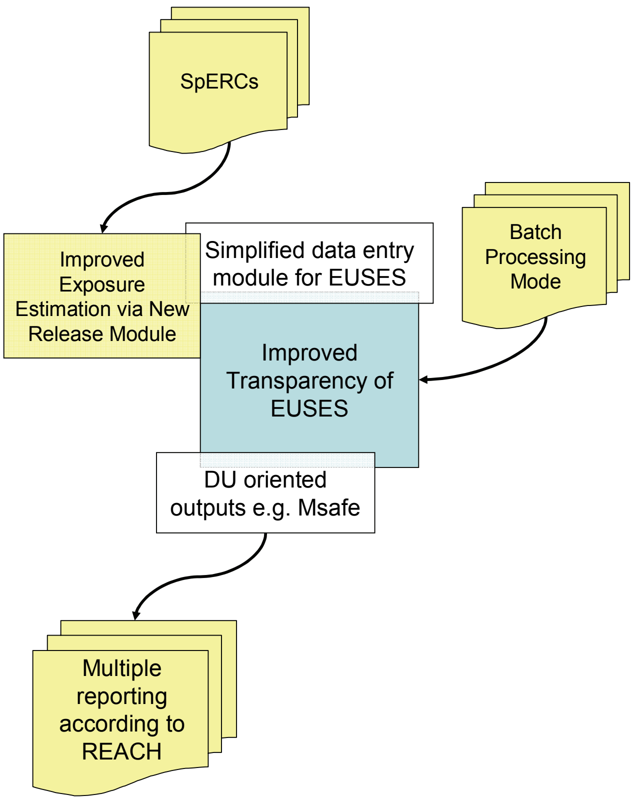
The IR&CSA TGD (Chapter 16) distinguishes three types of environmental concentrations. C_{Local} is the hypothetical concentration in the surroundings of an individual point source which results from the emissions of an individual point source. $PEC_{Regional}$ is the background concentration in the environment resulting from the cumulative emissions in a hypothetical region. PEC_{Local} represents the concentration downstream of a point source and is obtained as the sum of C_{Local} and $PEC_{Regional}$. The REACH Guidance on IR&CSA (Chapter 16) provides a set of algorithms and defaults for calculating the environmental concentrations C_{Local}, $PEC_{Regional}$, and PEC_{Local}. Note that C_{Local}, $PEC_{Regional}$, and PEC_{Local} are calculated for the different compartments (air, water, sediment, soil). The ECETOC TRA ENV also performs the calculations to assess the indirect exposure route of man via the environment.

4.3 Features of the ECETOC TRA ENV

4.3.1 ECETOC TRA ENV versus EUSES

The original version of the TRA (ECETOC, 2004) did not address the evaluation of environmental risks at beyond the Tier 0 level. Therefore, in order that the revised version of the TRA can be seen to reflect the expectations of the REACH TGD (Chapter R16), ECETOC has worked to both improve the user accessibility of the basic EUSES model, as well as enhance its general accuracy and relevance. Figure 6 illustrates the relationship between the core EUSES structure and those areas where ECETOC has been able to introduce improvements that help meet these objectives and which are further described in the following sections.

Figure 6: Illustration of what version 2 of the TRA has done to improve the basic EUSES model



Exposure modelling. The algorithms and defaults of the REACH Guidance on IR&CSA are implemented in the EU TGD spreadsheet and EUSES 2.1 (ECB, 2008a). According to a recent comparison the two approaches are equivalent (van de Meent, 2009). The ECETOC TRA ENV employs the EU TGD spreadsheet to calculate environmental exposure concentrations.

The algorithms used in the EU TGD spreadsheet (and thus the ECETOC TRA ENV) are written in Excel to maximise the transparency used in the calculations of Predicted Environmental Concentrations (PEC) and to give experienced users the option of obtaining detailed insight into the calculations.

Emission estimation. ECETOC TRA ENV differs from EUSES with regard to the emission estimation. The integrated Release Module of ECETOC TRA ENV is designed to establish a full overview of the emissions of a substance. At the Tier 1 level, ECETOC TRA ENV allows for emission assessments based on the Environmental Release Classes (ERC, as outlined in Chapter R16 of IR&CSA REACH Guidance). Appendix G gives an overview of the ERCs defined in Chapter R16 of the REACH Guidance on IR&CSA. In addition, the integrated release module supports the use of so-called specific Environmental Release Classes (SPERCs). Such SPERCs are currently under development. Appendix H provides guidance for developing and documenting SPERCs.

The TRA emission estimation defines the amount of a substance being emitted to air, water, sediment and soil. It differentiates between emissions to the regional and to a local environment. The results of the emission estimation are amounts emitted (in $kg \times d^{-1}$). These emitted quantities feed into the algorithms for obtaining PECs as laid down in the EU Technical Guidance Documents for the assessment of chemicals (EC, 2003).

The amount assigned to a given use (in $tons \times d^{-1}$) is the starting point of the emission estimation. The ERCs define sets of default values for the parameters used for emission estimation. These include the 'Fraction of tonnage to region' (i.e. the fraction of total amount being used at regional level) and the 'Fraction used by largest customer'. These fractions define the emissions to the regional and the local environment, respectively. Additional parameters are the fractions of the amount used which are released to air, water and soil, and the number of release days per year. Further characteristics of the emission situation detailed by the ERCs are the discharge rate to the receiving water and the treatment of wastewater in a municipal sewage treatment plant.

The emission assessment based on ERCs can be refined in the ECETOC TRA ENV Tier 1 using SPERCs. These refinements are described in Appendix I. SPERCs are currently developed as an element of Generic Exposure Scenarios. They will be implemented as they become available. Several draft SPERCs are currently included in the ECETOC TRA ENV. They illustrate how SPERCs specify ERC for uses in different sectors and provide standardised emission estimations on a sector level. The major differences between ERCs and SPERCs are that refined values of the release fractions are used and that the SPERCs account for typical risk management measures.

Three additional emission estimation approaches are described in more detail in Appendix I. Additionally, ECETOC TRA also facilitates emission assessment for individual, customised source of emissions based on measured data. In addition, the information from the A and B tables (EC, 2003) and from the OECD emission scenario documents can be used. These options require parameter values to be entered manually. The ECETOC TRA ENV differs from EUSES primarily by providing a transparent overview of the uses and corresponding emissions of a substances and by identifying the risk management measures.

4.3.2 ECETOC TRA ENV defaults and assumptions

General. As outlined above, the ECETOC TRA assessments are performed according to the REACH Guidance on IR&CSA. As a result, all environmental parameters relating to the size of the receiving regional and continental compartments are adopted in ECETOC TRA ENV and cannot be altered. The same is true for the transport parameters which determine the exchange between the local, regional and continental level. For local assessments, the default parameters outlined in the REACH Guidance on IR&CSA are employed. In case of specific assessments (see Appendix I), the parameter values can be adapted to the specific situation.

Point source versus wide dispersive uses. Industrial uses and wide dispersive uses are distinguished in Chapter R16 of the IR&CSA Guidance as ERCs 1 to 7 and ERCs 8 to 11, respectively (See Appendix I). Both types of uses are parameterised in the ECETOC TRA ENV in such a way to account for the underlying differences between the two types of release characteristics.

Wide dispersive uses are those by consumers and professionals, for whom the application of technical control of emissions is not possible. Wide dispersive uses result in emissions which are evenly distributed in the region and which are continuous over the whole year. As a result, the emissions from each wide dispersive use are concurrent in time and space with the emissions from the other wide dispersive uses. The ECETOC TRA ENV accounts for the contribution of all wide dispersive uses to a single $PEC_{Regional}$. Downstream communication can thus be confined to the statement that a dispersive use has been assessed to be safe, i.e. that the PEC_{Local} for a wide dispersive use does not exceed the PNEC.

Industrial uses occur in discrete locations and are associated with the use of specific amounts of material. The emissions from such sites are more readily controlled. Therefore these uses need to be assessed separately. The ECETOC TRA ENV uses the ERCs 1 to 7 and ERC 12 of the IR&CSA guidance and industry-developed SPERCs as standard sets of conditions for environmental assessments for defining conditions of safe use including the identification of appropriate control conditions for managing the environmental emissions from such sites. Downstream communication is therefore able to provide the required information about the emission estimation by delivering an indication of the parameters, including the amount used and the corresponding level of control, that constitute safe conditions of use.

Appendix I further discusses the considerations necessary for assigning values that describe the nature of emissions and any related control / reduction efficiencies. It also provides examples of such conditions as included in the SPERC emission estimations with a description of their underlying assumptions.

$PEC_{Regional}$. All emissions contribute to $PEC_{Regional}$. To derive $PEC_{Regional}$, each use is assigned a type of emission, an overall tonnage and its respective fraction being used in the region. For Tier 1 assessments, this fraction may assume a value of 0.1 or 1, for types of emissions which are dispersely distributed across Europe or for emissions which are highly concentrated, respectively. Additional guidance on the choice of this value can be found in Chapter R16 of the REACH Guidance on IR&CSA. The actual extent of the emissions is defined by the defaults underlying the 'ERCs', the 'SPERCs' or more detailed emission scenarios. The resulting regional emissions are obtained for each type of emission (ERC, SPERC or other) and their sum is calculated. The sum is used as input for the $PEC_{Regional}$ calculation. The $PEC_{Regional}$ calculation of the TRA adopts the EUSES assumption that 80% of the regional emissions to the water are subject to municipal wastewater treatment.

C_{Local}. Values of C_{Local} are calculated for each emission type (ERC, SPERC or other). Point source emissions are characterised by ERCs 1 to 7 and ERC 12 and their corresponding SPERCs. By default, they are assigned a value of 1 for the fraction of main local source. Wide dispersive emissions are characterised by ERCs 8 to 11 and their corresponding SPERCs. The fraction of main local source ($F_{mainsource}$) is 0.002 in alignment with EUSES default value (ECB, 2008a). It represents the fraction of the substance available to be released and accounts for spatial and temporal variability in use patterns across Europe. For detergent uses, EUSES considers the distribution homogeneous throughout Europe. In that case, $F_{mainsource}$ is the set value to 0.0005 (ECB, 2008a). This can be seen as a precedent for further homogeneously distributed uses to motivate the choice of the value of 0.0005 $F_{mainsource}$ rather than 0.002. For ERCs 1 to 12 and their corresponding SPERCs, the presence of the wastewater treatment is specified in a yes/no decision in the release module. According to EU legislation (EC, 2000), sewage has to undergo treatment prior to discharge, the presence of a sewage treatment plant is assumed to be the default situation. Hence, the preset default entry is yes.

PEC_{Local}. The values of PEC_{Local} are obtained for each emission type (ERC, SPERC or other) and each compartment by adding the respective values of C_{Local} to the $PEC_{Regional}$. They represent the exposure concentration relevant for the risk assessment, i.e. the comparison between PEC_{Local} and PNEC.

4.3.3 Simple and advanced assessments

Limited information on a substance is required to run the REACH environmental assessments and to generate PECs using ECETOC TRA ENV. The mandatory information on substance properties for Tier 1 assessment is specified in Table 5. In addition to specifying this information, the relevant environmental release classes have to be selected in order to define the emissions to the environment. With that done, the information required for Tier 1 environmental assessments is specified and the assessment can be performed.

Table 5: Mandatory substance property input data for ECETOC TRA ENV exposure calculations

Molecular weight	**100**	$g.mol^{-1}$	
Vapour pressure (temperature range 15-25°C)	**1000**	Pa	
Water solubility (temperature range 15-25°C)	**1000**	$mg.L^{-1}$	
Partition coefficient octanol-water	**0.10**	**K_{ow}**	
Biodegradability test result	**Readily biodegradable**		
Chemical class for K_{OC}-QSAR	**Alcohols**		Mandatory if QSAR estimation of $k_{soil}/_{water}$ and $k_{sediment}/_{water}$
K_{OC}			Optional - can be estimated by QSAR

Depending on the available information, the assessment may be refined by using more realistic estimates of emission rates (e.g. SPERCs, OECD-ESDs or measured data). Alternatively, the substance information can be refined by using measured data rather than predicted values for the following endpoints: sediment and soil partition coefficients, or environmental degradation rates. Additional information on refining the Tier 1 environmental assessments is given in Appendix I.

4.3.4 Input to the CSR

The substance specific input information required to calculate PECs are given in Tables 5 and 8 of the CSR-Template. The PNECs for different environmental compartments (if available) are documented in CSR-Template Tables 16-20. The output produced by the ECETOC TRA ENV is captured in three sections within the CSR-Template:

1. Environmental release estimates are shown in Tables 32 and 33.
2. PECs for the different compartments are shown in Tables 34 to 47.
3. Risk Characterisation Ratios (RCRs) for different environmental compartments are shown in Tables 54 and 55.

4.3.5 Risk characterisation and safety assessment

For each emission type (ERC, SPERC or other) and each compartment, PEC_{Local} is compared to the relevant PNEC. For screening assessments performed in GES[3]-development for instance, PNECs surrogates can be used. They can be obtained from various sources, such as Classification and Labelling. For each relevant emission type, ERC, SPERC or other, PECs are derived for each compartment and the corresponding PEC_{Local}/PNEC values calculated and termed risk characterisation ratio (RCR). If the RCR-value is smaller or equal to one, the PEC does not exceed the predicted no effect concentration and the environmental risks are deemed to be adequately controlled.

4.3.6 M_{Safe} and simplified supply chain communication

The substance use rate corresponding to RCR equalling 1 is termed M_{Safe}. M_{Safe} expresses the maximum amount of a substance which can be safely used under a defined set of conditions. Values of M_{Safe} are derived for each emission type (ERC, SPERC or other) according to

$$M_{Safe} = M_{Used} \times \frac{PNEC}{PEC_{Local}}.$$

As a result of the overall process, the environmental part of a REACH exposure assessment is obtained as a set of conditions which describe adequate control of the environmental risk of a substance. This set of conditions comprises the assumptions on emissions as defined in the emission scenario (including operational conditions, i.e. emission fractions and risk management measures) and M_{Safe}.

Supply chain communication of the conditions of safe use for the environment can be simplified by communicating M_{Safe} in combination with the emission scenario (i.e. ERC, SPERC). ERCs and SPERCs are codes for fixed sets of operational conditions. Hence, the communication of ERC- and SPERC-based assessments parameters can be reduced to specifying the ERC (or SPERC) and the corresponding value of M_{Safe}.

[3] Generic Exposure Scenario

4.3.7 Exposure scenario workflow

In the following section the workflow for establishing the environmental part of an exposure scenario is subdivided into eight steps, each being represented in the schemes given on the following pages. These schemes provide information on the input and output of each step and what activity is required by the assessor.

Step 1: Substance properties

The environmental exposure assessment starts with collecting and entering the substance data into the 'flat database' (Step 1). The minimum dataset required to conduct an environmental exposure assessment comprises four parameters and has been outlined in Table 5. None of the values need to be determined experimentally. Vapour pressure, water solubility and octanol-water partition coefficient can be estimated using quantitative structure activity relationships (QSAR). EPI Suite (US EPA, 2009)[4] is one example of a software package for obtaining such estimates. By specifying the parameter 'Chemical class for K_{OC}-QSAR' the appropriate EUSES algorithm for the K_{OC} estimation based on the octanol-water partition coefficient is selected. Providing additional substance input information such as sediment and soil partition coefficients, or dissipation rates is an option for refining the assessment (See Appendix I).

Process Step	**Output**	
1. Define Substance Properties	***Substance Data Collection***	
Specify substance properties – The minimum requirements are log K_{OW}, solubility in water, vapour pressure, and (bio)degradability. If experimental data are not available, the physico-chemical property data can be estimated by QSAR with sufficient degree of accuracy.	*Parameter*	*Value*
	Log K_{OW}	3
	Solubility in water	100 mg/L
	Vapour pressure	0.1 Pa
	Ready biodegradability	No
	Chemical class for K_{oc}-QSAR	Predominantly hydrophobic
	K_{oc}	-

Step 2: Emission estimation

At the same time as the substance property information is compiled, relevant emission information must also be entered into the Release Module. In order to execute this, firstly (Step 2a) the relevant uses are defined by mapping the uses to the assessment codes which refer to emission scenarios (such as ERCs, and SPERCs). In Step 2b, each use (via its assessment

[4] http://www.epa.gov/oppt/exposure/pubs/episuitedl.htm

code) is assigned the manufacturers/importers tonnage and the respective fraction being used in the region. In addition, it is specified whether the wastewater is subject to sewage treatment (indirect discharge) or not (direct discharge).

Process Step	Output
2a. Define Uses	***Filled-in TRA Release Module (1)***
In TRA 'Release Module': Map uses to assessment codes such as ERC, SPERC, etc.	***Example***

Use	*Assessment Code*
Formulation	ERC2
Industrial adhesive	ERC4
Metal cleaning	SPERC 5.X.1
Wide dispersive use	ERC8a, 8c, 9b

Process Step	Output
2b. Define Uses	***Filled-in TRA Release Module (2)***
In TRA 'Release Module': Assign tonnages to uses (M_{Assess}), assign fraction of M/I tonnage to the region (F_{Reg}), specify whether wastewater is treated in sewage treatment plant prior to discharge into a river (STP: Y or N).	***Example***

Assessment Code	*Tonnage (t/y)*	*Fraction of M/I tonnage to region*	*STP*
ERC2	5000	0.1	Y
ERC4	1500	0.1	Y
SPERC 5.X.1	1200	0.1	Y
ERC8a	2500	0.1	Y
ERC8c	100	0.1	Y
ERC9b	100	0.1	Y

The regional emission estimate is obtained as the sum of the contributions of the individual uses to the overall regional emission (Step 2c).

Process Step	Output
2c. Define Emissions to Region	***Regional emissions per use***
This step occurs in the background and does not require user input. The emission fractions pertinent for the uses are used to estimate the emission to the region. The sum of all emissions serves as input for the $PEC_{Regional}$ calculation.	

Assessment Code	*Regional Emission (t/y)*		
	Air	*Water*	*Soil*
ERC2	0.5	5	0
ERC4	0	15	0
SPERC 5.X.1	0	120	0
ERC8a	50	450	0
ERC8c	0.1	0.5	0
ERC9b	0	0.1	0
Sum	*50.6*	*590.6*	*0*

Step 3: PEC calculation

In Step 3a, the regional emissions are used to derive the $PEC_{Regional}$. The TRA generates PEC values for air, soil, freshwater, freshwater sediment, marine water, marine sediment and for the sewage treatment plant. Based on the assumptions underlying the emission scenarios, values of C_{Local} are calculated and values for PEC_{Local} are obtained (Step 3b).

Process Step	Output		
3a. Calculation of $PEC_{Regional}$	***$PEC_{Regional}$***		
This step occurs in the background without user input. The values of $PEC_{Regional}$ are provided as output.	*Air (ng/m³)*	*Water (mg/L)*	*Soil (mg/kg)*
	0.5	0.0006	0.05
3b. Industrial Uses: Calculation of C_{Local} and PEC_{Local}	***$PEC_{Local,i} = PEC_{Regional} + C_{Local}$***		
This step occurs in the background without user input. $PEC_{Local,i}$ is estimated as $C_{Local,i}$ + $PEC_{Regional}$ for each use and compartment* and provided as output.	*Use*	*PEC_{Local}* ***(mg/L)****	
	ERC2	0.002	
	ERC4	0.002	
	SPERC 5.X.1	0.006	
3c. Wide Dispersive Use: Calculation of C_{Local} and PEC_{Local}	***$PEC_{Local,wide\ dispersive} = PEC_{Regional} + C_{Local}$***		
This step occurs in the background without user input. $PEC_{Local,\ wide\ dispersive}$ is derived as $PEC_{Regional}$ + $C_{Local,\ wide\ dispersive}$ for each compartment* and provided as output.	*Use*	*C_{Local}* ***(mg/L)****	*$PEC_{Local,wide\ dispersive}$**
	ERC8a	0.00008	0.0006 mg/L
	ERC8c	0.000001	
	ERC9b	0.0000001	

* Display limited to water compartment output due to limited space.

Step 4: Risk Assessment

In Step 4, the PEC values are compared to the PNEC values. In the case of uses relating to point sources (ERC 1-7) this yields values of M_{Safe} according to the algorithm outlined in the box below. M_{Safe} specifies the quantities which correspond to adequate control of risk for a set of operational conditions, an emission assessment and a set of substance properties. If actual quantities used exceed the values of M_{Safe}, the exposure assessment needs to be refined. This can be achieved by introducing advanced information on operational conditions, emission assessment and the substance properties.

Wide dispersive uses are considered safe if the PEC is less than the PNEC, i.e. RCR <1. The individual user is provided with instructions for use. Beyond that, actual risk management measures cannot be implemented. For that reason, it is sufficient to communicate that RCR <1 for a wide dispersive use or to communicate that the risk from a wide dispersive use is adequately controlled. If M_{Use} exceeds M_{Safe}, the assessment may be refined by using refined emission estimation or substance properties.

Process Step	Output
4a. Risk Assessment	***RCR and M_{Safe}***

A: Obtain PNEC* as exposure level at which no significant effect is expected – Enter into program.

B: Calculate RCR as

$$RCR = \frac{C_{Ref}}{PEC_{Local}}$$

C: Obtain as additional output M_{Safe} for the regions as the amount used corresponding to $PEC_{Local} = C_{Ref}$

$$M_{Safe} = \frac{M_{Assess} \times F_{Reg}}{RCR \times d_{Emiss}}$$

Use	*M_{Assess} (t/y)*	*RCR*	*d_{Emiss} (d/y)***	*M_{safe}*
ERC2	5000 t/y	1.6	100	3.1 t/d
ERC4	1200 t/y	1.6	300	250 kg/d
SPERC 5.X.1	1500 t/y	5.6	300	90 kg/d
ERC8a	2500 t/y	0.7	365	370 t/y
ERC8c	100 t/y	0.6	365	17 t/y
ERC9b	100 t/y	0.6	365	17 t/y

* If PNEC is not available then a surrogate can be derived, based on C&L information for instance. For this illustration it is 0.001 mg/L.

** d_{Emiss} stands for the number of emission days per year.

Documentation in REACH exposure scenarios

The values of M_{Safe} are reported in the Exposure Scenario Format of the Chemical Safety Report in Section 4.3. They correspond to a certain level of emission control or risk management. As such they can be communicated in the supply chain and inform downstream users about the four parameters relevant for environmentally safe use of substances, i.e. the amount used, the discharge rate to the receiving water and the dilution rate, the relevant risk management measure and its efficiency (See example ERC 2). For wide dispersive uses, individual downstream users have no control on the emissions resulting from such use. For that reason, it is sufficient to state that a particular use is safe, i.e. PEC < PNEC (see Example ERC 8a).

Process Step

Documentation in REACH ES Format – Industrial Use

Output

Example- ERC 2

		Type of Information	**Content**
Annex Chapter	1	ERC2	SPERC2.1 – Formulation: water based products
	2/3	Duration / Frequency	100d/y
	4.3	Amount used	M_{Safe} = 4.8 t/d
	5	Operational conditions	100% to wastewater
	6	RMM	None - environment
	7	Waste related measures	Dispose of spillages and used containers according to local regulations.
	8	Exposure prediction	PEC = 0,001 mg/L = PNEC
	9	Methods to check compliance	ECETOC TRA

Process Step

Documentation in REACH ES Format – Wide dispersive use, an option*

Output

Example- ERC 8a

		Type of Information	**Content**
Annex Chapter	1	ERC8a	Processing aid – indoor use
	2/3	Duration / Frequency	365d/y
	4.3	Amount used	
	5	Operational conditions	100% to wastewater
	6	RMM	None - environment
	7	Waste related measures	Dispose of spillages and used containers according to local regulations.
	8	Exposure prediction	PEC = 0,0006 mg/L < PNEC
	9	Methods to check compliance	ECETOC TRA

Relevant for downstream communication: No risk

*Currently different options are under discussion for communicating the results of the assessments of wide dispersive uses.

5. OTHER CONSIDERATIONS

5.1 Simple user guides for the TRA

Experience with version 1 of the TRA indicated that although it is possible to develop a simple risk-based screening tool, it is also necessary to make available suitable supporting documentation that users can refer to at times of uncertainty. Although TR 93 (ECETOC, 2004) partly served such a purpose, it was too technically complex to be routinely accessed by non-expert users. Indeed, some non-experts found TR 93 to be technically intimidating and had to rely on their intuition and the 'usability' of the TRA web tool (and especially the help pop-ups) to guide them through the risk assessment process. For these reasons, version 2 of the TRA is supported both by a comprehensive technical report and simple user guides. These are available for free download at the TRA website (https://www.ecetoc-tra.org) with the intention that they will be updated as and when either the TRA is updated or substantive experience within the TRA user community suggests revisions to the guides are appropriate.

5.2 Maintaining the revised TRA

Version 2 of the TRA significantly differs from version 1 in three key respects: (a) the sensitivity and specificity of the exposure predictions has been improved; (b) the ability to routinely undertake and document risk assessments has essentially been removed (as this is now the intention of the ECHA CSA/CSR Tool), although the individual tools still provide the ability to evaluate the introduction of reference values (which can, for example, be either DNELs, PNECs, OELs or other suitable reference points dependent on the nature of the population being assessed); and (c) as the revised versions of the tool are PC-based, then the web-based version of the tool will no longer be supported. However, despite the ending of the web-based version of the tool, ECETOC will continue to support the TRA website, in order to maintain a portal for sharing and discussing experiences of the TRA. The website will be the hub through which users, subject to minimal registration requirements, will be able to download the tools and their supporting documentation, as well as receiving news of related developments.

5.3 Conclusions

The ECETOC targeted risk assessment (TRA) Task Force reported in 2004 and launched the supporting web-based TRA tool shortly after. Subsequently, the REACH Technical Guidance has recognised the TRA as offering a suitable approach for evaluating worker and consumer health risks (at the Tier 1 level).

The revised TRA accounts for both the comments made about the TRA during the REACH Implementation Processes (RIP) and received by ECETOC during various scientific and stakeholder discussions that it has engaged in since 2004. The sensitivity and specificity of both the worker and consumer exposure models has been significantly improved and their structure now aligns with that of the preferred process for risk assessment under REACH. At the same time, the Task Force has developed a more accessible and pragmatic approach to environmental risk assessment by using the principles laid down within the EUSES model. These developments are available both as separate models and as an integrated tool (enabling users to benefit from a common data entry module).

ABBREVIATIONS

AC	Article category
ACH	Air changes per hour
AISE	International Association for Soaps, Detergents and Maintenance Products
APF	Actual protection factor
ATO	Antinomy trioxide
BAuA	German Federal Institute for Occupational Safety and Health
BfR	German Federal Institute for Risk Assessment
BREF	Best available technique reference document
bw	Body weight
C&L	Classification & Labelling
CAS	Chemical Abstracts Service
COSHH	UK Control of Substances Hazardous to Health
CSA	Chemical safety assessment
CSAT	CSA/CSR tool
CSR	Chemical safety report
DIY	Do-it-yourself
DNEL	Derived no-effect level
EASE	Estimation and assessment of substance exposure
EC	European Commission
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EEC	European Economic Community
EMKG	Einfaches Maßnahmenkonzept Gefahrstoffe
EPA	Environmental Protection Agency
ERC	Environmental release classes
eSDS	Extended safety data sheet
EU	European Union
EUSES	European Union system for the evaluation of substances
GES	Generic Exposure Scenario
HERAG	Health Risk Assessment Guidance
HSE	Health and Safety Executive
INERIS	Institut National de l'environnement industriel et des risques
IR	Information requirements
IR&CSA	Information requirements and chemical safety assessment
IRV	Inhalation reference value

LEV	Local extract ventilation
mp	Melting point
MW	Mole weight
NPF	Nominal protection factor
OCs	Operational conditions
OECD	Organisation for Economic Co-operation and Development
OECD-ESD	OECD emission scenario document
OEL	Occupational exposure limit
PC	Product category
PCs	Product use categories
PEC	Predicted environmental concentration
PI	Product ingredient
PNEC	Predicted no effect concentration
PPE	Personal protective equipment
PROC	Process category
QSAR	Quantitative structure activity relationship
RAR	Risk assessment report
RCR	Risk characterisation ratio
REACH	Registration, evaluation, authorisation and restriction of chemicals
RIP	REACH implementation project
RIVM	The Netherlands National Institute for Public Health and the Environment
RMM	Risk management measure
RPE	Respiratory protective equipment
RWC	Reasonable/Realistic worst case exposure value (usually the 90^{th} or 95^{th} percentile of a data set of measured values)
SDA	Soap and Detergent Association
SPERCs	Specific environmental release classes
STP	Sewage treatment plant
SU	Sector of use
SVC	Saturated vapour concentration
TGD	Technical guidance document
TRA	Targeted risk assessment
VLE	Vapour-liquid equilibrium
VP	Vapour pressure

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APPENDIX A: RATIONALE BEHIND TRA WORKER v2 EXPOSURE PREDICTIONS

PROC	Exposure scenario	LEV	Fugacity	Predicted EASE Exposure (95th%)	TR93 exposure prediction	Industrial exposure prediction (1)	Professional exposure prediction (1)	EASE LEV Effectiveness Industrial (%) (2)	EASE LEV Effectiveness Professional (%) (2)	Comments on Choice of LEV %
1	**Use in closed process, no likelihood of exposure**	yes	High	1	0,01			N/a	N/a	
	(solids)	no		1	0,01	0,01	**0,1**			
	mg/m3	yes	Moderate	1	0,01			N/a	N/a	
		no		1	0,01	0,01	0,01			
		yes	Low	0,1	0,01			N/a	N/a	
		no		0,1	0,01	0,01	0,01			
	(volatiles)	yes	High	0,1	0,01			N/a	N/a	
	ppm	no		0,1	0,01	0,01	**0,1**			
		yes	Moderate	0,1	0,01			N/a	N/a	
		no		0,1	0,01	0,01	0,01			
		yes	Low	0,1	0,01			N/a	N/a	
		no		0,1	0,01	0,01	0,01			
2	**Use in closed, continuous process with occasional controlled exposure**	yes	High	1	1			**90**	80	EASE offers 80%
	(solids)	no		5	5	**1**	5			
	mg/m3	yes	Moderate	1	0,1			**90**	80	EASE offers 80%
		no		5	0,5	0,5	1			
		yes	Low	0,01	0,01			**90**	**80**	EASE offers 1%
		no		0,01	0,01	0,01	0,01			
	(volatiles)	yes	High	200	20			**90**	**80**	EASE offers 60%
	ppm	no		500	50	50	50			
		yes	Moderate	50	5			**90**	**80**	EASE offers 50%
		no		100	10	10	**20**			
		yes	Low	3	0,5			**90**	**80**	EASE offers 33%
		no		10	1	1	5			
3	**Use in closed batch process (synthesis or formulation)**	yes	High	1	0,1			**90**	80	EASE offers 80%
	(solids)	no		5	1	1	**5**			
	mg/m3	yes	Moderate	1	0,1			**90**	80	EASE offers 80%
		no		5	1	1	1			
		yes	Low	0,1	0,01			**90**	**80**	EASE offers 1%
		no		0,1	0,1	0,1	0,1			
	(volatiles)	yes	High	0,1	20			**90**	**80**	EASE offers 99.9%
	ppm	no		200	100	100	100			
		yes	Moderate	0,1	5			**90**	**80**	EASE offers 99.8%
		no		50	25	25	25			
		yes	Low	0,1	0,1			**90**	**80**	EASE offers 97%
		no		3	3	3	3			
4	**Use in batch and other process (synthesis) where opportunity for exposure arises (3)**	yes	High	5	5			**90**	**80**	EASE offers 60%
	(solids)	no		50	25	25	**50**			
	mg/m3	yes	Moderate	0,5	0,5			80	80	
		no		5	5	5	5			
		yes	Low	0,1	0,1			**90**	**80**	EASE offers 1%
		no		0,1	0,5	0,5	1			
	(volatiles)	yes	High	200	100			**90**	**80**	EASE offers 60%
	ppm	no		500	250	100	250			
		yes	Moderate	50	25			**90**	**80**	EASE offers 60%
		no		100	**100**	**20**	**50**			
		yes	Low	3	1			**90**	**80**	EASE offers 33%
		no		10	**10**	**5**	10			
5	**Mixing or blending in batch processes (multistage and/or significant contact) (4)**	yes	High	5	5			**90**	80	EASE offers 80%
	(solids)	no		50	50	**25**	50			
	mg/m3	yes	Moderate	0,5	0,5			**90**	80	EASE offers 80%
		no		5	5	5	5			
		yes	Low	0,1	0,1			**90**	**80**	EASE offers 1%
		no		0,1	1	0,5	1			
	(volatiles)	yes	High	200	100			**90**	**80**	EASE offers 60%
	ppm	no		500	500	**250**	500			
		yes	Moderate	50	20			**90**	**80**	EASE offers 50%
		no		100	100	**50**	100			
		yes	Low	3	3			**90**	**80**	EASE offers 33%
		no		10	10	**5**	10			

PROC	Exposure scenario	LEV	Fugacity	Predicted EASE Exposure (95th%)	TR93 exposure prediction	Industrial exposure prediction (1)	Professional exposure prediction (1)	EASE LEV Effectiveness Industrial (%) (2)	EASE LEV Effectiveness Professional (%) (2)	Comments on Choice of LEV %
6	**Calendering operations**	yes	High	5	**(5)**			**90**	80	EASE offers 80%
	(solids)	no		50		**25**	50			
	mg/m3	yes	Moderate	0,5				**90**	80	EASE offers 80%
		no		5		5	5			
		yes	Low	0,1				**90**	**80**	EASE offers 1%
		no		0,1		0,1	**1**			
	(volatiles)	yes	High	200				**90**	80	EASE offers 80%
	ppm	no		500		**250**	500			
		yes	Moderate	50				**90**	80	EASE offers 80%
		no		100		**50**	100			
		yes	Low	3				**90**	**80**	EASE offers 33%
		no		10		**5**	10			
7	**Industrial spraying**	yes	High	10	10			95	n/a	EASE offers 95%
	(solids)	no		200	200	**100**	n/a			
	mg/m3	yes	Moderate	1	1			95	n/a	EASE offers 95%
		no		20	20	20	n/a			
		yes	Low	0,1	0,1			**95**	n/a	EASE offers 90%
		no		1	1	1	n/a			
	(volatiles)	yes	High	500	100			**95**	n/a	EASE offers 50%
	ppm	no		1000	1000	**500**	n/a			
		yes	Moderate	200	50			**95**	n/a	EASE offers 60%
		no		500	500	**250**	n/a			
		yes	Low	200	20			**95**	n/a	EASE offers 60%
		no		500	100	100	n/a			
8a	**Transfer of chemicals from/to vessels/large containers at non dedicated facilities**	yes	High	5	5			**90**	80	EASE offers 80%
	(solids)	no		50	50	50	50			
	mg/m3	yes	Moderate	0,5	0,5			**90**	80	EASE offers 80%
		no		5	5	5	5			
		yes	Low	0,1	0,1			**90**	**80**	EASE offers 1%
		no		0,1	0,5	0,5	0,5			
	(volatiles)	yes	High	200	100			**90**	**80**	EASE offers 60%
	ppm	no		500	250	250	500			
		yes	Moderate	50	25			**90**	**80**	EASE offers 50%
		no		100	50	50	100			
		yes	Low	3	3			**90**	**80**	EASE offers 33%
		no		10	10	10	**25**			
8b	**Transfer of chemicals from/to vessels/large containers at dedicated facilities (6)**	yes	High	5	5			**95 (7)**	80 **(7)**	EASE offers 80%
	(solids)	no		50	50	**25**	50			
	mg/m3	yes	Moderate	0,5	0,5			**95**	80	EASE offers 80%
		no		5	5	5	5			
		yes	Low	0,1	0,1			**95**	**80**	EASE offers 1%
		no		0,1	0,5	**0,1**	0,5			
	(volatiles)	yes	High	200	100			**97 (8)**	**90 (8)**	EASE offers 60%
	ppm	no		500	250	**150**	250			
		yes	Moderate	50	25			**97**	**90**	EASE offers 50%
		no		100	50	50	50			
		yes	Low	3	3			**97**	**90**	EASE offers 33%
		no		10	10	**5**	10			
9	**Transfer of chemicals into small containers (dedicated filling line)**	yes	High	5	1			**90**	80	EASE offers 80%
	(solids)	no		50	20	20	20			
	mg/m3	yes	Moderate	0,5	0,5			**90**	80	EASE offers 80%
		no		5	5	5	5			
		yes	Low	0,1	0,1			**90**	**80**	EASE offers 1%
		no		0,1	0,5	**0,1**	0,5			
	(volatiles)	yes	High	200	50			**90**	**80**	EASE offers 60%
	ppm	no		500	250	**200**	250			
		yes	Moderate	50	13			**90**	**80**	EASE offers 50%
		no		100	100	**50**	100			
		yes	Low	3	1			**90**	**80**	EASE offers 33%
		no		10	10	**5**	10			

PROC	Exposure scenario	LEV	Fugacity	Predicted EASE Exposure (95th%)	TR93 exposure prediction	Industrial exposure prediction (1)	Professional exposure prediction (1)	EASE LEV Effectiveness Industrial (%) (2)	EASE LEV Effectiveness Professional (%) (2)	Comments on Choice of LEV %
10	**Roller application or brushing**	yes	High	5	1			90	80 (9)	EASE offers 90%
	(solids)	no		50	10	10	10			
	mg/m3	yes	Moderate	0,5	0,5			90	80 (9)	EASE offers 90%
		no		5	5	5	5			
		yes	Low	0,1	0,1			90	80	EASE offers 1%
		no		0,1	0,5	0,5	0,5			
	(volatiles)	yes	High	500	100			90	80	EASE offers 1%
	ppm	no		500	500	250	500			
		yes	Moderate	100	20			90	80	EASE offers 80%
		no		500	100	50	100			
		yes	Low	50	10			90	80	EASE offers 80%
		no		500	100	10	25			
11	**Non-industrial spraying**	yes	High	10	10			n/a	80 (9)	EASE offers 95%
	(solids)	no		200	200	n/a	200			
	mg/m3	yes	Moderate	1	1			n/a	80	EASE offers 95%
		no		20	20	n/a	20			
		yes	Low	0,1	0,1			n/a	80	EASE offers 90%
		no		1	1	n/a	1			
	(volatiles)	yes	High	500	100			n/a	80	EASE offers 50%
	ppm	no		1000	1000	n/a	1000			
		yes	Moderate	200	50			n/a	80	EASE offers 60%
		no		500	500	n/a	500			
		yes	Low	200	20			n/a	80	EASE offers 60%
		no		500	100	n/a	100			
12	**Use as a blowing agent**	yes	High	N/a	N/a			N/a	N/a	Solids will never be used as blowing agent. Incidental exposures to aereosoal as a consequence of blowing should be assessed under PROC13
	(solids)	no		N/a	N/a	N/a	N/a			
	mg/m3	yes	Moderate	N/a	N/a			N/a	N/a	
		no		N/a	N/a	N/a	N/a			
		yes	Low	N/a	N/a			N/a	N/a	
		no		N/a	N/a	N/a	N/a			
	(volatiles)	yes	High	200	40			80 (10)	80 (10)	EASE offers 60%
	ppm	no		500	100	100	500			
		yes	Moderate	50	10			80	80	EASE offers 50%
		no		100	20	20	100			
		yes	Low	3	0,5			80	80	EASE offers 33%
		no		10	2	2	10			
13	**Treatment of articles by dipping and pouring**	yes	High	1	1			90	80	EASE offers 80%
	(solids)	no		5	5	5	5			
	mg/m3	yes	Moderate	1	1			90	80	EASE offers 80%
		no		5	5	1	5			
		yes	Low	0,1	0,1			90	80	EASE offers 1%
		no		0,1	0,5	0,1	0,5			
	(volatiles)	yes	High	200	200			90	80	EASE offers 80%
	ppm	no		500	500	250	250			
		yes	Moderate	50	50			90	80	EASE offers 80%
		no		100	100	50	100			
		yes	Low	3	3			90	80	EASE offers 33%
		no		10	10	10	10			
14	**Production of preparations or articles by tabletting, compression, extrusion, pelletisation**	yes	High	5	5			90	80	EASE offers 90%
	(solids)	no		50	50	10	50			
	mg/m3	yes	Moderate	0,5	0,5			90	80	EASE offers 90%
		no		5	5	1	5			
		yes	Low	0,1	0,1			90	80	EASE offers 1%
		no		0,1	1	0,1	1			
	(volatiles)	yes	High	200	100			90	80	EASE offers 60%
	ppm	no		500	500	250	500			
		yes	Moderate	50	25			90	80	EASE offers 50%
		no		100	100	50	100			
		yes	Low	3	3			90	80	EASE offers 33%
		no		10	10	5	10			

PROC	Exposure scenario	LEV	Fugacity	Predicted EASE Exposure (95th%)	TR93 exposure prediction	Industrial exposure prediction (1)	Professional exposure prediction (1)	EASE LEV Effectiveness Industrial (%) (2)	EASE LEV Effectiveness Professional (%) (2)	Comments on Choice of LEV %
15	**Use of laboratory reagents in small scale laboratories**	yes	High	1	0,5			90	80	EASE offers 80%
	(solids)	no		5	5	5	5			
	mg/m3	yes	Moderate	1	0,1			90	80	EASE offers 80%
		no		5	0,5	0,5	0,5			
		yes	Low	0,1	0,01			90	80	EASE offers 1%
		no		0,1	0,1	0,1	0,1			
	(volatiles)	yes	High	200	10			90	80	EASE offers 60%
	ppm	no		500	50	50	50			
		yes	Moderate	50	1			90	80	EASE offers 50%
		no		100	10	10	10			
		yes	Low	3	0,1			90	80	EASE offers 33%
		no		10	5	5	5			
16	**Using material as fuel sources (limited exposure to unburned product to be expected)**	yes	High	5	5			90	80	EASE offers 90%
	(solids)	no		50	50	10	50			
	mg/m3	yes	Moderate	5	5			90	80	EASE offers 90%
		no		50	50	5	20			
		yes	Low	0,1	1			90	80	EASE offers 1%
		no		0,1	5	0,1	5			
	(volatiles)	yes	High	200	20			90	80	EASE offers 60%
	ppm	no		500	50	25	50			
		yes	Moderate	50	5			90	80	EASE offers 50%
		no		100	10	5	10			
		yes	Low	3	0,1			90	80	EASE offers 33%
		no		10	1	1	1			
17	**Lubrication at high energy conditions and in partly open process**	yes	High	10	10			95	90	EASE offers 95%
	(solids)	no		200	200	50	200			
	mg/m3	yes	Moderate	10	5			95	90	EASE offers 95%
		no		200	50	20	50			
		yes	Low	0,1	1			95	90	EASE offers 1%
		no		0,1	10	1	10			
	(volatiles) **(11)**	yes	High	200	200			95	90	EASE offers 60%
	ppm	no		500	500	100	500			
		yes	Moderate	200	100			95	90	EASE offers 60%
		no		500	500	50	200			
		yes	Low	200	50			95	90	EASE offers 60%
		no		500	100	20	50			
18	**Greasing at high energy conditions (12)**	yes	High	10	**(13)**			95	90	EASE offers 95%
	(solids)	no		200		50	200			
	mg/m3	yes	Moderate	10				95	90	EASE offers 95%
		no		200		20	50			
		yes	Low	0,1				95	90	EASE offers 1%
		no		0,1		1	5			
	(volatiles)	yes	High	200				95	90	EASE offers 60%
	ppm	no		500		100	500			
		yes	Moderate	200				95	90	EASE offers 60%
		no		500		50	200			
		yes	Low	200				95	90	EASE offers 60%
		no		500		20	50			
19	**Hand-mixing with intimate contact (only PPE available) (14)**	yes	High	5	**(13)**			90	80	EASE offers 90%
	(solids)	no		50		25	50			
	mg/m3	yes	Moderate	0,5				90	80	EASE offers 90%
		no		5		5	5			
		yes	Low	0,1				90	80	EASE offers 1%
		no		0,1		0,5	0,5			
	(volatiles)	yes	High	500				90	80	EASE offers 1%
	ppm	no		500		250	500			
		yes	Moderate	100				90	80	EASE offers 80%
		no		500		50	100			
		yes	Low	50				90	80	EASE offers 90%
		no		500		10	25			

PROC	Exposure scenario	LEV	Fugacity	Predicted EASE Exposure (95th%)	TR93 exposure prediction	Industrial exposure prediction (1)	Professional exposure prediction (1)	EASE LEV Effectiveness Industrial (%) (2)	EASE LEV Effectiveness Professional (%) (2)	Comments on Choice of LEV %
20	**Heat and pressure transfer fluids (closed systems) in dispersive use (15)**	yes	High	1	**(16)**			n/a	80	EASE offers 80%
	(solids)	no		5		n/a	5			
	mg/m3	yes	Moderate	1				n/a	80	EASE offers 80%
		no		5		n/a	**1**			
		yes	Low	0,01				n/a	**80**	EASE offers 1%
		no		0,01		n/a	0,01			
	(volatiles) **(17)**	yes	High	200				n/a	**80**	EASE offers 60%
	ppm	no		500		n/a	**50**			
		yes	Moderate	50				n/a	**80**	EASE offers 50%
		no		100		n/a	**20**			
		yes	Low	3				n/a	**80**	EASE offers 33%
		no		10		n/a	**5**			
21	**Low energy manipulation of substances bound in materials and/or articles (18)**	yes	High		**(19)**			**90 (20)**	**80**	EASE offers no LEV efficiency for this PROC as activity falls outside domain of reliable EASE application
	(solids)	no			**1**	**10**	**20**			
	mg/m3	yes	Moderate					**90**	**80**	
		no			**0,5**	**3**	**5**			
		yes	Low					**90**	**80**	
		no			**0,2**	**1**	**3**			
	(volatiles)	yes	High					n/a	n/a	
	ppm	no				n/a	n/a			
		yes	Moderate					n/a	n/a	
		no				n/a	n/a			
		yes	Low					n/a	n/a	
		no				n/a	n/a			
22	**Potentially closed operations with minerals at elevated temperature**	yes	High		**(21)**		**(22)**	**90 (20)**	**n/a (23)**	EASE offers no LEV efficiency for this PROC as activity falls outside domain of reliable EASE application
	(solids)	no			**3**	**10**	**n/a**			
	mg/m3	yes	Moderate					**90**	**n/a**	
		no			**1,6**	**3**	**n/a**			
		yes	Low					**90**	**n/a**	
		no			**n/a**	**1**	**n/a**			
	(volatiles)	yes	High					n/a	n/a	
	ppm	no				n/a	n/a			
		yes	Moderate					n/a	n/a	
		no				n/a	n/a			
		yes	Low					n/a	n/a	
		no				n/a	n/a			
23	**Potentially closed operations with minerals at elevated temperature**	yes	High	5	**(25)**			**90 (20)**	**80**	EASE offers no LEV efficiency for this PROC as activity falls outside domain of reliable EASE application
	(solids)	no		50	**1,6**	**10**	**20**			
	mg/m3	yes	Moderate	0,5				**90**	**80**	
		no		5	**1,6**	**3**	**5**			
		yes	Low	0,1				**90**	**80**	
		no		0,1	**n/a**	**1**	**3**			
	(volatiles) **(24)**	yes	High	200				N/a	N/a	
	ppm	no		500		N/a	N/a			
		yes	Moderate	50				N/a	N/a	
		no		100		N/a	N/a			
		yes	Low	3				N/a	N/a	
		no		10		N/a	N/a			
24	**High (mechanical) energy work-up of substances bound in materials and/or articles (26)**	yes	High		**(27)**			**90 (20)**	**75 (23)**	EASE offers no LEV efficiency for this PROC as activity falls outside domain of reliable EASE application
	(solids)	no			**1,6**	**10**	**20**			
	mg/m3	yes	Moderate					**90**	**75**	
		no			**0,5**	**3**	**5**			
		yes	Low					**90**	**75**	
		no			**0,5**	**1**	**3**			
	(volatiles)	yes	High					n/a	n/a	
	ppm	no				n/a	n/a			
		yes	Moderate					n/a	n/a	
		no				n/a	n/a			
		yes	Low					n/a	n/a	
		no				n/a	n/a			

PROC	Exposure scenario	LEV	Fugacity	Predicted EASE Exposure (95th%)	TR93 exposure prediction	Industrial exposure prediction (1)	Professional exposure prediction (1)	EASE LEV Effectiveness Industrial (%) (2)	EASE LEV Effectiveness Professional (%) (2)	Comments on Choice of LEV %
25	**Hot work operations with metals (26)**	yes	High		**(28)**			**90 (20)**	**80 (23)**	EASE offers no LEV efficiency for this PROC as activity falls outside domain of reliable EASE application
	(solids)	no			1	**5**	**10**			
	mg/m3	yes	Moderate					**90**	**80**	
		no			1	**5**	**10**			
		yes	Low					**90**	**80**	
		no			1	**5**	**10**			
	(volatiles) **(29)**	yes	High					N/a	N/a	
	ppm	no				N/a	N/a			
		yes	Moderate					N/a	N/a	
		no				N/a	N/a			
		yes	Low					N/a	N/a	
		no				N/a	N/a			

1 Blue indicates upward and Red a downward revision to TR 93

2 EASE % represents basic LEV level for ventilation options except where indicated (red, increased %; blue, reduced %)

3 Assumed to represent batch chemical synthesis with opportunity for breaching

4 Assumed to represent typical batch formulating type activities

5 PROC not specifically addressed in TR 93. Calendaring assumed to yield similar exposures to mixing/blending. TRA predictions given against EASE

6 PROC added as PROC8 only refers to non-dedicated facilities. Many large transfers occur at dedicated facilities e.g. tanker loading

7 95% chosen rather than 97% as dusts generally more of a challenge to control

8 Higher LEV % used as PROC relates to dedicated facilities

9 80% chosen as spraying RMM efficiencies are notoriously variable

10 80% chosen because of effect that blowing can have with respect to ventilation capture

11 LEV efficiency reflects that typically experienced for metal working fluids (MWF) at the industrial level

12 The exposure predictions in this PROC are informed by those of PROC17 which is similar

13 Not included in TR 93. TRA predictions given against EASE values

14 Exposures represent a synthesis of PROC5 and PROC9

15 Only address professional use. Industrial use probably covered by PROC2. PROC2 basis used to inform PROC20 exposure estimates

16 PROC not included in TR 93. Basis for exposure estimates derives from EBRC data

17 Exposures align with PROC2

18 No obvious TRA equivalent

19 PROC not included in TR 93. Basis for exposure estimates derives from EBRC data and accounting for cutting, sawing, slitting, punching, cold rolling, assembly or disassembly of non-metal materials/articles. Actual EBRC data indicated in green

20 Values based upon likely efficiency of typical good LEV. EBRC field data indicates lower median actual efficiencies for the metals sector

21 PROC not included in TR 93. Basis for exposure estimates derives from EBRC data but also accounts for refineries, coke ovens

22 Professional exposures arising from PROC22 highly unlikely and will demand case-by-case assessment if considered relevant

23 Values based upon EBRC field data

24 Minerals are not considered to present any risk from inhalation exposure to volatile components. Any such risk e.g. process fumes is covered under exposures to solids

25 PROC not included in TR 93. Basis for exposure estimates derives from EBRC data but where account made for bitumen paving. Actual EBRC data indicated in green

26 Not directly addressed in 2004 TRA due to explicit limitations of EASE

27 PROC not included in TR 93. Basis for exposure estimates derives from EBRC data. Changes made to account for other data from grinding, mechanical cutting, drilling or sanding. Actual EBRC data indicated in green

28 PROC not included in TR 93. Basis for exposure estimates derives from EBRC data. No differentiation on dustiness as exposures relate to welding, soldering, gouging, brazing, flame cutting etc. Actual EBRC data indicated in green

29 Metals are not considered to present any risk from inhalation exposure to volatile components. Any such risk e.g. process fumes is covered under exposures to solids

APPENDIX B: BASIS OF THE WORKER EXPOSURE ESTIMATES FOR PROCs 18 TO 25

Background

Beyond the 16 PROCs identified in the original TRA (ECETOC, 2004), nine new PROCs have been introduced into the Technical Guidance Document (IR&CSA Part R12) as a consequence of the RIP 3.2 stakeholder consultations during 2006-2008.

Table 1 (section 2.1.1) summarises the relationships between the exposure scenarios contained in version 1 of the TRA and the PROCs. In order that the TRA is also able to address these new PROCs, relevant exposure estimates must also be developed. For several of the new PROCS, estimates can be made by use of EASE. However, as many of the new PROCs specifically relate to situations outside the domain of application of EASE, an alternative strategy for estimating exposures is required. As the majority of these new PROCs (# 21-25; and shown in grey in Table 1) concern the handling of metals at elevated temperatures, ECETOC worked with Eurometaux (through Eurometaux's technical consultants, EBRC[5]) in order to identify a basis for reliable exposure estimates as well as values for the efficiency of LEV for the new PROCs.

The following summarises the rationale for the choice of both the inhalation and dermal exposure estimates for these PROCs.

[5] ECETOC acknowledges the considerable technical input made to this section by Rüdiger Battersby and Daniel Vetter of EBRC.

Table B-1: Relationship between new PROCs and previous TRA exposure scenario types

REACH Process Categories		Basis for Revised TRA Worker Exposure Estimates (2009)
PROC 6	Calendering operations	No direct equivalent in 2004 TRA. Estimates based upon application of PROC5 (mixing) but with advice given on need to account for processing temperature. Exposure estimates exclude any potential for fume generation
PROC 8b	Transfer of chemicals from / to vessels / large containers at dedicated facilities	TRA 7 addressed this in 2004 TRA. PROC 8a specifically addresses 'non-dedicated' transfer facilities
PROC 11	Non industrial spraying	Not directly addressed in 2004 TRA due to concern with limitations of EASE for this use. TRA v2 uses enhanced PROC7 values
PROC 18	Greasing at high energy conditions	TRA 15 was intended to also reflect such exposures and has been applied
PROC 19	Hand-mixing with intimate contact (only PPE available)	No direct equivalent in 2004 TRA. Estimates based upon application of PROC5 (mixing) and PROC9 (transfer of chemicals)
PROC 20	Heat and pressure transfer fluids (closed systems) in dispersive use	Not directly addressed in 2004 TRA. Such exposures were intended to be addressed under TRA 2. Revised exposure estimates reflect this
PROC 21	Low energy manipulation of substances bound in materials and/or articles	No direct equivalent in 2004 TRA. Estimates derived from Eurometaux/EBRC data
PROC 22	Potentially closed operations with minerals at elevated temperature	No direct equivalent in 2004 TRA. Estimates derived from Eurometaux/EBRC data
PROC 23	Open processing and transfer of minerals	Not directly addressed in 2004 TRA. Such exposures intended to be addressed under TRA 8. Estimates derived from Eurometaux/EBRC data
PROC 24	High (mechanical) energy work-up of substances bound in materials and/or articles	Not directly addressed in 2004 TRA due to explicit limitations of EASE. Estimates derived from Eurometaux/EBRC data
PROC 25	Hot work operations with metals	Not directly addressed in 2004 TRA due to explicit limitations of EASE. Estimates derived from Eurometaux/EBRC data

Methodology

(1) Inhalation exposure data:

Previous EU risk assessments for metals include zinc, cadmium, nickel, antimony trioxide, copper and lead. For this exercise, relevant data were selected from within the risk assessment reports (RARs) on lead, antimony trioxide and zinc, for the following reasons:

- The risk assessment on lead and 12 lead compounds covers a vast range of occupational scenarios, including primary/secondary production of lead metal, production of inorganic lead compounds and also dozens of downstream user scenarios. In view of the chronic health effects already exerted at low exposures, OELs as low as 100 µg/m³ have been set in many countries, so that exposure controls are usually required to be rather strict. For this reason, the data contained in the lead RAR were not considered to be likely as being representative of the exposures for those PROCs addressing metals handling processes.

- Antimony trioxide is produced by 'burning' antimony metal, and is then employed as a powder in a range of industries for a range of applications; a common OEL for this is 0.5 mg/m³ in consideration of the existing health classification, rendering the required exposure controls as moderately strict.
- The exposure to zinc metal and zinc compounds is not usually associated with any form of systemic toxicity, and negative health effects are only known to occur under extreme circumstances (i.e. welding). This is why rather high OELs have been set in some countries at 5 mg/m³ (fume); exposure controls for zinc may therefore be expected to be less strict than for the two other metals above.

(2) Dermal exposure data:
Prior to the initiation of EU Risk Assessments on metals and their inorganic compounds, the availability of dermal exposure data for the metals sector was limited, except for a few published investigations. During the course of the RAR procedures, high quality dermal monitoring studies were initiated by the industry associations for zinc, lead, nickel and antimony trioxide. It was concluded that there is now a reliable and consistent data base on dermal exposure to metals that covers a wide range of industries and processes, which is considered sufficient for use in model extrapolations.

In conclusion, the selection of these three data bases on occupational exposure is considered to reflect a whole range of exposure controls, ranging from very strict to low. In addition, each of these data sets is coupled to a consistent, high-quality dermal exposure data set.

Available data on occupational inhalation exposure from the metal industry

Inhalation exposure data for the metals industry often exist when OELs have been previously set, because compliance to these limits has had to be demonstrated through regular air monitoring. However, access to such data is sometimes difficult due to confidentiality issues, linguistic barriers or simply due to the fact that their existence is not known by individuals other than those who generated the data. Published data often lack the qualifying auxiliary information, as well as the desired summary statistics and the full raw data; an assessment of representativeness for a specific sector is also often not available.

In order to overcome those problems, specific occupational exposure surveys often need to be conducted. Examples of such are the data sets selected for this report, which were all prepared in the context of Risk Assessments under the "Existing Substances Regulation (EEC) 793/93". Since the quality, extent and representative nature of the collected data was assessed and agreed between the member state and industry and later subjected to approval by TCNES, the level of scientific peer-review may be considered as high.

Due to its involvement in several metal RARs in the past, Eurometaux (and its consultant EBRC) have obtained detailed insight into existing occupational inhalation monitoring data from a wide range of metals industries and specifically the risk assessments of the three metals whose data bases were selected for this report [i.e. lead (LDAI, 2008), antimony trioxide (ECB, 2008b) and zinc (ECB, 2003a-e)] where full access to the underlying raw data is available.

Available data on occupational dermal exposure from the metal industry

For the dermal exposure route, several metal industries have recently generated a comprehensive data base using a standard validated sampling procedure. These investigations were performed and validated by IOM (Institute of Occupational Medicine, Edinburgh, UK), using a 'moist wipe' technique. This sampling procedure and other methodological aspects are discussed in detail in the "HERAG fact sheet on dermal exposure and absorption" (EBRC, 2007).

Full access to the dermal exposure raw data is available for zinc, lead, antimony trioxide and nickel. Published dermal exposure data for calcium carbonate, lead and diantimony trioxide were also obtained from downstream user industries although these were not considered further due to methodological differences in the sampling techniques precluding direct comparisons. Figure B-1 below shows the available data sorted by industry and job activity in relations to the EASE dermal exposure bands, thus allowing an allocation of dermal exposure according to PROCs, as specified in more detail further below in this report.

For comparative purposes, Figure B-2 presents the same data on the basis of the involved handling patterns in direct association with the EASE categories.

Figure B-1: Dermal exposure levels (mass loading of handled compound) for different chemical agents and activities, in comparison to model approaches proposed by the TGD for solids/dust (EASE bands labelled in mg/cm²)

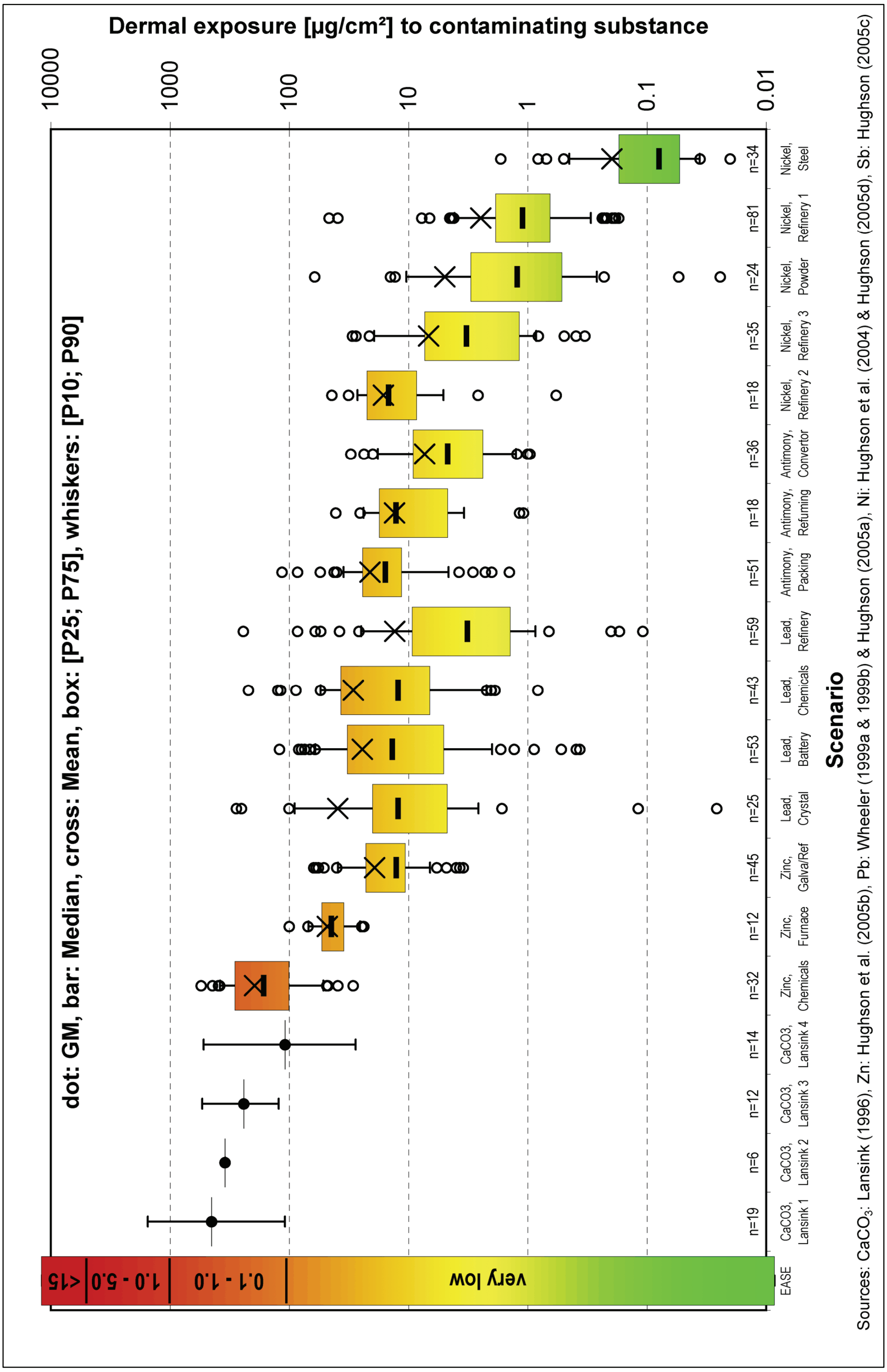
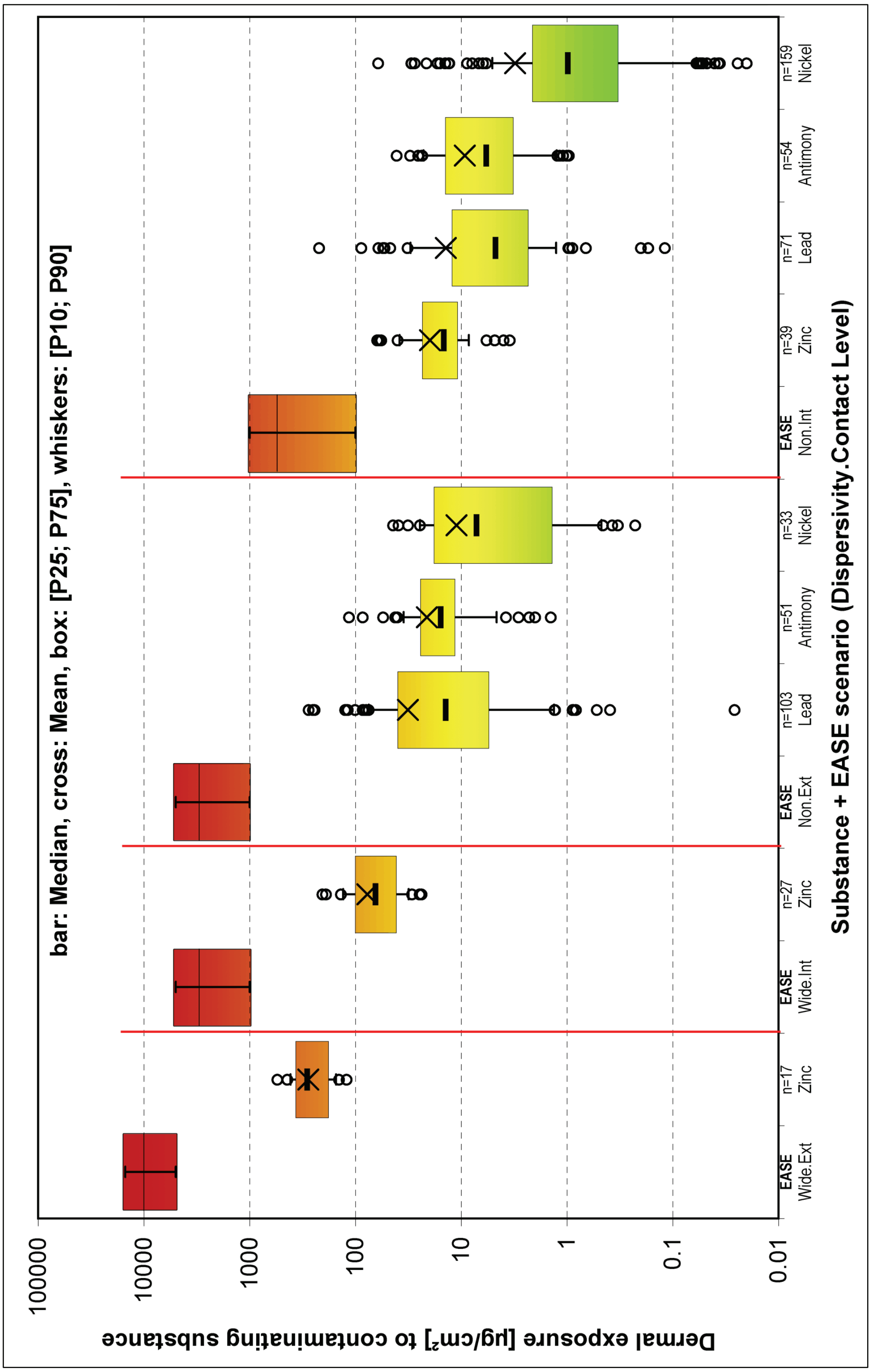


Figure B-2: Dermal exposure levels for different chemical agents and activities, in comparison to EASE predictions, based on the contaminating substance



Use pattern: wide and non-dispersive use; contact level (direct handling): inc = incidental, int = intermittent, ext = extensive.

Assignment of existing occupational inhalation exposure data to new PROCs

In Table B-2, typical and reasonable inhalation exposure values are assigned by workplace to their corresponding PROC. This assignment was based on data generated for zinc, lead and antimony. The basis for the selection of these data is further explained below. PROC assignments in Table B-2 were made according to workplaces/tasks, as defined in the corresponding RARs on a workplace-by-workplace basis. However, some of the reported data for workplaces involving potential exposures to metals which were identified in the EU RARs are not listed in Table B-2 for the following reasons:

- Lead: Cleaning/maintenance (all sectors) → not a metal-specific workplace.
- Desulphurisation (Sec3) → not a metal-specific workplace.
- Battery formation (Bat4) → not a metal-specific workplace.
- (Acid) Polishing processes (Cry4) → not a metal-specific workplace.
- Lithography (Cem3) → not a metal-specific workplace.
- Decoration (Cem4) → not a metal-specific workplace.
- Dipping (Cem5) → not a metal-specific workplace.
- Lead: Complete PVC (lead stabilisers) → no exposure data available.
- Lead: Brass foundry → measured data lacks qualifiers.
- Further lead scenarios → exposure from use of articles → not a metal-specific workplace.
- ATO textile: Processing, further handling→ not a metal-specific workplace.
- Zinc oxide: Paint production → measured data lacks qualifiers.
- Zinc oxide: Use of paints → not a metal-specific workplace.
- Zinc distearate → not a metal-specific workplace.
- Zinc sulphate: Production/use of animal feed and fertilisers → not a metal-specific workplace.
- Zinc phosphate, paint production, use of paint → not a metal-specific workplace.

Table B-2: Inhalation exposure values assigned to new PROCs (in mg/m³ of personal [full-shift] exposure)

PROC	PROC Name	Involved workplaces			Typical Exposures			RWC Exposures			Number of values		
		Zinc	Lead	ATO	Zinc	Lead	ATO	Zinc	Lead	ATO	Zinc	Lead	ATO
21	Forming operations on substances/metals as such or bound in materials and/or articles		Shredding and sorting (Sec2)			0.04			0.27			208	
			Milling (She3)			0.05			0.31			20	
			Plate treatment (Bat2)			0.20			0.76			338	
			Assembly (Bat3)			0.06			0.26			1,220	
			Forming processes (Cry2)			0.02			0.06			53	
			Abatement, demolition, scrap			0.05			0.18			Lit[b)]	
22	Potentially closed operations with minerals/metals at elevated temperature	Pyrom. process (ZM)	Sintering (Pri2)	Oxidation (Production)	0.30	0.24	0.54	1.90	2.12	2.89	Ext[d)]	31	47
		Kiln/furnace operations (ZO)	Smelting (Pri3)		0.60	0.08		1.60	0.94		54	53	
		Kiln maintenance (ZO)	Melting and smelting (Sec4)		0.60	0.07		1.60	0.74		12	859	
			Melting and refining (She2)			0.14			0.86			76	
23	Open processing and transfer of minerals/metals at elevated temperature	Die casting (ZO)	Refining and casting (Pri4)		0.10	0.10		1.00	0.46		Lit[b)]	158	
		Brass casting (ZO)	Refining and casting (Sec5)		0.40	0.05		1.60	0.31		22	1,174	
		Galvanising (ZC)	Plate manufacturing (Bat1)		0.50	0.07		0.10	0.28		Lit[b)]	1,190	
24	High (mechanical) energy workup of substances bound in materials and/or articles or of massive metal		Sawing and slitting (She4)			0.06			1.90			10	
			Cutting processes (Cry3)			0.06			0.33			136	
25	Other hot work operations with metals	Welding (ZO)[f)]			0.10			0.80			Lit[b)]		

nd: no data available but workplace defined in the corresponding RAR, () at workplaces for zinc: ZM=zinc metal, ZO=zinc oxide, ZC=zinc chloride, ZS=zinc sulphate, ZP=zinc phosphate, for lead PriX=Primary, SecX=Secondary, SheX=Sheet, BatX=Battery, O&S=Oxide & Stabiliser, CryX=Crystal glass, CemX=Ceramic ware a) taken from data from the Spanish tile industry; b) literature data, i.e. raw data not available at EBRC, please refer to the corresponding RAR for more information, the reported value for the 90th percentile represents the highest reported value from all considered sources of that report, in cases where no 90th percentile was not reported the next highest value was used (e.g. the 95th percentile or the maximum value), if no median values were reported the most similar value was used (e.g. arithmetic or geometric mean); c) Extrapolated data as reported by the Swedish *rapporteur* in the ATO RAR; d) Extrapolated data as reported by the Dutch *rapporteur* in the Zinc Metal RAR; e) data (n=27) contain static samples but the entire data set was used by the *rapporteur*; f) assessed as rather old data and therefore likely to overestimate today's exposure settings.

Assignment of existing occupational dermal exposure data to new PROCs

In agreement with the assignment made for the inhalation exposure data, dermal exposure data for zinc, lead and antimony were selected using essentially the same rationale as for inhalation exposures. The 'continuum' in exposure control measures that is identified in Figure B-1 also applies to these data. Furthermore, the data available for nickel also fit well into this picture (but are included for comparative reasons only).

It is relevant to note the logarithmic scale which indicates a strong 'downward' trend in dermal exposure with increasing hazard potential of the handled substance, suggesting that current exposure controls/risk management measures have a clear positive impact.

Table B-3: Dermal exposure values assigned to new PROCs (in µg/cm²), full-shift

PROC	Metal	Workplace	Typical exposure (EBRC)	RWC exposure (EBRC)	Number of values	Reference
21 and	Lead	Crystal glass	12	90	25	Wheeler and Sams, 1999
24	Lead	Battery	14	60	53	Wheeler *et al*, 1999
22	Zinc	Furnace	44	69	12	Hughson, 2005a
	Lead	Refinery	3	25	59	Hughson, 2005b
	Antimony	Refuming	13	24	18	Hughson, 2005c
	Antimony	Converter	5	18	36	Hughson, 2005c
23	Zinc	Galvanising	13	39	62	Hughson, 2005a
25	Negligible (see below for justification)					

For PROC 25, exposure is assessed to be negligible for the following reasoning: Due to the process temperatures involved in the activity, it is assumed that workers are not in direct contact with the material handled during this process. Furthermore, the relatively small amount of releases (which are not negligible for inhalation exposure due to the associated particle sizes) is considered not to represent any appreciable dermal exposure. Consideration of the processes[6] as well as the available data for PROC 21 and PROC 24 suggest that both PROCs are very similar in their potential for dermal exposure. The data sets were therefore pooled and the derived values are assumed to be applicable to both PROCs.

[6] Both types of processes have potential for dermal exposure due to their 'abrasive nature' and the involved dust formation.

Proposed values for occupational inhalation exposure

The ECETOC TRA model distinguishes between predicted exposure and the effectiveness of LEV between industrial and professional uses. Though this approach is useful for general occupational exposure assessment purposes, not all 'metals' PROCs would be expected to be undertaken by professionals (and especially for kiln and furnace operations).

Except for PROC 1, the current ECETOC TRA model generally assumes a direct relationship between fugacity and exposure. However, the term 'fugacity' is not considered to be equally applicable to all metal-specific PROCs. For PROCs which involve some kind of 'material-invasive' processes (such as hot-forming and melting) it is proposed to base the fugacity classification on the involved process temperature in relation to the melting point (mp) of the material/substance handled (see Table B-4). The reasoning for this is briefly as follows:

- At process temperatures below mp, mechanical wear or physical abrasion of particles is assumed to contribute most to dust formation.
- At process temperatures close to mp, thermal convection may be assumed to cause oxide layers to be 'lifted' from the surface of a molten metal, although the volatility of the metal itself at this process temperature is negligible.
- At process temperatures well above the mp, generation of fumes can be assumed to occur, which for example will be emitted from the surface of molten metals or slags during tapping or casting operations.

Thus the proposed fugacity classes given in column 2 are proposed for use with PROCs 21-25 only.

Table B-4: Fugacity classifications for process temperature / melting point relations

Process temperature* in relation to melting point (mp)	Fugacity
Process temp < mp	Low
Process temp ≈ mp	Moderate
Process temp > mp	High

* In drilling or 'abrasion' techniques (e.g. grinding) the temperature of the 'tool-material contact area' may be used instead of the process temperature.

The following values are proposed (see also Appendix A) as inhalation exposure estimates for the relevant PROCs within the ECETOC TRA refinement, in consideration of the fugacity considerations given above and based on the assignment of data presented in detail in Table 2. The proposed exposure estimates were derived directly as typical (50th percentile; LEV = yes) and worst-case (90th percentile;

LEV = no) levels taken from actual measured data sets assigned to individual PROCs. The 'LEV effectiveness' grades applied in the TRA are consistent with those described elsewhere (HSE, 2008), although a comparison of the paired exposure data indicates that median values for the metals sector are often significantly less than expected values.

Table B-5: Proposed inhalation exposure estimates and effectiveness values for LEVs

PROC	LEV	Fugacity	Exposure estimate suggested by data	Exposure estimate used in TRA	'Actual' effectiveness of LEV in the Metals sector
21	yes	high	0.6	**1**	40%
	no		1.0		
	yes	moderate	0.4	**0.5**	40%
	no		0.5		
	yes	low	0.1	**0.2**	40%
	no		0.2		
22	yes	high	1.5	**3**	50%
	no		3.0		
	yes	moderate	0.8	**1.6**	50%
	no		1.6		
	yes	low	not applicable	**0.5**	50%
	no		not applicable		
23	yes	high	0.4	**10**	75%
	no		1.6		
	yes	moderate	0.3	**1.6**	50%
	no		0.5		
	yes	low	not applicable	**0.5**	50%
	no		not applicable		
24	yes	high	1.2	**2.0**	40%
	no		2.0		
	yes	moderate	0.4	**1**	40%
	no		0.5		
	yes	low	0.4	**0.5**	40%
	no		0.5		
25	yes	high	0.2	5	80%
	no		1.0		
	yes	moderate	0.2	3	80%
	no		1.0		
	yes	low	0.2	1	80%
	no		1.0		

Proposed values for occupational dermal exposure

Within the HERAG dermal exposure project (EBRC, 2007), all available data were screened and grouped into categories. Exposure ranges were derived as 'rounded' values (instead of 'precise' calculated 90th percentile values), which were proposed to be used in a tiered dermal 'screening model' approach. These are adapted here, but slightly modified in consideration of the specific requirements for each PROC.

Further to this, it is recommended to assume an exposed skin area of 1,980 cm² for PROCs 21-25, reflecting a conservative estimate of the area of hands and forearms. This is in-line with the assumptions made in previous EU RARs for metals and their inorganic compounds. For the same reasons it is also proposed to assume a PPE effectiveness of 90 %. The values in Table B-6 are proposed as dermal exposure estimates for the ECETOC TRA based on the actual data derived from the metal-specific activities (see also Appendix C).

Table B-6: Proposed dermal exposure estimates

Proc	PPE	Predicted dermal exposure based on actual data [µg/cm²]	Dermal exposure estimate within TRA [µg/cm²]	Exposed skin surface [cm²]
21 and 24	yes	10	**10**	1,980
	no	100	**100**	
22	yes	10	**30**	1,980
	no	100	**100**	
23	yes	5	**10**	1,980
	no	50	**100**	
25	yes	negligible	**5**	1,980
	no	negligible	**10**	

APPENDIX C: GENERIC EXPOSURE SCENARIOS FOR TIER 1 ASSESSMENT

PROC	Wide Dispersive Uses	Containment or LEV present?	Predicted EASE dermal exposure (ug/cm²/day)[1]	Exposed skin surface (cm²)	Predicted dermal exposure (mg/kg/day)	Comments
1	**Use in closed process, no likelihood of exposure**	Yes	10	240	0.03	PROC expected to have minimal exposure are assigned predicted exposures consistent with RiskofDerm and other comparable source data. One hand face only
		No	100		0.34	
2	**Use in closed, continuous process with occasional controlled exposure**	Yes	20	480	0.14	EASE predicts very low (non-dispersive, non-direct handling).0.1g/cm[2] a realistic worst case. 2 hands face only
		No	200		1.37	EASE predicts (significant breaching, direct handling, intermittent exposure). Assumes 2 hands face only
3	**Use in closed batch process (synthesis or formulation)**	Yes	10	240	0.03	PROC expected to have minimal exposure are assigned predicted exposures consistent with RiskofDerm and other comparable source data. One hand face only
		No	100		0.34	
4	**Use in batch and other process (synthesis) where opportunity for exposure arises[2]**	Yes	100[3]	480	0.69	EASE predicts very low (non-dispersive, non-direct handling). 0.1g/cm[2] a realistic worst case. 2 hands face only
		No	1000		6.86	EASE predicts (significant breaching, direct handling, intermittent exposure). Assumes 2 hands face only
5	**Mixing or blending in batch processes (multistage and/or significant contact)**	Yes	10	480	0.07	EASE predicts very low. Assumes 2 hands face only
		No	2000		13.71	EASE predicts 5g/cm[2] (wide-dispersive, mobile dust, direct handling, intermittent). 2g/cm[2] a more realistic worst case. 2 hands face only

PROC	Wide Dispersive Uses	Containment or LEV present?	Predicted EASE dermal exposure (ug/cm²/day)	Exposed skin surface (cm²)	Predicted dermal exposure (mg/kg/day)	Comments
6	**Calendering operations**	Yes	100	960	1.37	EASE predicts (wide-dispersive, mobile dust, no direct handling) very low. Assumes 2 hands face only
		No	2000		27.43	EASE predicts 5g/cm^2 (wide-dispersive, mobile dust, direct handling, intermittent). 2g/cm^2 a more realistic worst case. 2 hands face only
7	**Industrial spraying**	Yes	100	1500	2.14	EASE predicts 0.1 (wide-dispersive, mobile dust, direct handling, incidental). Assumes 2 hands and forearms
		No	2000		42.86	EASE predicts (wide-dispersive, mobile dust, no direct handling) very low. Assumes 2 hands and forearms
8a	**Transfer of chemicals from/to vessels/ large containers at non dedicated facilities**	Yes	10	960	0.14	EASE predicts (wide-dispersive, direct handling, intermittent exposure). Assumes 2 hands
		No	1000		13.71	EASE predicts 5g/cm^2 (wide-dispersive, direct handling, intermittent exposure). 1g/cm^2 a more realistic worst case. 2 hands
8b	**Transfer of chemicals from/to vessels/ large containers at dedicated facilities**[4]	Yes	100[5]	480	0.69	EASE predicts (wide-dispersive, direct handling, intermittent exposure). Assumes 2 hands
		No	1000		6.86	EASE predicts 5g/cm^2 (wide-dispersive, direct handling, intermittent exposure). 2g/cm^2 a more realistic worst case. 2 hands
9	**Transfer of chemicals into small containers (dedicated filling line)**	Yes	100	480	0.69	EASE predicts very low (non-dispersive, non-direct handling).0.1g/cm^2 a realistic worst case. 2 hands face only
		No	1000		6.86	EASE predicts (significant breaching, direct handling, intermittent exposure). Assumes 2 hands face only

PROC	Wide Dispersive Uses	Containment or LEV present?	Predicted EASE dermal exposure (ug/cm²/day)	Exposed skin surface (cm²)	Predicted dermal exposure (mg/kg/day)	Comments
10	**Roller application or brushing**	Yes	100	960	1.37	EASE predicts (wide dispersive, mobile dust, direct handling, incidental). Assumes 2 hands
		No	2000		27.43	EASE predicts 5g/cm^2 (wide dispersive, mobile dust, direct handling, intermittent). 2g/cm^2 a more realistic worst case. 2 hands
11	**Non industrial spraying**	Yes	100	1500	2.14	EASE predicts (wide-dispersive, mobile dust, direct handling, incidental). Assumes 2 hands and forearms
		No	5000		107.14	EASE predicts 5g/cm^2 (wide dispersive, mobile dust, direct handling, intermittent). Assumes 2 hands and forearms
12	**Use of blowing agents for foam production**	Yes	10	240	0.03	PROC expected to have minimal exposure are assigned predicted exposures consistent with RiskofDerm and other comparable source data. One hand face only
		No	100		0.34	
13	**Treatment of articles by dipping and pouring**	Yes	100	480	0.69	EASE predicts very low (wide-dispersive, mobile dust, no direct handling). 0.1g/cm^2 a realistic worst case. 2 hands face only
		No	2000		13.71	EASE predicts 5g/cm^2 (wide-dispersive, mobile dust, direct handling, intermittent).2g/cm^2 a more realistic worst case. 2 hands face only
14	**Production of preparations or articles by tabletting, compression, extrusion, pelletisation**[6]	Yes	50	480	0.34	EASE predicts very low (non-dispersive, non- direct handling). 0.1g/cm^2 a realistic worst case. 2 hands face only
		No	500		3.43	EASE predicts (significant breaching, direct handling, intermittent exposure). Assumes 2 hands face only
15	**Use of laboratory reagents in small scale laboratories**	Yes	10	240	0.03	PROC expected to have minimal exposure are assigned predicted exposures consistent with RiskofDerm and other comparable source data. One hand face only
		No	100		0.34	

PROC	Wide Dispersive Uses	Containment or LEV present?	Predicted EASE dermal exposure (ug/cm²/day)	Exposed skin surface (cm²)	Predicted dermal exposure (mg/kg/day)	Comments
16	**Using material as fuel sources, limited exposure to unburned product to be expected**	Yes	10	240	0.03	PROC expected to have minimal exposure are assigned predicted exposures consistent with RiskofDerm and other comparable source data. .One hand face only
		No	100		0.34	
17	**Lubrication at high energy conditions and in partly open process**	Yes	100	960	1.37	EASE predicts (dispersive, mobile dust, direct handling, incidental contact). Assumes 2 hands
		No	2000		27.43	EASE predicts (dispersive, mobile dust, direct handling, intermittent contact). Assumes 2 hands
18	**Greasing at high energy conditions**[7]	Yes	50	960	0.69	EASE predicts (dispersive, mobile dust, direct handling, incidental contact). Assumes 2 hands
		No	1000		13.71	EASE predicts (dispersive, mobile dust, direct handling, intermittent contact). Assumes 2 hands
19	**Hand-mixing with intimate contact (only PPE available)**[8]	Yes	500	1980	14.14	Values approximate to those identified in 2003 TGD and RiskofDerm papers. Assumes 2 hands
		No	5000		141.43	
20	**Heat and pressure transfer fluids (closed systems) in dispersive use**[9]	Yes	20	480	0.14	EASE predicts very low (non-dispersive, non- direct handling). 0.1g/cm^2 a realistic worst case. 2 hands face only
		No	250		1.71	EASE predicts (significant breaching, direct handling, intermittent exposure). Assumes 2 hands face only
21	**Low energy manipulation of substances bound in materials and/or articles**[10]	Yes	10	1980	0.28	
		No	100		2.83	
22	**Potentially closed operations with minerals at elevated temperature**[11]	Yes	30	1980	0.85	
		No	100		2.83	

PROC	Wide Dispersive Uses	Containment or LEV present?	Predicted EASE dermal exposure ($ug/cm^2/day$)	Exposed skin surface (cm^2)	Predicted dermal exposure (mg/kg/day)	Comments
23	**Open processing and transfer of minerals at elevated temperature[12]**	Yes	5	1980	0.14	
		No	50		1.41	
24	**High (mechanical) energy work-up of substances bound in materials and/or articles[13]**	Yes	10	1980	0.28	
		No	100		2.83	
25	**Hot work operations with metals[14]**	Yes	5	1980	0.14	
		No	10		0.28	

NOTE: Figures in **blue** reflect where predicted EASE estimates have been revised upwards. Figures in **red** indicate downward revisions.

[1] EASE predictions modified to better reflect typical exposures in-line with REACH RMM advice
[2] Dermal exposures calibrated against data obtained from EBRC/Eurometaux data and 'rounded up' to ensure RWC
[3] Note: actual EBRC data for metal powders production indicates lower measured exposures
[4] Dermal exposures calibrated against data obtained from EBRC/Eurometaux data and 'rounded up' to ensure RWC
[5] 100 versus 10 predicted by EASE. Based on EBRC data
[6] Exposures assumed to be 50% of those of PROC9 based on RiskofDerm data
[7] Greasing assumed to yield 50% less exposure to lubricants due to increased viscosity/shear of grease
[8] Values taken from 2003 TGD and RiskofDerm papers
[9] Dermal exposures obtained from EBRC/Eurometaux data and 'rounded up' to ensure RWC
[10] Exposure estimates obtained from Eurometaux data (Appendix B of TRA Update Addendum)
[11] Exposure estimates obtained from Eurometaux data (Appendix B of TRA Update Addendum)
[12] Exposure estimates obtained from Eurometaux data (Appendix B of TRA Update Addendum)
[13] Dermal exposures obtained from EBRC/Eurometaux data and 'rounded up' to ensure RWC
[14] Exposure estimates obtained from Eurometaux data (Appendix B of TRA Update Addendum)

APPENDIX D: APPLYING ADDITIONAL SCIENCE TO ENHANCE THE ACCURACY OF TIER 1 WORKER EXPOSURE PREDICTIONS

Appendix D-1: Handling substances of very low volatility

For substances of very low volatility, EASE and the ECETOC TRA tend to significantly overestimate vapour concentrations. For non-aerosol applications, vapour concentrations of a substance higher than its saturated vapour concentration are estimated by these tools. To account for this a correction using the saturated vapour concentration can be applied. Jayjock (1994) has pointed out that even for large volatilisation sources (e.g. a painted wall) the concentration cannot exceed the saturated vapour concentration (SVC). This can also be demonstrated based on the ideal gas law. When the concentration of a substance reaches a significant portion of its equilibrium (partial) pressure, the gradient and the net volatilisation rate decrease and it will take *ad infinitum* until saturation is reached. This significant retarding pressure is termed 'back-pressure'.

Jayjock's models became a part of the current ConsExpo program (Bremmer *et al*, 2006). If information on the vapour pressure of the compound is known, the checkbox in front of the phrase "limit the air concentration to the vapour pressure of pure substance" can be checked. When the box is checked, air concentrations as calculated in the 'instantaneous release' or the 'constant rate' model are limited by the maximal air concentration corresponding to the saturated air concentration of the compound.

The saturation air concentration C_{sat} can be calculated from the saturated vapour pressure using the ideal gas law:

$$C_{sat} = MP_{sat} / RT$$

where:

M	:	molecular weight of the compound	[kg/mole]
P_{sat}	:	saturated vapour pressure	[Pa]
R	:	universal gas constant	[J/mole.k]
T	:	temperature	[K].

Application of Dalton's laws leads to the same result. The pressure of a mixture of gases can be defined as the summation of the partial pressures of the individual gas components:

$$P_{total} = p_1 + p_2 + \ldots + p_n$$

The relationship below provides a way to determine the volume based concentration C_i of any individual gaseous component.

$$P_i = P_{total} \times C_i / 1000000.$$

For example, for a substance with a vapour pressure of 0.01 Pa and the surrounding atmospheric vapour pressure P_{total} of ca. 100,000 Pa, the solution of the last equation would lead to a maximum concentration of 0.1 ppm.

In conclusion for non-aerosol applications the saturated vapour concentration can replace the conservative EASE or TRA estimation when dealing with substances with very low vapour pressure. In the ECETOC TRA a cut off value of 0.01 Pa (corresponding with an estimate based on the saturated vapour concentration of 0.1 ppm) will be used to address these situations. Note that the ECETOC TRA assumes processes to take place at ambient temperature (and utilises the corresponding vapour pressure). When dealing with processes at higher temperature, one has to take the effect of the process temperature on the vapour pressure into consideration.

Appendix D-2: Theoretical Background – Individual vapour pressures for components in a mixture

Raoult's law relates the vapour pressure of components to the composition of the solution. It states that the vapour pressure of an ideal solution is dependent on the vapour pressure of each chemical component and the mole fraction of the component present in the solution. Once the components in the solution have reached chemical equilibrium, the total vapour pressure of the solution is:

1) $$p_{tot} = \sum_{I} p_i \chi_i$$

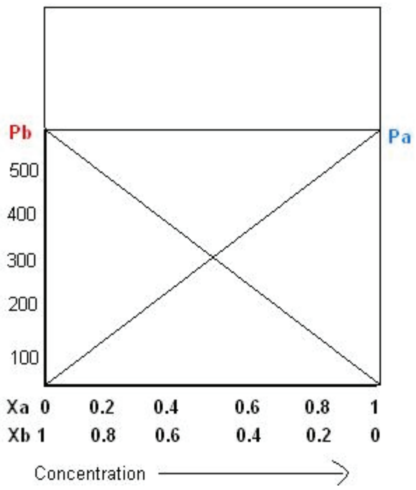
where *p* is vapour pressure, *i* is a component index, and χ is a mole fraction. The term $p_i \chi_i$ is the vapour pressure of component *i* in the mixture.

Furthermore, the individual vapour pressure P_i for each component is:

2) $$P_i = x_i P_i^*$$

where P_i^* is the vapour pressure of the pure component and x_i is the mole fraction of the component in solution.

Raoult's law assumes ideal behaviour. It gives a simple picture of the situation just as the ideal gas law does. Also being not correct from a pure scientific point of view the ideal gas law is very useful and for example typically used by toxicologist to convert ppm into mg/m^3. Raoult's law is similar in that it assumes that the physical properties of the components of a mixture are similar.



Graph 1: Solution of two liquids, a and b, to explain Raoult's law: if no other gases are present, then the total vapour pressure P_{tot} above the solution is equal to the weighted sum of the 'pure' vapour pressures of the two components, P_a and P_b.

Following Dalton's laws the pressure of a mixture of gases can be defined as the summation of the partial pressures of the individual gas components:

3) $$P_{total} = p_1 + p_2 + \cdots + p_n$$

The relationship below provides a way to determine the volume based concentration C_i of any individual gaseous component.

4) $$P_i = \frac{P_{total} C_i}{1,000,000}$$

Example: for a substance with a vapour pressure of 1 Pa and the surrounding atmospheric vapour pressure P_{total} of ca. 100,000 Pa solution of equation 4) would lead to a maximum concentration of 10 ppm.

Often it is useful to employ alternatives to mole fractions x_i, e.g. volume fractions in the case of polymer solutions (where there is a large disparity between the sizes of different kinds of molecules) or for lower concentrations (where the activity coefficient approaches 1) simply the components concentrations C_i based on mass percentages. For a simple online substance amount fraction calculator, see for instance http://www.nightlab.ch/tools/molcalc3.php.

Negative and positive deviations from Raoult's law

When adhesive forces between molecules a and b are greater than the cohesive forces between substances a and a or b and b, respectively, then the vapour pressure of the solution is less than the expected vapour pressure from Raoult's law. This is called a negative deviation from Raoult's law. These cohesive forces are lessened not only by dilution but also attraction between two molecules through formation of hydrogen bonds, e.g. in aqueous systems. An example is a mixture of chloroform and acetone, which boils above the boiling point of either pure component. Systems that have vapour pressures higher than indicated by the above formulas 1 and 2 are said to have positive deviations. Such a deviation suggests weaker intermolecular attraction than in the pure components, so that the molecules can be thought of as being held in the liquid phase less strongly than in the pure liquid. An example is the system of chloroform and ethanol. Chemical engineers have done a significant amount of research to develop equations for correlating and/or predicting Vapour-Liquid Equilibrium (VLE) Diagrams for various kinds of mixtures which do not obey Raoult's law well.

Henry's law versus Raoult's law

Both Henry's law and Raoult's law state that the vapour pressure of a component *p* is proportional to its concentration in the solution. Henry's law uses an additional empirically-derived constant, "*k*", based on an infinitely-dilute solution, i.e. $x = 0$, that is specific to the components in the mixture and the temperature ($P_i = k_i \times C_i$). If the chemical structure is known the Henry constant can be calculated for unknown substances with a reasonable accuracy.

In many systems, the two laws can only be applied over limited concentrations at the ends of the mole-fraction range. Raoult's law, which uses the vapour pressure of the *pure* component (see above) is best used for the major component (solvent) and in mixtures of similar components while Henry's law applies to the minor component in dilute solutions. In ideal-dilute solutions, the minor component follows Henry's law, while the solvent obeys Raoult's law.

Appendix D-3: Refining TRA estimates for dermal exposures and risks

As outlined in section 2.1.7, the ECETOC dermal exposure estimates for workers are based on consideration of an EASE for the PROC (process category), expressed as dermal loading in mass/surface area unit/day, multiplied by the total skin surface likely to be exposed, together with consideration of the presence of Local Exhaust Ventilation (EASE predicts that exposure can be in most cases 10-20 times lower if LEV is in place). The resulting exposure is converted into a systemic dose (assuming 100% dermal absorption), expressed in mg/kg body weight/day, for a standard 70 kg person. No further exposure modifiers are applied to these estimates.

In comparison with the inhalation module of the ECETOC Tier 1 tool, however, three additional Exposure Modifiers are identified that may also be considered relevant for dermal exposure:

- The presence of the substance in a mixture at level < 100%. The inhalation modifiers (1; 0.6; 0.2; 0.1) are linked to concentration bands (>25%; 5-25%; 1-5%; <1%) and skewed based on potential differences in volatility of the components of the vapour phase of a mixture. As the dermal exposure will normally be to the bulk mixture, however, correction on the basis of actual (typical high-end) percentage in the mixture can be applied rather than resorting to bands.
- Personal Protective Equipment: protection afforded by gloves is much less well researched than that offered by respiratory protection. However some studies that have been undertaken on the effectiveness of different dermal protection ensembles and practices suggest that the following levels of actual protection are afforded in practice.

Dermal Protection Characteristics	Indicated Efficiency %	Exposure Reduction Factor
a. Any glove / gauntlet without permeation data and without employee training	0	1
b. Gloves with available permeation data indicating that the material of construction offers good protection for the substance	80	5
c. Chemically resistant gloves (i.e. as #b above) with 'basic' employee training	90	10
d. Level 'c' in combination with specific activity training (e.g. procedures for glove removal and disposal) for tasks where dermal exposure can be expected to occur	95	20

In addition to the above, available evidence indicates that at operating temperatures over 60°C, dermal exposure can be considered as unlikely to occur as any exposed individual will receive burns from (direct) skin contact. This also applies when handling substances with boiling points below 0°C (e.g. during handling liquefied gases). In practice, this means that any quantitative estimate may be set at the level of PROC 1 and 3.

Furthermore although EASE (and hence the TRA) provides an exposure estimate for high volatility liquids (i.e. with a vapour pressure >10 kPa), in practice, such exposures would not occur in the case of gases and very volatile substances as the substance would never be in contact with the skin for a sufficient period to enable significant dermal permeation to occur (Patel *et al*, 2002). Therefore, this means that any quantitative estimate may be set at the level of PROC 1 and 3 for substances having a vapour pressure greater than c. 30kPa). Also note that Appendix 1F of the ESR TGD (EC, 2003) provides an alternative method to evaluate the consequence of short duration exposures to moderate/high volatility substances. This provides the possibility to calculate how long a substance may actually be present on the skin until it has fully evaporated. This should be considered as a Tier 2 adaptation of the duration estimate. It will mostly be relevant for volatile substances, provided the number of repeat contacts between substance and skin is limited. The examples shown in the ESR TGD indicate that 1 mg of ethylbenzene takes 1 minute to evaporate from the skin, whereas 5 mg takes 5 minutes.

APPENDIX E: CONSUMER PRODUCT USE TEMPLATES AND REFERENCES

Appendix E-1: List of product and article categories

Chapter R12 of the REACH Information Requirements and Chemical Safety Assessment (IR&CSA) Technical Guidance Documents (ECHA, 2008) lists those Product Categories (PCs) and Article Categories (ACs) that are considered as being potentially relevant for the registration of substances. R12 has been updated, the most recent version is v2.0 dated 07.11.09. Examination of the PCs indicates, however, that while many describe consumer uses of chemical products, others refer to uses that are already regulated by other legislation (and hence which, in most cases, are exempt from REACH). In order that the TRA could be applied as an efficient screening tool, the list of PCs and ACs was reviewed to determine those which describe uses covered by REACH and which are generally considered to potentially result in significant exposures to the general public (including specific sub-sectors). The process used to achieve this was based on discussions during 2008-2009 within the ECHA consumer expert group, comprised of representatives of ECHA, ECETOC, RIVM, BfR, INERIS and the Danish EPA.

Please note that the user input tab of the TRA Consumer tool (May09,v1 and Dec09,v2) lists the PC and AC categories. An "n" notation on a PC or AC category on the TRA tool user input tab denotes that this category is not considered in the TRA. A PC or AC category is not addressed by the TRA Consumer tool when one of the three following reasons apply: (1) No relevant consumer use is expected to be associated with the category ["n- Consumer use not relevant"]; (2) Consumer use may not be totally ruled out for the category but there is a lack of adequate information for estimating a relevant value of consumer exposure at the present time [n-Assessment not in TRA], and (3) The category's consumer use and assessment is covered by other legislation (e.g. cosmetics, pharmaceuticals etc) [n-Use and assessment covered by other legislation]. See R12 for further information.

Table E-1 below lists the source/reference for the values of the parameters that are used in the exposure estimation for each of the categories within the tool. This table lists the product categories used in the December 2009 version of the ECETOC TRA consumer tool which are the same as those described in the R12 guidance document of November 2009 (v2.0 dated 07.11.09). The R12 PC and AC categories were revised in November 2009 and the new TRA tool v2 (December 2009) fully reflects this R12 update.

Table E-1: Source/reference for the values of the parameters used within the tool

Descriptor	Product Subcategory	Reference for values
PC1: Adhesives, sealants	Glues, hobby use	RIVM report 320104007/2007 ConsExpo DIY* product fact sheet: Glues from tubes section 3.1.1
	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	RIVM report 320104007/2007 ConsExpo DIY* product fact sheet: Tile glue section 3.7
	Glue from spray	RIVM report 320104007/2007 ConsExpo DIY* product fact sheet: Glue from spray section 3.10
	Sealants	RIVM report 320104007/2007 ConsExpo DIY* product fact sheet: Glue assemble sealants section 4.2
PC2_n: Adsorbents		n-Assessment not in TRA
PC3: Air care products	Air care, instant action (aerosol sprays)	Values are Conservative Expert estimates based on AISE 2009: Users can use other values if justified by appropriate data and references
	Air care, continuous action (solid and liquid)	Values are Conservative Expert estimates based on AISE 2009: Users can use other values if justified by appropriate data and references
PC4_n: Anti-freeze and de-icing products		n-Assessment not in TRA
PC7_n: Base metals and alloys		n-Consumer use not relevant
PC8_n: Biocidal products		n-Use and assessment covered by other legislation
PC9a: Coatings and paints, fillers, putties, thinners	Waterborne latex wall paint	RIVM report 320104008/2007 ConsExpo Paint fact sheet: Wall paint section 2.6
	Solvent rich, high solid, water borne paint	RIVM report 320104008/2007 ConsExpo Paint fact sheet: High solid paint section 2.4
	Aerosol spray can	RIVM report 320104008/2007 ConsExpo Paint fact sheet spraying paint section 3.2
	Removers (paint-, glue-, wallpaper-, sealant-remover)	RIVM report 320104007/2007 ConsExpo DIY* product fact sheet: Glue remover section 8.2
PC9b: Fillers, putties, plasters, modelling clay	Fillers and putty	RIVM report 320104007/2007 ConsExpo DIY* product fact sheet: Large hole fillers section 5.2.1
	Plasters and floor equalisers	RIVM report 320104007/2007 ConsExpo DIY* product fact sheet: Wall plaster section 6.2
	Modelling clay	RIVM report 612810012/2002 ConsExpo Children's toys fact sheet: sections 3.2.1 and 5.5.1
PC9c: Finger paints	Finger paints	RIVM report 612810012/2002 ConsExpo Children's toys fact sheet: Sections 5.4.2, 5.5.2, 3.4.3 and 3.4.4
PC11_n: Explosives		n-Consumer use not relevant
PC12: Fertilisers	Lawn and garden preparations	RIVM report 612810012/2002 ConsExpo Product fact sheet: Children's toys fact sheet section 3.3.1
PC13: Fuels	Liquids	Conservative Expert judgment based on the weight/volume of fuel contained in a 5 litre consumer petrol container and the surface area of hands; see below
PC14_n: Metal surface treatment products		n-Consumer use not relevant

Table E-1: Source/reference for the values of the parameters used within the tool *(cont'd)*

Descriptor	**Product Subcategory**	**Reference for values**
PC15_n: Non-metal surface treatment products		n-Assessment not in TRA
PC16_n: Heat transfer fluids		n-Assessment not in TRA
PC17_n: Hydraulic fluids		n-Assessment not in TRA
PC18_n: Ink and toners		n-Assessment not in TRA
PC19_n: Intermediate		n-Consumer use not relevant
PC20_n: Products such as ph-regulators, flocculants, precipitants etc		n-Consumer use not relevant
PC21_n: Laboratory chemicals		n-Consumer use not relevant
PC23_n: Leather tanning, dye, finishing, impregnation and care products		n-Assessment not in TRA
PC24: Lubricants, greases, and release products	Liquids	Conservative Expert judgment based on the weight/volume of oil contained in a 5 litre consumer oil container and the surface area of hands; see below
	Pastes	Conservative Expert judgment based on the weight/volume of an average paste lubricant of this type; see below
	Sprays	Conservative Expert judgment based on the weight/volume of a average spray lubricant of this type; see below
PC25_n: Metal working fluids		n-Consumer use not relevant
PC26_n: Paper and board dye, finishing and impregnation products etc		n-Consumer use not relevant
PC27_n: Plant protection products		n-Use and assessment covered by other legislation
PC28_n: Perfumes, fragrances		n-Use and assessment covered by other legislation
PC29_n: Pharmaceuticals		n-Use and assessment covered by other legislation
PC30_n: Photo-chemicals		n-Assessment not in TRA
PC31: Polishes and wax blends	Polishes, wax/cream (floor, furniture, shoes)	RIVM report 320104003/2006 ConsExpo Cleaning products fact sheet, furniture polish section 8.3.1
	Polishes, spray (furniture, shoes)	RIVM report 320104003/2006 ConsExpo Cleaning products fact sheet, furniture spray section 8.3.2
PC32_n: Polymer preparations and compounds		n-Consumer use not relevant
PC33_n: Semiconductors		n-Consumer use not relevant

Table E-1: Source/reference for the values of the parameters used within the tool *(cont'd)*

Descriptor	Product Subcategory	Reference for values
PC34_n: Textile dyes, finishing and impregnating products etc		n-Assessment not in TRA
PC35: Washing and cleaning products (including solvent based products)	Laundry and dish washing products	RIVM report 320104003/2006 ConsExpo Cleaning products fact sheet: Laundry hand wash and dishwashing section 3.1.2 and 4.1.3
	Cleaners, liquids (all purpose cleaners, sanitary products, floor-, glass-, carpet-, metal-cleaners)	RIVM report 320104003/2006 ConsExpo Cleaning products fact sheet floor cleaning liquids section 8.1.1
	Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners)	RIVM report 320104003/2006 ConsExpo Cleaning products fact sheet, sections 5.3, 7.1.1 and 9.1 (general, bathroom and glass respectively)
PC36_n: Water softeners		n-Consumer use not relevant
PC37_n: Water treatment chemicals		n-Consumer use not relevant
PC38_n: Welding and soldering products, flux products		n-Assessment not in TRA
PC39_n: Cosmetics, personal care products		n-Use and assessment covered by other legislation
PC40_n: Extraction agents		n-Assessment not in TRA
AC1_n: Vehicles		n-Assessment not in TRA
AC2_n: Machinery		n-Assessment not in TRA
AC3_n: Electrical batteries		n-Assessment not in TRA
AC4_n: Stone, plaster, cement, glass and ceramic articles		n-Assessment not in TRA
AC5: Fabrics, textiles and apparel	Clothing (all kinds of materials), towel	Könemann, 1998 RIVM report 613320002
	Bedding, mattress	Conservative Expert judgment based on weight/volume of bedding/mattress and estimated contact area; see below
	Toys (cuddly toy)	RIVM report 612810012/2002 Children's toys fact sheet section 2.2.2
	Car seats, chairs, flooring	Conservative Expert judgment based on weight/volume of seats/chairs/flooring and estimated contact area; see below
AC6: Leather articles	Purse, wallet, covering steering wheel (car)	Conservative Expert judgment based on weight/volume of this type of leather article and estimated contact area; see below
	Footwear (shoes, boots)	Conservative Expert judgment based on weight/volume of this type of leather article and estimated contact area; see below
	Furniture (sofa)	Conservative Expert judgment based on weight/volume of this type of leather article and estimated contact area; see below
AC7_n: Metal articles		n-Assessment not in TRA

***Table E-1: Source/reference for the values of the parameters used within the tool** (cont'd)*

Descriptor	Product Subcategory	Reference for values
AC8: Paper products	Diapers	Conservative Expert judgment based on weight/volume of this type of paper article and estimated contact area; see below
	Sanitary towels	Conservative Expert judgment based on weight/volume of this type of article and estimated contact area; see below
	Tissues, paper towels, wet tissues, toilet paper	RIVM report 320104003/2006 ConsExpo Cleaning products fact sheet: Wet tissues section 5.4 Weerdesteijn *et al*, 1999 RIVM report 612810008, appendix 1
	Printed paper (papers, magazines, books)	RIVM report 612810012/2002 ConsExpo Children's toys fact sheet sections 3.3.1 and 3.4.1
AC10: Rubber articles	Rubber handles, tyres	Conservative Expert judgment based on weight/volume of this type of article and estimated contact area; see below
	Flooring	Conservative Expert judgment based on weight/volume of this type of article and estimated contact area; see below
	Footwear (shoes, boots)	RIVM report 320104003/2006 ConsExpo General fact sheet section 4.2
	Rubber toys	Conservative Expert judgment based on weight/volume of this type of article and estimated contact area; see below
AC11: Wood and wood furniture	Furniture (chair)	Conservative Expert judgment based on weight/volume of this type of article and estimated contact area; see below
	Walls and flooring (also applicable to non-wood materials)	Conservative Expert judgment based on weight/volume of this type of article and estimated contact area; see below
	Small toys (car, train)	RIVM report 612810012/2002 ConsExpo Children's toys fact sheet section 3.2.2
	Toys, outdoor equipment	Conservative Expert judgment based on weight/volume of this type of article and estimated contact area; see below
AC13: Plastic articles	Plastic, larger articles (plastic chair, PVC-flooring, lawn mower, PC)	Könemann, 1998 RIVM report 613320002
	Toys (doll, car, animals, teething rings)	Könemann, 1998 RIVM report 613320002 RIVM report 612810012/2002 ConsExpo Children's toys fact sheet sections 2.2.1 and 2.2.3
	Plastic, small articles (ball pen, mobile phone)	Könemann, 1998 RIVM report 613320002
AC30_n: Other articles		n-Assessment not in TRA
AC31_n: Scented clothes		n-Assessment not in TRA
AC32_n: Scented eraser		n-Assessment not in TRA
AC34_n: Scented Toys		n-Assessment not in TRA
AC35_n: Scented Paper articles		n-Assessment not in TRA
AC36_n: Scented CD		n-Assessment not in TRA
AC38_n: Packaging material for metal parts, releasing grease/metal corrosion inhibitors		n-Assessment not in TRA

* DIY: Do it yourself. AISE 2009=AISE Habits and Practices table at http://www.aise.eu/reach/exposureass_sub2.htm

Appendix E-2: Default assumptions underpinning the TRA

The basis of the default values used to populate the TRA for those relevant Product Categories and subcategories is shown in the above and in the 'Default' tab in the TRA tool. The RIVM report 320104002/2006 ConsExpo general fact sheet has been used as general reference. Where specific default values have been incorporated, their source has been identified (e.g. relevant ConsExpo fact sheet). In some instances, recourse to expert judgement has been used. In these cases, the expert judgement reflects discussions during 2008-2009 within the ECHA consumer expert group comprised of representatives of ECHA, ECETOC, RIVM, BfR, INERIS and the Danish EPA.

The 'Defaults' tab of the consumer TRA tool lists the routes of exposure that are considered to be relevant for each PC and AC category. The 'Defaults' tab also offers a brief explanation of the basis on which the relevant routes have been decided. This information is reproduced in Table E-2 below.

Table E-2: Justifications for route of exposure exemptions in ECETOC TRA

		Default Route of Relevance					
		ADULT			*CHILD*		
Descriptor	***Product Subcategory***	***Dermal***	***Oral***	***Inhalation***	***Dermal***	***Oral***	***Inhalation***
PC1: Adhesives, sealants	Glues, hobby use	y	n [0]	y			
	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	y	n [0]	y			
	Glue from spray	y	n [0]	y			
	Sealants	y	n [0]	y			
PC3: Air care products	Air care, instant action (aerosol sprays)	n [1]	n [0]	y			
	Air care, continuous action (solid and liquid)	y	n [0]	y			
PC9a: Coatings, paints, thinners, removers	Waterborne latex wall paint	y	n [0]	y			
	Solvent rich, high solid, waterborne paint	y	n [0]	y			
	Aerosol spray can [5]	n [1]	n [0]	y			
	Removers (paint-, glue-, wallpaper-, sealant-remover)	y	n [0]	y			
PC9b: Fillers, putties, plasters, modelling clay	Fillers and putty	y	n [0]	y			
	Plasters and floor equalizers	y	n [0]	y			
	Modelling clay				y	y	n [2]
PC9c: Finger paints	Finger paints				y	y	n [2]
PC12: Fertilizers	Lawn and garden preparations	y	n [0]	n [2]		y [3]	
PC13: Fuels	Liquids	y	n [0]	y			

Table E-2: Justifications for Route of exposure exemptions in ECETOC TRA *(cont'd)*

		Default Route of Relevance					
		ADULT			*CHILD*		
Descriptor	***Product Subcategory***	***Dermal***	***Oral***	***Inhalation***	***Dermal***	***Oral***	***Inhalation***
PC24: Lubricants, greases, and release products	Liquids	y	n [0]	y			
	Pastes [5]	y	n [0]	n [2]			
	Sprays	y	n [0]	y			
PC31: Polishes and wax blends	Polishes, wax / cream (floor, furniture, shoes)	y	n [0]	y			
	Polishes, spray (furniture, shoes)	y	n [0]	y			
PC35: Washing and cleaning products (including solvent based products)	Laundry and dish washing products	y	n [0]	y			
	Cleaners, liquids (all purpose cleaners, sanitary products, floor-, glass-, carpet-, metal-cleaners)	y	n [0]	y			
	Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners)	y	n [0]	y			
AC5: Fabrics, textiles and apparel	Clothing (all kind of materials), towel	y	n [0]	y [6]		y	
	Bedding, mattress	y	n [0]	y [7]		y	
	Toys (cuddly toy) [4]				y	y	n [2]
	Car seat, chair, flooring	y	n [0]	y [6]			
AC6: Leather articles	Purse, wallet, covering steering wheel (car)	y	n [0]	y			
	Footwear (shoes, boots)	y	n [0]	y			
	Furniture (sofa)	y	n [0]	y			
AC8: Paper articles	Diapers				y	n [0]	n [2]
	Sanitary towels	y	n [0]	n [2]			
	Tissues, paper towels, wet tissues, toilet paper	y	n [0]	y			
	Printed paper (papers, magazines, books)	y	n [0]	y		y [3]	
AC10: Rubber articles	Rubber handles, tyres	y	n [0]	y			
	Flooring	y	n [0]	y			
	Footwear (shoes, boots)	y	n [0]	y			
	Rubber toys [4]				y	y	n [2]
AC11: Wood articles	Furniture (chair)	y	n [0]	y			
	Walls and flooring (also applicable to non-wood materials)	y	n [0]	y			
	Small toys (car, train) [4, 8]				y	y	n [2]
	Toys, outdoor equipment [4, 9]				y	y	n [2]

***Table E-2: Justifications for Route of exposure exemptions in ECETOC TRA** (cont'd)*

		Default Route of Relevance					
		ADULT			*CHILD*		
Descriptor	***Product Subcategory***	***Dermal***	***Oral***	***Inhalation***	***Dermal***	***Oral***	***Inhalation***
AC13: Plastic articles	Plastic, larger articles (plastic chair, PVC-flooring, lawn mower, PC)	y	n [0]	y			
	Toys (doll, car, animals, teething rings) [4]				y	y	n [2]
	Plastic, small articles (ball pen, mobile phone)	y	y	y			

Justifications for route:

[0] Oral exposure does not occur as part of the intended product use
[1] Aerosol: Spray jet is diverted from user – no dermal exposure
[2] Formulations contain negligible amounts of volatiles or particulate matter – no inhalation exposure
[3] Mouthing behaviour – no other relevant exposure
[4] Sentinel child
[5] Exposure during application
[6] Exposure example: flame retardants and plasticizers
[7] Exposure example: flame retardants
[8] Article, including e.g. dried paints
[9] Exposure example: wood preservatives or varnishes on climbing frame

Blank field indicates that no exposure assessment is performed because the adult (usually) or the child exposure is judged to adequately cover the exposure estimation for the category.

Figure E-2: Default parameters for estimating exposure in different product categories

Default Parameters for Estimating Exposure in Different Product Categories

Descriptor	Product Subcategory	Default Route of Relevance ADULT Dermal	ADULT Oral	ADULT Inhalation	CHILD Dermal	CHILD Oral	CHILD Inhalation	Product Ingredient (g/g)	Dermal Exposure: Body Part Considered	Adult Contact Area (cm²)	Child Contact Area (cm²)
PC1:Adhesives, sealants	Glues, hobby use	y	n	y	n	n	n	0,3	1: fingertips	35,7	
	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	y	n	y	n	n	n	0,3	3 hands	428,8	
	Glue from spray	y	n	y	n	n	n	0,3	1: fingertips	35,7	
	Sealants	y	n	y	n	n	n	0,3	1: fingertips	35,7	
PC2_n: Adsorbents											
PC3:Air care products	Aircare, instant action (aerosol sprays)	n	n	y	n	n	n	0,5			
	Aircare, continuous action (solid & liquid)	y	n	y	n	n	n	0,1	1: fingertips	35,7	
PC4_n:Anti-freeze and de-icing products											
PC5_n											
PC6_n											
PC7_n: Base metals and alloys											
PC8_n: Biocidal products											
PC9a: Coatings, paints, thinners, removers	Waterborne latex wall paint	y	n	y	n	n	n	0,5	2: inside hands / one hand / palm of hands	428,8	
	Solvent rich, high solid, water borne paint	y	n	y	n	n	n	0,5	2: inside hands / one hand / palm of hands	428,8	
	Aerosol spray can	n	n	y	n	n	n	0,5			
	Removers (paint-, glue-, wall paper-, sealant-remover)	y	n	y	n	n	n	0,9	3: hands	857,5	
PC9b: Fillers, putties, plasters, modelling clay	Fillers and putty	y	n	y	n	n	n	1	1: fingertips	35,7	
	Plasters and floor equalizers	y	n	y	n	n	n	1	3: hands	857,5	
	Modelling clay	n	n	n	y	y	n	0,1	3: hands		254,4
PC9c: Finger paints	Finger paints	n	n	n	y	y	n	0,5	3: hands		254,4

User Input | Results by Sentinel Prod | Results by Prod Subcat | Dermal (Prod Subcat) | Oral (Prod Subcat) | Inhalation (Prod Subcat) | **Defaults**

Appendix E-3: Population specific values for adults and children

The basis of the core default values that describe population parameters (for adults and children) and are used to populate the TRA is shown below (Default2 tab in the tool). The RIVM report 320104002/2006 ConsExpo general fact sheet has been used as a general reference. It should be noted that the room volume of 20 m³ is the value used for an 'unspecified room' in the above fact sheet (Table 4, page 14) and that this would cover a range of room types as values between 15 and 22 m³ are stated in the same report for Dutch kitchens and bedrooms (Tables 3 and 4, pages 13 and 14).

Figure E-3: Sub-population specific default parameters (Defaults2 tab)

Sub-Population Specific Default Parameters

Default Surface Areas (Dermal Exposure)					
	Child	Adult	Child	Adult	
	Skin Contact Area		% of body surface		Comment
Whole body	4800	17500			
1: fingertips	10,6	35,7	0,2	0,20	5 finger tips
2: inside hands / one hand / palm of hands	127,2	428,8	2,7	2,5	inside hands = one hand
3: hands	254,4	857,5	5,3	4,9	
4: hands and forearms	556,8	2082,5	11,6	11,9	
5: upper part of the body	2400	8750	50	50	half body surface
6: lower part of the body	2400	8750	50	50	half body surface
7: whole body except feet, hands and head	3393,6	14315	70,7	81,8	
8: whole body	4800	17500	100	100	
Default Surface Areas (Oral Exposure)					
	Child	Adult			
1: some fingertips	10,6	35,7			same as dermal
2: fingers one hand	63,6	214,4	1,3	1,2	
3: inside one hand, all fingers	127,2	428,8	2,7	2,5	
4: area product mouthed	10	NA			
Other default parameters					
	Child	Adult			
Body Weight (kg)	10	60			
Inhalation Rate (m^3/hr)	not used	1,37			
Room volume (m^3)	not used	20			
Weight fraction (sprays only)	not used	1			

od Subcat / Dermal (Prod Subcat) / Oral (Prod Subcat) / Inhalation (Prod Subcat) / Defaults / **Defaults2**

APPENDIX F: SIMPLE STEPS FOR REFINEMENT BEYOND TIER 1 CONSUMER EXPOSURE PREDICTIONS

There are some instances in which the conservative nature of the TRA tool is such that it results in consumer exposure estimates that exceed plausible levels. A few fairly simple 'reality checks' can be applied to the TRA approach that result in exposure levels that, while conservative, are closer to plausible values. These simple applications result in more appropriate exposure estimates and require limited or no additional data without the need for more sophisticated modelling tools associated with a Tier 2 consumer exposure assessment.

This appendix lists a number of possible refinements that can be used with the Consumer part of the TRA. These refinements, workarounds and fixes allow revision of certain parameters to allow a 'Tier 1+' or 'Tier 1.5' iteration of the exposure estimates made by the TRA tool, in order to provide more realistic estimates, if appropriate.

The simplest element of refinement is to substitute realistic values for the defaults in the parameters that are susceptible of selection by the user in the User Input sheet. These 'selectable' parameters are the fraction of substance in product (PI) and a second route specific parameter for each relevant exposure route (the contact area [CA] for the dermal and oral routes, and the amount of product used [A] for the inhalation route).

Some additional possibilities for refinement are described below.

Appendix F-1: Inhalation

F-1.1 Use of saturated vapour concentration as a limit on exposure

For non-aerosol products, instantaneous release of 100% of any substance with vapour pressure ≥10 Pa is assumed. This assumption can result in air concentrations that far exceed the upper bound saturated vapour concentration for many scenarios in the tool (example below). The impact of this assumption on the estimated exposure, expressed in mg/kg/day, increases linearly with exposure duration. The calculation of saturated vapour concentration as an upper bound can be applied to any of the inhalation scenarios for non-spray products. This can be done as a two-step process:

a. Using the standard equation (Hawkins *et al*, 1991), saturated vapour concentration (SVC) of a substance 'i' in ppm can be calculated from its vapour pressure:

$$SVC_i \text{ (ppm)} = (VP_i \text{ X } 10^6) / VP_{ambient}$$

b. Using the standard equation [(ACGIH booklet 'Threshold Limit Values (TLVs™) for Chemical Substances and Physical Agents and Biological Exposure Indices (BEIs™)] the saturated vapour concentration in ppm can be converted to mg/m³.

SVC (in mg/m³) = (SVC in ppm) X (MW/24.45) [at standard temperature and pressure]

This can be used in place of the (amount used X weight fraction/room size) component of the TRA equation. Instead, the saturated vapour concentration in mg/m³ can be multiplied by the inhalation rate, duration of exposure and divided by body weight to get the exposure in mg/kg/day.

Example – TRA Lubricant Scenario (Liquids, non-spray)

- TRA Scenario: 2500 g (5000 g used X 0.5 weight fraction) released into 20 m³ room, complete instantaneous volatilisation, no air exchange, 4-hour exposure.
- Estimated air concentration using TRA calculation (5000 g X 0.5 weight fraction released instantaneously into 20 m³ room):

VP Band	Concentration in mg/m³
≥10	125000
1 - <10	12500
0.1 - <1	1250
<0.1	125

- Comparison with saturated vapour concentration:

VP in Pa	MW	Saturated vapour concentration (mg/m³)	SVC lower than TRA by factor of:
1	10	4	3125
1	100	40	310
10	300	121	103
10	10	40	3125
10	100	404	310
50	300	1211	103
50	10	202	619
50	100	2018	62
50	300	6055	21

F-1.2 Inclusion of air change rates

Even in homes with closed doors and windows and no active ventilation a certain low level of air exchange occurs. Default values for Air Changes per Hour (ACH) include 0.6 (RIVM General Fact Sheet, 2007) and 0.45 ACH (US EPA Exposure Factors Handbook, 1997). Higher rates of air change would be expected when active steps are taken to increase home ventilation.

Table F-1 provides an estimate of the dilution factor that is obtained when the associated air changes per hour are utilised for the exposure times (0.3, 1, 2, 2.2, 4, 6, and 8 hours) specified in the TRA tool.

The dilution factor X exposure estimate with no ventilation = exposure estimate with ventilation.

The dilution factor is calculated as:

(room volume) / (room volume + [ACH X time in hours X room volume])

Table F-1: Dilution factors to apply based upon air changes per hour (factors are independent of room volume)

Time (Hrs)	Air Changes per Hour (ACH)				
	0.5	**1**	**2**	**3**	**6**
0.3	0.86	0.75	0.6	0.5	0.34
1	0.67	0.5	0.33	0.25	0.14
2	0.5	0.33	0.2	0.14	0.08
2.2	0.48	0.31	0.19	0.13	0.07
4	0.33	0.2	0.11	0.08	0.04
6	0.25	0.14	0.08	0.05	0.03
8	0.2	0.11	0.06	0.04	0.02

F-1.3 Interdependence of variables

In several scenarios, using the most conservative assumptions (small room size and high use volume) result in combinations of use descriptors that are inappropriate as they are mismatched. For example, for the lubricant scenario, while the amount of product used (5000 g) may be representative of lubrication of a larger motor, such a scenario would take place in a garage or outdoors. Similarly, lawn care products are designed for outdoor use, and so large amounts should be matched with a scenario that reflects outdoor use, or use amounts should be adjusted lower for indoor use. The TRA tool does not allow for such changes *per se*, but because the supporting default assumptions are clearly stated (see Appendix E), then it is possible for users to identify where such mismatch might be considered to occur and to account accordingly (assuming suitable supporting justification can be provided).

Appendix F-2: Dermal

F-2.1 Use of dermal absorption

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

- The fixed fraction model is a simple model for which the only parameter required is the uptake fraction ('percentage absorbed via skin'). The disadvantage is that experimental results are hardly available and therefore 100% absorption has to be assumed as default value.
- Skin permeation uptake values can be easily calculated - at least for aqueous solutions. They are either based on the steady-state rate of absorption ('flux' measured in µg/h/cm^2) or the permeability constant K_p (in cm/hr) calculated by dividing the flux by the concentration of the test substance (measured in µg/cm^3). A simple diffusion through skin uptake model has already been described in the HERA Guidance Document Methodology (HERA, 2005) on page 75:

$$C' = C \times K_p \times t$$

C product concentration, in mg/cm^3
K_p dermal penetration rate, in cm/hr
t duration of exposure or contact, in hr

C' is the steady-state dermally absorbed dose per unit area per event using an adapted equation of Fick's first law (designated as equation 5.10 in US EPA, 1992). This equation is intended for preparations and not for exposure to particles. Therefore, it should not be used for modifying dermal exposure to articles (e.g. footwear) or should be used with caution. The US EPA recommends the use of this equation for inorganic substances or highly ionised organic chemicals. And for organic compounds, it proposes to consider a more complex model that accounts for continued exposure to the substance absorbed in the *stratum corneum* after exposure has ended (US EPA, 2004).

K_p can be estimated using experimental data or empirical formulae which use the octanol/water partition coefficient K_{ow} and the molecular weight to predict permeability. Alternatively, the US EPA (2004) provides K_p values for some substances that can also be considered. [Six of these empirical formulae have been implemented in the ConsExpo 4.1 program, those from Fiserova-Bergerova *et al*, Guy and Potts, McKone and Howd, Robinson, Wilschut *et al*, and Bogen].

The following general estimation equation can be used to predict K_p for organic compounds in aqueous solutions. It is designated as equation 5.8 in US EPA (1992) implemented in the EpiSuite/DermWin Software:

$$\log K_p \text{ (cm/hr)} = -2.72 + 0.71 \log K_{ow} - 0.0061 \text{ MW}.$$

In the case of LAS the calculated log K_{ow} is 2.02 and the molecular weight MW is 320.4 g/mol resulting in a log K_p of -3.245 and a K_p of 0.00057 cm/hr.

(Note that the equation mentioned and used above was very slightly revised by US EPA in 2004 upon consideration of an additional data set. The revised equation is referred to as Equation 3.8 in US EPA (2004) and is as follows:

$$\log K_p = -2.80 + 0.66 \log K_{ow} - 0.0056 \text{ MW}.$$

It is important to mention that modifying the dermal exposure using the K_p value results in an internal dose. It may be necessary to modify the reference value (e.g. DNEL) if the reference value is based on an external dose.

F-2.2 Introduction of additional manual transfer factors

Users can choose to make simple modifications, such as addition of manual transfer factors, to make more realistic exposure estimates. Consumer exposure equations which include the use of transfer factors are described in SDA (2005) and HERA (2005). Equations are similar to those in the TRA, but with the addition of a factor to represent percent retained on skin or transferred to skin, depending upon product type. Values for transfer factors are provided for several specific chemicals in the SDA document.

Appendix F-3: Use of product sub category only

When a substance is used only in a specific subcategory or subcategories of an overall product category, the user can select the relevant category(ies) rather than use the sentinel product. As the sentinel product represents the most conservative exposure for all products that belong to it, selecting a specific subcategory will result in a lower exposure value for all scenarios except the one upon which the sentinel product is based.

Appendix F-4: Checks on mass balance

The TRA tool provides conservative assumptions for each exposure route which should be checked for mass-balance particularly when estimating multi-route exposures for a single product. For example, the inhalation route assumes 100% of product is released to air and the dermal routes assume that 100% of the product in contact with skin is absorbed dermally. The user may consider if, in application, 'double-counting' occurs and should be adjusted for.

Appendix F-5: Modification of default parameters with justification

For each scenario, there are default parameters that can be readily modified and also a number of 'fixed' default parameters that are documented in the two 'Default' spreadsheets. When a user has a rationale to alter these values, they can choose to do so, including justification that supports the change. If these changes apply to locked values in the 'Default' spreadsheet, then the user can apply these changes in a manual calculation outside of the tool using the algorithm in the TRA.

F-5.1 Revise existing default values e.g. Input of sector specific additional data

If available, input of sector specific additional data on operational conditions such as duration of use or amount of product per use from Sector specific Tier 2 tools may be used. These data can be entered into a TRA format to give a Tier 1.5 refined screening exposure estimate, that is more realistic than pure TRA Tier 1 but less complicated that full Tier 2. These refinements may be called Specific PCs (SPCs) or Specific ACs (SACs). Since some of these parameters are locked, the user will need to perform manual calculations outside of the tool. As the parameters are linearly related, this can be calculated by multiplying the estimated exposure concentration by the ratio of the new parameter to the default parameter.

F-5.2 Checks with product purpose / lifetime

There are several instances where defaults may be adjusted by considering information on product function or lifetime. For example, for the TRA subcategories 'fillers and putties' and 'plasters and floor equalisers', the default assumptions are that the weight fraction is 1 and 100% volatilises for the inhalation exposure estimate; under these assumptions the product would be ineffective for the intended use. As another example, fabric dyes are designed to meet colour fastness specifications which set limits on transfer from the fabric. When data are available to support adjustments, these could be provided and the TRA exposure estimate could be adjusted by an appropriate factor.

Possible data sources to consider for refinement of default factors include:

a. Emission Scenario Documents (may contain information such as service life, % volatile and % non-volatile components): http://www.oecd.org/document/46/0,3343,en_2649_34373_2412462_1_1_1_37465,00.html.
b. Product performance specifications.

F-5.3 Reality check on exposure activity patterns

Based on knowledge of use, modifications to TRA worst case assumptions related to exposure duration and frequency of use can be made, applied again in a manual calculation based on TRA algorithms. For example, while the TRA tool assumed daily product use, for many of the products typical frequency of use is much lower (some examples are in Table F-2). These considerations may be important in particular when exposures are being compared with chronic systemic DNELs. The WESTAT (1987) document cited below also includes information on duration of use.

Table F-2: Data on product use frequency

Product type			Frequency of use	
TRA product category	**TRA product subcategories**	**EPA-defined product category**	**TRA default value**	**WESTAT (EPA report) values median (5^{th}- 95^{th} percentile range)**
PC1: Adhesives, sealants	Glues DIY-use (carpet glue, tile glue, wood parquet glue); Glues, hobby use; Sealants	Contact cements, super glues, spray adhesives	1 event/day	3/year (1-28/year)
PC4: Anti-freeze and de-icing products	Removers (paint-, glue-, wallpaper-, sealant-remover)	Adhesive removers (general purpose, tile, and wallpaper)	1 event/day	1/year (1-17/year)
PC6_n: Automotive care products		Tire/hubcap cleaners	No data	4/year (1-50/year)
PC9: Coatings and paints, fillers, putties, thinners	Waterborne latex wall paint; Solvent rich, high solid, water borne paint; Hardened dried paint; Finger paint, face paint; Fillers and putty; Plasters and floor equalisers	Latex paint	1 event/day	2/year (1-10/year)
		Oil paint		1/year (1-12/year)
	Aerosol spray can	Aerosol spray paint	1 event/day	2/year (1-12/year)
	Removers (paint-, glue-, wallpaper-, sealant-remover)	Paint removers/strippers	1 event/day	3/year (1-12/year)
PC10: Building and construction preparations not covered elsewhere	Removers (paint-, glue-, wallpaper-, sealant-remover)	Paint removers/strippers	1 event/day	3/year (1-12/year)
PC24: Lubricants, greases, and release products	Liquids; Paints; Sprays	Other lubricants (excl. automotive)	1 event/day	4/year (1-50/year)

APPENDIX G: NAME, DESCRIPTION AND BACKGROUND OF ENVIRONMENTAL RELEASE CATEGORIES (COPIED FROM CHAPTER R16 OF THE REACH GUIDANCE)

ERC no.	Name	Description
ERC1	Production of chemicals	Production of organic and inorganic substances in chemical, petrochemical, primary metals and minerals industry including intermediates, monomers using continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions
ERC2	Formulation of preparations	Mixing and blending of substances in (chemical) preparations in all types of industries such as paints and do-it-yourself products, pigment paste, fuels, household products (cleaning products), lubricants etc.
ERC3	Formulation in materials	Mixing or blending of substances, which will be physically or chemically bound into or onto a matrix (material) such as plastics additives in master batches or plastic products. For instance a plasticizers or stabilizers in PVC-master batches or products, crystal growth regulator in photographic films etc.
ERC4	Industrial use of processing aids	Industrial use of processing aids in continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions. For example, solvents used in chemical reactions or the ‘use’ of solvents during the application of paints, lubricants in metal working fluids, anti-set off agents in polymer moulding/casting
ERC5	Industrial use resulting in inclusion into or onto a matrix	Industrial use of substances (non-processing aids), which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyeing of textile fabrics and leather products, metal plating and galvanizing.
ERC6a	Industrial use of intermediates	Use of intermediates in primarily the chemical industry using continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions, for the synthesis (manufacture) of other substances. For instance the use of chemical building blocks (feedstock) in the synthesis of agrochemicals, pharmaceuticals, monomers etc.
ERC6b	Industrial use of reactive processing aids	Industrial use of reactive processing aids in continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions. For example the use of bleaching agents in the paper industry.
ERC6c	Production of plastics	Industrial use of monomers in the production of plastics (thermoplastics), polymerization processes. For example the use of vinyl chloride monomer in the production of PVC.
ERC6d	Production of resins/rubbers	Industrial use of chemicals (cross-linking agents, curing agents) in the production of thermosets and rubbers, polymerization processes. For instance the use of styrene in polyester production or vulcanization agents in the production of rubbers.
ERC 7	Industrial use of substances in closed systems	Industrial use of substances in closed systems. Use in closed equipment, such as the use of liquids in hydraulic systems, cooling liquids in refrigerators and lubricants in engines and dielectric fluids in electric transformers and oil in heat exchangers.
ERC8a	Wide dispersive indoor use of processing aids in open systems	Indoor use of processing aids by the public at large or professional use. Use (usually) results in direct release into the environment, for example, detergents in fabric washing, machine wash liquids and lavatory cleaners, automotive and bicycle care products (polishes, lubricants, de-icers), solvents in paints and adhesives or fragrances and aerosol propellants in air fresheners.

ERC no.	Name	Description
ERC8b	Wide dispersive indoor use of reactive substances in open systems	Indoor use of reactive substances by the public at large or professional use. Use (usually) results in direct release into the environment, for example, sodium hypochlorite in lavatory cleaners, bleaching agents in fabric washing products, hydrogen peroxide in dental care products
ERC8c	Wide dispersive indoor use resulting in inclusion into or onto a matrix	Indoor use of substances (non-processing aids) by the public at large or professional use, which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyeing of textile fabrics.
ERC8d	Wide dispersive outdoor use of processing aids in open systems	Outdoor use of processing aids by the public at large or professional use. Use (usually) results in direct release into the environment, for example, automotive and bicycle care products (polishes, lubricants, de-icers, detergents), solvents in paints and adhesives.
ERC8e	Wide dispersive outdoor use of reactive substances in open systems	Outdoor use of reactive substances by the public at large or professional use. Use (usually) results in direct release into the environment, for example, the use of sodium hypochlorite or hydrogen peroxide for surface cleaning (building materials)
ERC8f	Wide dispersive outdoor use resulting in inclusion into or onto a matrix	Outdoor use of substances (non-processing aids) by the public at large or professional use, which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives.
ERC9a	Wide dispersive indoor use of substances in closed systems	Indoor use of substances by the public at large or professional (small scale) use in closed systems. Use in closed equipment, such as the use of cooling liquids in refrigerators, oil-based electric heaters.
ERC9b	Wide dispersive outdoor use of substances in closed systems	Outdoor use of substances by the public at large or professional (small scale) use in closed systems. Use in closed equipment, such as the use of hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids in automotive brake systems.
ERC10a	Wide dispersive outdoor use of long-life articles and materials with low release	Low (no intended) release of substances included into or onto articles and materials during their service life from outdoor use. Such as metal, wooden and plastic construction and building materials (gutters, drains, frames etc.)
ERC10b	Wide dispersive outdoor use of long-life articles and materials with high or intended release	Substances included into or onto articles and materials with high or intended release during their service life from outdoor use. Such as tires, treated wooden products, treated textile and fabric like sun blinds and parasols and furniture, zinc anodes in commercial shipping and pleasure craft, and brake pads in trucks or cars.
ERC11a	Wide dispersive indoor use of long-life articles and materials with low release	Low (no intended) release of substances included into or onto articles and materials during their service life from indoor use. For example, flooring, furniture, toys, construction materials, curtains, footwear, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing).
ERC11b	Wide dispersive indoor use of long-life articles and materials with high or intended release	Substances included into or onto articles and materials with high or intended release during their service life from indoor use. For example: release from fabrics, textiles (clothing, floor rugs) during washing.
ERC12a	Industrial processing of articles with abrasive techniques (low release)	Substances included into or onto articles and materials are released (intended or not) from the article matrix as a result of processing by workers. These are processes typically related to PROC 21, 24, 25. Processes where the removal of material is intended but the expected release remains low include for example cutting of textile, cutting, machining or grinding of metal or polymers in engineering industries.
ERC12b	Industrial processing of articles with abrasive techniques (high release)	Substances included into or onto articles and materials are released (intended or not) from/with the article matrix as a result of processing by workers. These are processes typically related to PROC 21, 24, 25. Processes, where the removal of material is intended and high amounts of dust may be expected include for example sanding operations or paint stripping by shotblasting.

APPENDIX H: GUIDANCE FOR DEVELOPING AND DOCUMENTING SPECIFIC ERCS

Background for developing specific ERCs

The IR&CSA guidance generally acknowledges that an "ERC should be used as a starting point for emission estimation". The IR&CSA guidance explicitly encourages the use of more refined or specific information for emissions from industrial sources. Describing the typical use of substances in a sector may lead to emission estimations which are typical for a sector. Such emission estimations are a first refinement of the ERCs. They can be refined further by site-specific emission estimates (taking into account specific risk management measures, amounts used, discharge rates, dilution, etc) or by measured emission data.

Specific ERC development – Multistep-process

This section outlines the general process via which SPERCs can be obtained. It is intended as guidance for the development of SPERCs. In theory, sector SPERCs encompass emission relevant information for all life-cycle stages and are based on sector specific knowledge. Where possible they should capture information on use rates, emission fractions, and risk management measures (including their efficiency). In that manner, SPERCs represent typical emission situations for applications / processes for sector specific uses of substances. The development of SPERCs encompasses the collection and evaluation of information, to yield realistic and validated SPERCs.

Sector organisations and specific ERCs

Sector organisations may play a central role in constructing such typical emission scenarios. Via their members they may collect and evaluate the information. Applying judgement based on the application knowledge in the sector, they define typical values of substance use rates, emission fractions, and risk management measures. In that manner, the sector organisations apply a form of peer review and thus ensure that the SPERCs are based on reliable information. The judgements made in the development of the SPERCs may become part of the documentation of the SPERCs.

Developing SPERCs in five steps

Definition of scope

First, the scope of the emission estimation needs to be defined. This involves clarifying which processes and/or application types need to be described. As a result, the applicability domain of a SPERC is clearly defined and can be communicated in the supply chain. In order to ensure consistency, a link should be made to the ERC which is pertinent to the SPERC under development (See Appendix I for the AISE examples on technical cleaning and surface treatment). All these SPERCs for the industrial use of cleaning and maintenance products are based on the ERC Industrial use of processing aids (ERC 4).

Information

SPERCs require information reflecting, for example, typical emission fractions, risk management measures which are implemented in a typical operation and typical product use rates. Such information can be obtained from OECD-ESDs, in-house application knowledge, or information gathered via customer queries. Emission fractions need to be developed. Where available they may be based on measured emitted amounts. Alternatively, the application knowledge may be used to develop approximations of the emission fractions. Measures for managing environmental risks generally reduce emissions. Hence, SPERCs need to specify the type of risk management measure and its respective efficiency. The efficiency may be inferred e.g. from measurements, or by specific knowledge in the sector. As implemented so far, RMMs are a key element. They are listed in the release sheets of the ECETOC TRA ENV.

Evaluation and processing

SPERCs are a refinement to the conservative ERCs and represent typical sector specific emission scenarios. The information obtained in the collection process should be evaluated with regard to what extent the collected information represents typical emission situations. This evaluation may encompass the definition of typical values for e.g. emission fractions, risk management efficiency, or product use rates. Among others, professional judgment or statistical evaluation may be applied in the evaluation process. Developing SPERCs in a sector organisation can be viewed as a peer-review process to ensure that SPERCs reflect the relevant knowledge available in the sector.

Documentation of SPERCs

The regulatory acceptance of SPERCs hinges on the reliability and transparency of the information used in their creation. Consequently, it should be possible to grasp from a single document to what extent a SPERC differs for the ERC given in the IR&CSA guidance, what input information was used and how this information was processed in their construction. Appendix 1 shows, for a selection of SPERCs, how the information underlying the emission assessment can be tabulated. The evaluation process for each SPERC may be documented in a separate fact sheet, two draft examples of which are shown in Tables H-1 and H-2.

Availability of SPERCs

Currently, few SPERCs have been constructed and reside with the sector organisations. In the future, they should be available for the generation of REACH Exposure Scenarios. To that end, it is desirable that they be deposited in a central database. At present, such a database does not exist. However, it may be developed as part of the exposure scenario libraries of the CSA/CSR IT-tool or as part of the Generic Exposure Scenario libraries.

SPERC coding

A systematic coding naming of SPERCs is desirable to facilitate electronic searches and, hence, a prerequisite for rendering them available in the yet to be developed Exposure Scenario library. The codes for SPERCs consist of several elements. Part 1 identifies the entity responsible for the SPERC development (e.g. AISE, FEICA, ECETOC etc). Part 2 uses a letter code to identify the scope of the SPERC (i.e. M for substance manufacturing, F for formulation, I for industrial use, and CP to indicate wide dispersive uses by consumers and/or professionals, and S for service life). Part 3 is for further specification, i.e. for distinguishing emission patterns. It relates directly to emission fractions (i.e. solvent- and water-borne uses of substances). This third element can have further subclasses which are indicated by hyphenation (e.g. AISE.I.1-1A systematic coding naming of FEICA, ECETOC etc).

Table H-1: SPERC Fact Sheet 'Manufacturing of solvent borne coatings'

	Characteristics of specific ERC	Type of input information	Processing of input information
Title of specific ERC	Manufacture of organic solvent borne coatings and inks		
ERC-code	CEPE-F-1		
Based on ERC	2 (Formulation of preparations)		
Scope	Formulation of organic solvent borne coatings and inks		
Use rates	A maximum safe use rate of a substance can be specified as the outcome of an environmental assessment using the parameter set defined in the present SPERC and the environmentally relevant properties of the substance under assessment		
Emission fractions	<u>1. To air</u> *VOCs*: - Maximum 5% to air (< 1000 t/a solvent) - Maximum 3% to air (> 1000 t/a solvent) *Particulates*: - 0.005% to air (< 1000 t/a solvent) <u>2. To wastewater / sewer / water courses</u> 0% liquids and solids <u>3. To soil</u> 0% liquids and solids	Draft OECD Emission Scenario Document 'Emission scenario document on coatings industry (paints, lacquers and varnishes)', June 2006	Reviewed and adopted from OECD-ESD
Type of RMM	<u>VOC Controls</u> RMMs are primarily aimed at controlling emissions of VOCs at source, rather than at 'end of pipe' to meet the relevant total emission limit value set out in section 17, Annex IIA,1999/45/EC (SED). A wide range of RMMs are used to minimise emissions to atmosphere: - Use of closed storage facilities (e.g. bulk storage tanks, IBCs, drums) for VOC-containing raw materials - Use of closed transfers of liquids from storage to production equipment (e.g. metered piped or pumped additions) - Use of closed production equipment, with no extraction, except when opening vessels for additions/sampling, etc - Use of semi-closed production vessels with extraction to atmosphere to maintain workplace airborne VOC concentrations below respective OELs - Use of impermeable covers on work in progress - Use of closed filling equipment - Use of closed equipment cleaning and use of non-organic solvent based cleaning fluids - Storage of finished products in closed containers (bulk tanks, IBCs, drums, cans etc) - Recycling and reuse of overmake product in subsequent batches - Storage of all VOC-containing wastes in closed, secure containers (bulk tanks, IBCs, drums)		

	Characteristics of specific ERC	Type of input information	Processing of input information
Type of RMM (cont'd)	<u>Particulates</u> RMMs are primarily aimed at controlling emissions of particulates at the most significant emission points to atmosphere from sources within the manufacturing process where airborne particulates can be created. Typically: - Particulate raw materials are delivered in bulk tankers and discharged to closed silos - Particulate raw materials are delivered in closed packaging (IBCs, drums, boxes, sacks) - Closed transfers of particulates from storage to production equipment (e.g. metered piped or pumped additions) are used - No extraction is used on closed production equipment, when adding and incorporating particulate raw materials - Use of semi-closed production vessels with extraction to atmosphere are used to maintain workplace airborne particulate concentrations below respective OELs - Cyclone and bag filters, connected to (often multiple) emission sources, are used to control emissions from manufacturing plant - Particulate wastes are stored in closed containers		
Efficiency of RMMs	<u>VOC RMMs</u> As the SED VOC emission controls are focused on controlling global emissions from the manufacturing plant, the performance of individual RMMs is not relevant – the overall efficiency of the total manufacturing process (process steps + RMMs) is a minimum either 95% or 98%. <u>Particulate RMMs</u> Bag and cyclone filters are typically rated at 99% efficient.		
Narrative description of / justification for specific ERC	<u>Description</u>: The manufacture of solvent-borne coatings and inks is a multi-stage batch process. The process is arranged to maximise the efficiency of use of input raw materials, through the highest conversion into formulated products. Process losses are reduced to the absolute minimum, through use of general and manufacturing plant extraction to maintain workplace concentrations of airborne VOCs and particulates below respective OELs; and through use of closed or covered manufacturing equipment to minimise evaporative losses of VOCs. The composition of products and the overall process are such that there are no discharges of raw materials or products to waste-water or to soil from the manufacturing plant. <u>Justification</u>: The overall high efficiency of the coatings and inks manufacturing process is reflected in the low emission factors identified in independent assessment carried out by the UK's Environment Agency, as part of the development of an Emission Scenarios Document for the OECD.		

Table H-2: SPERC Fact Sheet 'Metal cleaning / pre-treatment'

	Characteristics of specific ERC	Type of input information	Processing of input information
ERC-code	AISE.1.1-1		
Title of specific ERC	Industrial use in 'Metal Pretreatment and Cleaning' operations		
Based on ERC	4 (Industrial use of processing aid)		
Scope	Industrial uses in 'Metal treatment / coating' operations		
Product use rates	Typical substance use rate: 5 kg/d [1]	Quantitative estimate	Consensus in sector
Emission fractions	0% to air [2] 100% to water [2]	Generally accepted knowledge	Consensus in sector
Type of RMM	Flocculation		
Efficiency of RMMs	98% for metal cations 30% for other substances	Measurements Default value from Det. Reg.	Estimate based on measured data None
Narrative description of / justification for specific ERC	[1]: In 'Metal treatment / coating' operations metal parts are immersed in water baths, which contain etching, cleaning, coating products. These products are solutions of substances in water. The default concentration of a substance is 2%. The typical application solution contains the product at a concentration of 5%. With each metal part, a small quantity of bath solution is carried-over from the treatment bath, and via a cascade of rinsing steps emitted to the wastewater. Replenishing the bath solution needs on average 5m^3 water per day. As a result, the substance emissions are calculated as (20 g Substance / 1 Litre Product) × (50 Litre Product / 1 m^3 Application solution) × (5 m^3 Application solution /d) = 5 kg/d. [2]: Justification: Metal treatment coating processes are carried out in enclosed equipment, hence aerosols that might be formed in high energy processes cannot escape to the ambient air. The water baths are operated at temperatures below 40°C. The process chemicals used in these processes are non-volatile and cannot evaporate. Hence, emissions to air can be neglected. With each metal part a small quantity of bath solution is carried-over from the treatment bath, and via a cascade of rinsing steps emitted to the wastewater. Hence, it can be assumed that the substances in the treatment bath are quantitatively emitted to the wastewater.		

APPENDIX I: REFINING ENVIRONMENTAL ASSESSMENTS

General considerations

The environmental risk assessment of the TRA requires two types of input: Substance property input and emission estimation input (see Scheme 1 in Chapter 4). In refining the assessments both types of input information can be refined, thus leading to improved exposure estimates where required. Refinement of emission estimation occurs per use. Hence, it may be the strategy of choice when only for one or a small number of uses the actual amounts used (M_{Use}) exceed M_{Safe}. In contrast, when for a large number of uses a risk is indicated, substance properties may need to be refined, since those affect the assessments of all uses.

Refining substance property input

As outlined in Chapter 4.3 a limited set of information is mandatory for performing Tier 1 environmental exposure assessments. The partition coefficients required to describe soil-water, sediment-water, suspended solids-water, and water-air partitioning should be estimated according to the rules of the EU TGD (EC, 2003). In addition, environmental half-lives are assigned based on the results from ready or inherent biodegradation tests.

Based on the minimum substance data input, sorption coefficients are predicted based on the octanol-water partition coefficients. For many substances, this extrapolation does not yield satisfactory results. This is particularly true for metals and charged organic molecules such as surfactants. In those cases, the substance input can be refined. Suitable input information can be obtained from experimental results or by more specific estimation methods.

The rules for assigning of environmental degradation half-lives are conservative, in line with the philosophy of Tier 1 assessments. Refined exposure estimates can be obtained by overriding the default estimation of half-lives by inputting half-lives for different compartments. Atmospheric half-lives for instance can be estimated with the QSAR methodology implemented in EPI Suite ™ (US EPA, 2009). For information on refining half-life estimations in freshwater and marine water, please refer to ECETOC report No 108 (ECETOC, 2009). Pertinent die-away tests may be used as a source of an experimentally derived half-life. Table I-1 shows the options for additional and/or refined substance property data into the ECETOC TRA ENV.

Table I-1: Substance properties which can be refined by additional / refined input

Partitioning data		
K_{oc}		K_{oc}
Partition coefficient $k_{soil/water}$		$L.kg^{-1}$
Partition coefficient $k_{sediment/water}$		$L.kg^{-1}$
Partition coefficient to suspended solids		$L.kg^{-1}$
Solids-water partition coefficient raw sewage sludge		
Solids-water partition coefficient settled sewage sludge		
Solids-water partition coefficient activated sewage sludge		
Solids-water partition coefficient effluent sewage sludge		
Degradation and transformation rates		
Rate constant for degradation in STP		d^{-1}
Total rate constant for degradation in surface water at env. temp		d^{-1}
Total rate constant for degradation in marine water at env. temp		d^{-1}
Total rate constant for degradation in bulk sediment at env. temp		d^{-1}
Rate constant for degradation in air		d^{-1}
Total rate constant for degradation in bulk soil at env. temp		d^{-1}

Refining emission assessment

In the REACH Guidance on IR&CSA ERCs are introduced as generic, broadly applicable emission scenarios. They define the fractions of a substance emitted during a process/application, and provide default assumptions for the local environmental properties. In combination with an amount used per ERC, a generic emission estimate can be derived. As Tier 1 scenarios, they are simple and provide conservative emission estimates.

The IR&CSA guidance generally acknowledges that an "ERC should be used as a starting point for emission estimation". The IR&CSA guidance explicitly encourages the use of more refined or specific information for emissions. The TRA version 2 accounts for that by offering four options to refine the emission estimations based on the ERCs.

Specific ERC

One of the options is the specific ERCs or SPERCs. ECETOC has provided a framework for specifying the emission estimations based on the ERCs (see Appendix J). According to this framework, the emission estimation parameters for each of the ERCs can be made specific for emissions as they occur in different sectors. SPERCs are developed by sector organisations. This ensures that SPERCs are standardised and can feed into a standardised communication. The responsibility for the SPERCs resides with the sector organisations. The parameter values of the SPERCs in the TRA tool have been proposed by the sector organisations. It is their obligation to provide documentation on the SPERCs. ECETOC has provided guidance on the development and documentation of the SPERCs such that the required quality and transparency are warranted.

The refinement of the ERCs is achieved by, for example, replacing the default values of parameters such as the emission fraction or the number of emission days with the values typical for the use described by a given SPERC. Relevant sources of information for developing SPERCs can be the OECD-ESDs, BREF documents and also the technical knowledge of application processes in the sectors.

A range of risk management measures is available and can be accounted for in the development of SPERCs. They act to reduce the amount of substances emitted into the environment and thus lead to reduced emission fractions. Measures included trapping evaporated volatiles, combustion of process air, physical chemical treatment of wastewater (flocculation and filtration, reverse osmosis, UV-treatment) and on-site biological treatment of wastewaters. In the latter case it is important to note that the microorganisms in industrial biological wastewater treatment systems are adapted to the specific substances present in the industrial wastewater streams. For that reason their biological removal efficiencies are generally higher than those of municipal wastewater treatment plants. Appendix J provides an overview of the default values of the currently available (draft) SPERCs.

Example – processing aid

The SPERCs for processing aids may be seen as an example of how SPERCs serve to refine the emission estimation based on ERC 4 from Chapter R16 of the REACH Guidance on IR&CSA. ERC 4 specifies (see row 2 of Appendix I) that the use of a processing aid results in 95% and 100% emission to air and water, respectively. In addition, ERC 4 stipulates that the number of days at which emissions occur is 20, and that the total amount of a substance going to a region is used at one single site (i.e. point source). This set of assumptions leads to a conservative estimate of the amount of a substance emitted per day.

Given the high likelihood of failing risk assessments with the default values of ERC 4, refinements have been developed by several sector organisations. Among them are AISE and TEGEWA, the sector organisation representing the marketers of industrial cleaning products and of textile treatment products, respectively. Their respective SPERCs are implemented in the ECETOC TRA version 2. In addition to the sector developed SPERCs, Appendix J contains SPERCs developed by ECETOC (rows 3 to 5). Emission estimates based on ERC 4 indicate twice the amount of substance being emitted from a process than went into the process. Such a flagrant violation of the law of mass conservation is not deemed scientific and for that reason ECETOC developed a refinement based on a more differentiated approach to processing aids.

This differentiation accounts for the properties of the products and the process design used in handling the products. For that reason three types of uses of processing aids are distinguished. Processing aids used in water-based processes typically end up in wastewater which may be discharged to the sewer. Emissions to the air are negligible. This is reflected by assigning values of 0% and 100% to the fractions emitted to air and water, respectively. In contrast, solvents in solvent-borne processing aids are used in processes which, by emission control legislation, are designed such that emissions to water must be avoided, and emissions to air are subject to the VOC-Directive (EC, 1999). This is reflected by assigning values of 100% and 0% to the fractions emitted to air and water, respectively. The third type of processing aid applications involves the non-volatile constituents of solvent-borne processing aids. Here, the process design ensuring no emissions to wastewater is applied to the non-volatile substances. For that reason, the emissions to water are set to 0%. In view of the low volatility of the substances, the fraction emitted to air is set to 1%.

In addition to the refined values of the emission fractions, the SPERCs take the normally continuous operation of industrial processes at downstream user level into account. This leads to assigning a value of 220 to the number of days during which releases take place instead of 20. The SPERCs also allow for differentiating between a value of 10% and 100% for the fraction of the total amount of substance being used as input to the emission assessment. Typically a value of 100% would be assigned to a large scale manufacturing plant. Metal treatment operations are usually small to medium sized and multiple operations are located within a geographical region. Hence, if a use occurs in multiple sites, 10% is a more appropriate value for the fraction of the total amount of substance being used as input to the emission assessment.

The last two rows of Appendix I display two SPERCs which have been developed by AISE. The first one is coded AISE.I.1 and refers to the use of substances in 'general industrial cleaning' as defined by AISE. The parameter assignment is identical to that of ECETOC.I.1. In order to account for the standard risk management measures as they are implemented in more specific applications, AISE has introduced a further level of specification by introducing the SPERC coded with AISE.I.1.1. It refers to metal cleaning process and prescribes the use of a risk management measure which is 98% efficient in removing metals and 35% efficient in removing general organic chemicals. This requirement coincides with the performance of a flocculation / filtration treatment, which is the typical method for wastewater treatment in metal treatment sites prior to release of the wastewater to the public sewer.

The A and B Tables

The A and B Tables are available in the Technical Guidance Document on the Assessment of Chemicals (EC, 2003). These tables provide information on the number of emission days, and emission fractions. This information is available for a variety of sectors and their respective applications. The A and B Tables have been the basis of the emission assessment of the risk assessments of existing chemicals.

OECD emission scenario documents

For several sectors of industry, OECD has collected and compiled emission information in Emission Scenario Documents (OECD-ESD). Appendix K shows the Emission Scenario Documents which are currently available from OECD[7].

These OECD-ESDs contain detailed emission information as well as information on risk management measures implemented in the different processes relevant for the sector. For that reason, the OECD-ESDs represent valuable reference documents. The information contained in the OECD-ESD may be used for the development of emission scenarios, for instance for the development of SPERCs.

The information contained in the OECD-ESDs may reflect a state of technology which has been replaced by improved technologies. Where this is the case information pertaining to the current technology may supersede that of the OECD-ESD, when developing emission estimates. Information from a draft OECD-ESD, if available e.g. to a sector organisation, may also be used in emission estimation.

Site specific emission estimation

Site specific emission estimation can also be used as a refinement option. The resulting estimate then reflects the local situation regarding the actual emissions to air, water and soil if measured data are available. Alternatively, site specific information on amounts of substance used, risk management measures, their efficiency, the fraction emitted, and the respective sizes of the wastewater treatment plant and the receiving water can be used to derive refined emission estimates. It may prove useful to construct a generic emission scenario for a chemical manufacturing site where many substances have to be registered.

[7] http://www.oecd.org/document/46/0,3343,en_2649_34373_2412462_1_1_1_1,00.html

APPENDIX J: COMPARISON OF THE RELEVANT PARAMETERS FOR THE ENVIRONMENTAL RELEASE CLASS 4 AND RELATED SPERCs

Relates to ERC	SPERC-Code	LC, Stage	Short description	Detail	Indoor / outdoor	Release promotion during service life	Amount of substance used as input to emission calculation[1] (% of volume going to region)	Fraction used at main source (largest customer)	Release time in days per year	With STP	Default release to air from process	Default release to water from process	Default release to soil	Dilution to be applied for PEC derivation (m^3/day)	Equivalent to dilution factor	Efficiency of typical on-site RMM	Release to water considering typical on-site RMM
4	ERC4	Use, Industrial	Processing aids	na	In	na	100% / 10%	1	20	Yes / No	95%	100%	na	18000	10	na	na
4	ECETOC. I.1 (Draft)	Use, Industrial	Industrial cleaning and other uses of water-borne processing aids	Water-borne cleaning products and others	In	na	100% / 10%	1	220	Yes	0%	100%	0%	18000	10	na	100%
4	ECETOC. I.2 (Draft)	Use, Industrial	Use of solvents in solvent-borne processing aids	Solvent-borne processing aid	In	na	100% / 10%	1	220	Yes	100%	0%	0%	18000	10	na	
4	ECETOC. I.3 (Draft)	Use, Industrial	Non-volatile constituents in solvent-borne processing aids	Solvent-borne processing aid	In	na	100% / 10%	1	220	Yes	1%	0%	0%	18000	10	na	
4	AISE. I.1	Use, Industrial	Industrial cleaning	General industrial cleaning	In	na	100% / 10%	1	220	Yes	0%	100%	0%	18000	10	na	100%
4	AISE. I.1-1	Use, Industrial	Processing aid – industrial cleaning	Metal cleaning	In	na	100% / 10%	1	220	Yes	0%	100%	0%	18000	10	98% [2] 35% [2]	2% 65%

[1] Select 100% if use is concentrated to one or a few sites. If use occurs in many sites, select 10%.
[2] Removal efficiencies relate to metals and to general organic chemicals, respectively. These efficiencies are typically achieved by flocculation / filtration treatment of the wastewater prior to release to the sewer.

APPENDIX K: LIST OF THE CURRENTLY AVAILABLE OECD EMISSION SCENARIO DOCUMENTS WITH THE SERIES NUMBER OF THE OECD-ESD PROGRAM AND THE ESD TITLE

ESD Series Number	Title
Series No. 2	Wood preservatives, (joint project with OECD Biocides Programme)
Series No. 3	Plastic Additives
Series No. 4	Water Treatment Chemicals
Series No. 5	Photographic Industry
Series No. 6	Rubber Additives
Series No. 7	Textile Finishing
Series No. 8	Leather Processing
Series No. 9	Photoresist Use in Semiconductor Manufacturing
Series No. 10	Lubricants and Lubricant Additives
Series No. 11	Automotive spray application
Series No. 12	Metal finishing
Series No. 13	Antifoulants main document and ANNEX (joint project with OECD Biocides Programme)
Series No. 14	Insecticides for Stables and Manure Storage Systems (joint project with OECD Biocides Programme)
Series No. 15	Kraft Pulp Mills
Series No. 16	Non-Integrated Paper Mills
Series No. 17	Recovered Paper Mills
Series No. 18	Adhesive Formulation
Series No. 19	Formulation of Radiation Curable Coatings, Inks and Adhesives

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ECETOC PUBLISHED REPORTS

Monographs

No.	Title
No. 1	Good Laboratory Practice (Published October 1979)
No. 2	A Contribution to Strategy for Identification and Control of Occupational Carcinogens (Published September 1980)
No. 3	Risk Assessment of Occupational Chemical Carcinogens (Published May 1985)
No. 4	Hepatocarcinogenesis in Laboratory Rodents: Relevance for Man (Published October 1982)
No. 5	Identification and Assessment of the Effects of Chemicals on Reproduction and Development (Reproductive Toxicology) (Published December 1983)
No. 6	Acute Toxicity Tests, LD_{50} (LC_{50}) Determinations and Alternatives (Published May 1985)
No. 7	Recommendations for the Harmonisation of International Guidelines for Toxicity Studies (Published December 1985)
No. 8	Structure-Activity Relationships in Toxicology and Ecotoxicology: An Assessment (Summary) (Published June 1986)
No. 9	Assessment of Mutagenicity of Industrial and Plant Protection Chemicals (Published June 1987)
No. 10	Identification of Immunotoxic Effects of Chemicals and Assessment of their Relevance to Man (Published August 1987)
No. 11	Eye Irritation Testing (Published June 1988)
No. 12	Alternative Approaches for the Assessment of Reproductive Toxicity (with emphasis on embryotoxicity/teratogenicity) (Published November 1989)
No. 13	DNA and Protein Adducts: Evaluation of their Use in Exposure Monitoring and Risk Assessment (Published October 1989)
No. 14	Skin Sensitisation Testing (Published March 1990)
No. 15	Skin Irritation (Published July 1990)
No. 16	Early Indicators of Non-Genotoxic Carcinogenesis (Published June 1991)
No. 17	Hepatic Peroxisome Proliferation (Published May 1992)
No. 18	Evaluation of the Neurotoxic Potential of Chemicals (Published September 1992)
No. 19	Respiratory Allergy (Published August 1993)
No. 20	Percutaneous Absorption (Published August 1993)
No. 21	Immunotoxicity: Hazard Identification and Risk Characterisation (Published September 1994)
No. 22	Evaluation of Chemicals for Oculotoxicity (Published November 1994)
No. 23	Receptor Mediated Mechanisms in Chemical Carcinogenesis (Published December 1995)
No. 24	Risk Assessment for Carcinogens (Published July 1996)
No. 25	Practical Concepts for Dose Selection in Chronic Toxicity and Carcinogenicity Studies in Rodents (Published February 1996)
No. 26	Aquatic Toxicity Testing of Sparingly Soluble Volatile and Unstable Substances (Published September 1996)
No. 27	Aneuploidy (Published August 1997)
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No. 31	Guidance on Evaluation of Reproductive Toxicity Data (Published February 2002)
No. 32	Use of Human Data in Hazard Classification for Irritation and Sensitisation (Published July 2002)

No. 33	Application of Physiological - Toxicokinetic Modelling to Health Hazard Assessment of Chemical Substances (Published February 2003) Toxicology Letters, Volume 138, Issues 1-2 www.sciencedirect.com/science/journal/03784274
No. 34	Toxicogenomics in Genetic Toxicology and Hazard Determination (Published August 2005) Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis, Volume 575, Issues 1-2 www.sciencedirect.com/science/journal/00275107
No. 35	Biomarkers and molecular epidemiology (Published August 2006) Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis, Volume 600, Issues 1-2 www.sciencedirect.com/science/journal/00275107
No. 36	Environmental Genotoxins in Children and Adults (Published August 2006) Mutation Research/Genetic Toxicology and Environmental Mutagenesis, Volume 608, Issue 2 www.sciencedirect.com/science/journal/13835718
No. 37	Biomarkers in Children and Adults (Published July 2007) Toxicology Letters, Volume 172, Nos. 1-2 www.sciencedirect.com/science/journal/03784274
No. 38	Toxicity of Engineered Nanomaterials (published May 2009) Toxicology Letters, Volume 186, Issue 3 http://www.sciencedirect.com/science/journal/03784274

Technical Reports

No.	Title
No. 1	Assessment of Data on the Effects of Formaldehyde on Humans (Published January 1979) (Updated by TR No. 6)
No. 2	The Mutagenic and Carcinogenic Potential of Formaldehyde (Published May 1981)
No. 3	Assessment of Test Methods for Photodegradation of Chemicals in the Environment (Published August 1981)
No. 4	The Toxicology of Ethylene Glycol Monoalkyl Ethers and its Relevance to Man (Published June 1982) (Updated by TR No. 17)
No. 5	Toxicity of Ethylene Oxide and its Relevance to Man (Published September 1982)
No. 6	Formaldehyde Toxicology: An Up-Dating of ECETOC Technical Reports 1 and 2 (Published September 1982)
No. 7	Experimental Assessment of the Phototransformation of Chemicals in the Atmosphere (Published September 1983)
No. 8	Biodegradation Testing: An Assessment of the Present Status (Published November 1983)
No. 9	Assessment of Reverse-Phase Chromatographic Methods for Determining Partition Coefficients (Published December 1983)
No. 10	Considerations Regarding the Extrapolation of Biological Data in Deriving Occupational Exposure Limits (Published February 1984)
No. 11	Ethylene Oxide Toxicology and its Relevance to Man: An Up-Dating of ECETOC Technical Report No. 5 (Published March 1984)
No. 12	The Phototransformation of Chemicals in Water: Results of a Ring-Test (Published June 1984)
No. 13	The EEC 6th Amendment: A Guide to Risk Evaluation for Effects on the Environment (Published March 1984)
No. 14	The EEC 6th Amendment: A Guide to Risk Evaluation for Effects on Human Health (Published March 1984)
No. 15	The Use of Physical-Chemical Properties in the 6th Amendment and their Required Precision, Accuracy and Limiting Values (Published June 1984)
No. 16	A Review of Recent Literature on the Toxicology of Benzene (Published December 1984)

No. 17 The Toxicology of Glycol Ethers and its Relevance to Man: An Up-Dating of ECETOC Technical Report No. 4) (Published April 1985) (Updated by TR No. 64)
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No. 19 An Assessment of Occurrence and Effects of Dialkyl-o-Phthalates in the Environment (Published May 1985)
No. 20 Biodegradation Tests for Poorly-Soluble Compounds (Published February 1986)
No. 21 Guide to the Classification of Carcinogens, Mutagens, and Teratogens under the 6th Amendment (Published February 1986)
No. 22 Classification of Dangerous Substances and Pesticides in the EEC Directives. A Proposed Revision of Criteria for Inhalational Toxicity (Published January 1987)
No. 23 Evaluation of the Toxicity of Substances to be Assessed for Biodegradability (Published November 1986)
No. 24 The EEC 6th Amendment: Prolonged Fish Toxicity Tests (Published October 1986)
No. 25 Evaluation of Fish Tainting (Published January 1987)
No. 26 The Assessment of Carcinogenic Hazard for Human Beings exposed to Methylene Chloride (Published January 1987)
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No. 28 Evaluation of Anaerobic Biodegradation (Published June 1988)
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No. 35 Fate, Behaviour and Toxicity of Organic Chemicals Associated with Sediments (Published January 1990)
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No. 37 Tetrachlorethylene: Assessment of Human Carcinogenic Hazard (Published May 1990)
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No. 106	Guidance on Identifying Endocrine Disrupting Effects (Published June 2009)

Joint Assessment of Commodity Chemicals (JACC) Reports

No.	Title
No. 1	Melamine (Published February 1983)
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No. 12	1-Chloro-1,2,2,2-tetrafluoroethane (HFA-124) (Published May 1990) (Updated by JACC No. 25)
No. 13	1,1-Dichloro-2,2,2-trifluoroethane (HFA-123) (Published May 1990) (Updated by JACC No. 33)
No. 14	1-Chloro-2,2,2-trifluoromethane (HFA-133a) (Published August 1990)
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No. 16	Dichlorofluoromethane (HCFC-21) (Published August 1990)
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No. 27 *n*-Butyl Acrylate (CAS No. 141-32-2) (Published August 1994)
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No. 30 Methyl Methacrylate (CAS No. 80-62-6) (Published February 1995)
No. 31 1,1,1,2-Tetrafluoroethane (HFC-134a) (CAS No. 811-97-2) (Published February 1995) (Updated by JACC No. 50)
No. 32 Difluoromethane (HFC-32) (CAS No. 75-10-5) (Published May 1995) (Updated by JACC No. 54)
No. 33 1,1-Dichloro-2,2,2-trifluoroethane (HCFC-123) (CAS No. 306-83-2) (Published February 1996) (Updated by JACC No. 47)
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No. 42 Tetrafluoroethylene (CAS No. 116-14-3) (Published December 2003)
No. 43 *sec*-Butanol (CAS No. 78-92-2) (Published December 2004)
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Special Reports

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No. 17 Risk Assessment Report for Existing Substances Methyl *tertiary*-Butyl Ether (Published December 2003)

Documents

No. Title

No. 32 Environmental Oestrogens: Male Reproduction and Reproductive Development (Published January 1996)
No. 33 Environmental Oestrogens: A Compendium of Test Methods (Published July 1996)
No. 34 The Challenge Posed by Endocrine-disrupting Chemicals (Published February 1996)
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No. 36 Comments on OECD Draft Detailed Review Paper: Appraisal of Test Methods for Sex-Hormone Disrupting Chemicals (Published August 1997)
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Workshop Reports

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No. 2 Strategy Report on Challenges, Opportunities and Research needs arising from the Definition, Assessment and Management of Ecological Quality Status as required by the EU Water Framework Directive based on the workshop EQS and WFD versus PNEC and REACH - are they doing the job? 27-28 November 2003, Budapest (Published March 2004)
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No. 8 Workshop on Societal Aspects of Nanotechnology
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No. 12 Workshop on Triggering and Waiving Criteria for the Extended One-Generation Reproduction Toxicity Study
14-15 April 2008, Barza d'Ispra (Published August 2008)

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No. 16 Guidance on interpreting endocrine disrupting effects. 29-30 June 2009, Barcelona (Published October 2009)

No. 17 Significance of Bound Residues in Environmental Risk Assessment.
14-15 October 2009, Brussels (In press 2010)

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