REACH Exposure Scenarios for Fragrance Substances

19 April 2012

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PREFACE

This guidance document is primarily intended for IFRA members that have to register fragrance substances under REACH and are required to include a CSR in their dossier. It is also recommended to be used by registrants that are not members of IFRA, but supply substances to the fragrance industry, or who act as lead registrant of a substance that has a significant use in fragrances. Downstream Users of fragrance substances (either in pure form or as part of a fragrance compound) will find this document helpful in order to verify that their own use(s) are sufficiently covered. Information on uses made available by DU Associations (AISE, Cosmetics Europe) has been taken into account where relevant.

The aim of this guidance is to provide registrants of fragrance substances with a standardized methodology of describing Identified Uses and preparing Exposure Scenarios for the entire life cycle. By including the provided Identified Uses and related Use Mapping in their registration dossiers, registrants will cover all the important uses of fragrance substances and should meet the needs of their Downstream Users in nearly all cases. Consistent use of the Identified Uses titles and Use Mapping in extended-SDSs will greatly facilitate compliance checks and will ultimately enable more efficient preparation of Exposure Scenarios for fragrance compounds. By applying the included Generic Exposure Scenarios as the basis for their CSRs, registrants can start straight away with a Tier 1.5 exposure assessment based on validated industry-specific data and will not have to rely on worst-case Tier 1 values that are otherwise used as default in exposure modelling tools.

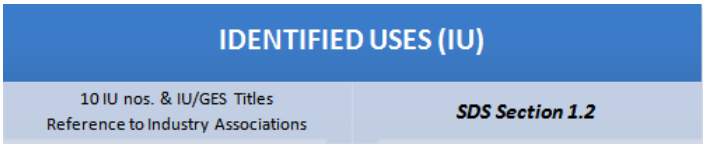
A concise overview of the complex process of Chemical Safety Assessment under REACH is provided for relative non-experts as an easy-to-read alternative to the very detailed ECHA Guidance Documents on this topic. Internal and/or external specialists in the field of exposure and risk assessment can go straight to the Use Mapping tables and Generic Exposure Scenarios and start working on their dossiers.

Questions regarding the content of this document or any perceived errors can be addressed to IFRA. IFRA encourages further distribution of this document, especially to other registrants of fragrance substances.

EXECUTIVE SUMMARY

The present document provides a step by step guidance on how to prepare Exposure Scenarios for substances used in fragrances. A list of ten Identified Uses is included that are recommended to be included in all registrations of fragrance substances. For the life cycle stage "formulation of fragrance compounds", which is unique for the fragrance industry, the Use Mapping, a Generic Exposure Scenario (GES) and "IFRA spERCs" have been specifically developed for this guidance document. For the life cycle stages further downstream, the Use Mapping and GESs have been based on information published by DU Associations AISE and Cosmetics Europe (the former Colipa).

A schematic overview of the different steps to prepare Exposure Scenarios for a fragrance substance is shown below in Figure 1.



As a **first step**, uses of the substance are identified at a high level, following its entire life cycle: manufacturing, formulation, industrial end-use, professional end-use and consumer end-use. As a result of this, **ten main Identified Uses** (IUs) can be identified for fragrance substances, covering all common uses as reported by DU Associations (see Table 1). IFRA strongly recommends registrants of fragrance substances to **include all of these in their REACH registrations** as a minimum. Registrants can always decide to include additional Identified Uses to the dossier of a specific substance, when these have been communicated by DUs and none of the exemptions of REACH Article 37.4 apply. IFRA members and their suppliers are advised to adhere to these exact IU numbers and titles in order to maximize industry alignment when reporting them in their dossiers or in section 1.2 of the extended-SDS.

Table 1: Identified Uses (IU) and Generic Exposure Scenarios (GES) relevant for the fragrance industry

IU n°	IU Title	Reference
IU 0	Manufacturing of fragrance substances *	**Site specific**
IU 1	GES1 - Formulation of fragrance compounds (mixing of fragrance substances into fragrance compounds)	**IFRA**
IU 2	GES2 - Formulation of fragranced end-products (mixing of fragrance compounds into fragranced end-products)	**AISE / Cosm. Eur.**
IU 3	GES3 - Industrial end-use of washing and cleaning products	**AISE**
IU 4	GES4 - Professional end-use of washing and cleaning products	**AISE**
IU 5	GES5 - Professional end-use of polishes and wax blends	**AISE**
IU 6	GES6 - Consumer end-use of washing and cleaning products	**AISE**
IU 7	GES7 - Consumer end-use of air care products	**AISE**
IU 8	GES8 - Consumer end-use of biocides	**AISE**
IU 9	GES9 - Consumer end-use of polishes and wax blends	**AISE**
IU 10	GES10 - Consumer end-use of cosmetics **	**Cosm. Eur.**

** No GES for manufacturing (site specific)*

*** Only includes environmental exposure, assessment of human exposure is exempt from REACH*

USE MAPPING	
ECHA Use Descriptors, Contributing Scenarios, Life Cycle Stage	***Supply Chain Communications IUCLID Section 3.5***

In the **second step**, a **Use Mapping** process is performed on each Identified Use. All applicable handling activities (e.g. sampling, transferring and mixing of substances) are described in Contributing Scenarios (CS). Standardized ECHA Use Descriptors are assigned (SU, PROC, PC, ERC, etc.) and the life cycle stage is indicated. Use Mapping tables developed by AISE and Cosmetics Europe have been taken over where applicable. Use Mapping for the Manufacturing step is not included, because this needs to be done specifically for each site (and is also not required for imported substances). The included Use Mapping Tables are advised to be used for communication in the supply chain and between registrants and should be used as input for IUCLID section 3.5.

GENERIC EXPOSURE SCENARIOS (GES)	
Typical OCs & RMMs for workers (1-4 hrs, 5-25%, LEV) and environment (SpERCs)	***Input for Exposure Estimations (CSA)***

As a **third step**, **Generic Exposure Scenarios (GES)** are provided for all Identified Uses, except the manufacturing step that is always site specific. GESs describe the Operational Conditions (OC) and Risk Management Measures (RMM) that are typically in place. They form the basis for a Tier 1.5 exposure assessment based on validated industry-specific data instead of the worst-case values that are used by default in Tier 1 exposure estimation tools (e.g. ECETOC TRA). For occupational exposure, OCs (e.g. exposure duration, substance concentration) and RMMs (e.g. local exhaust ventilation, gloves) are described for workers for each handling activity and are expressed as Contributing Scenarios. For environmental exposure, OCs (e.g. river flow rate, STP size, working days) and RMMs (e.g. oil skimmer, carbon filter) are described as part of “Specific ERCs” (spERC).

As part of this document, IFRA has established a new GES for formulation of fragrance compounds for workers and the environment. As part of this GES, two new IFRA spERCs have been developed for large/medium sites and for small sites. For the other Identified Uses the existing GESs (including spERCs) from AISE and Cosmetics Europe have been used.

Registrants are advised to use the included GESs as the starting point for exposure estimations and for their substance specific exposure scenarios. They may consider supplementing the GES data with site-specific scenarios especially for the formulation of fragrance compounds, as this information may be readily available either internally or from immediate Downstream Users.

EXPOSURE ESTIMATIONS	
Estimated exposure levels / PECs	***Input for Risk Charactization (CSR)***

As a **fourth step**, after establishing the GES, the **Exposure Estimation** needs to take place for each Identified Use. This step and any subsequent steps are **outside the scope** of this guidance document, because for these estimations substance specific data are needed. The exposure estimation is the input for the risk characterisation in which safe use (no risks, all RCRs <1) will need to be demonstrated before the

substance specific Exposure Scenarios can be finalized and the substance can be registered. When the estimated exposure results in a risk after a comparison against the safe limit values (DNELs/PNECs), further refinement is needed either on exposure or hazard.

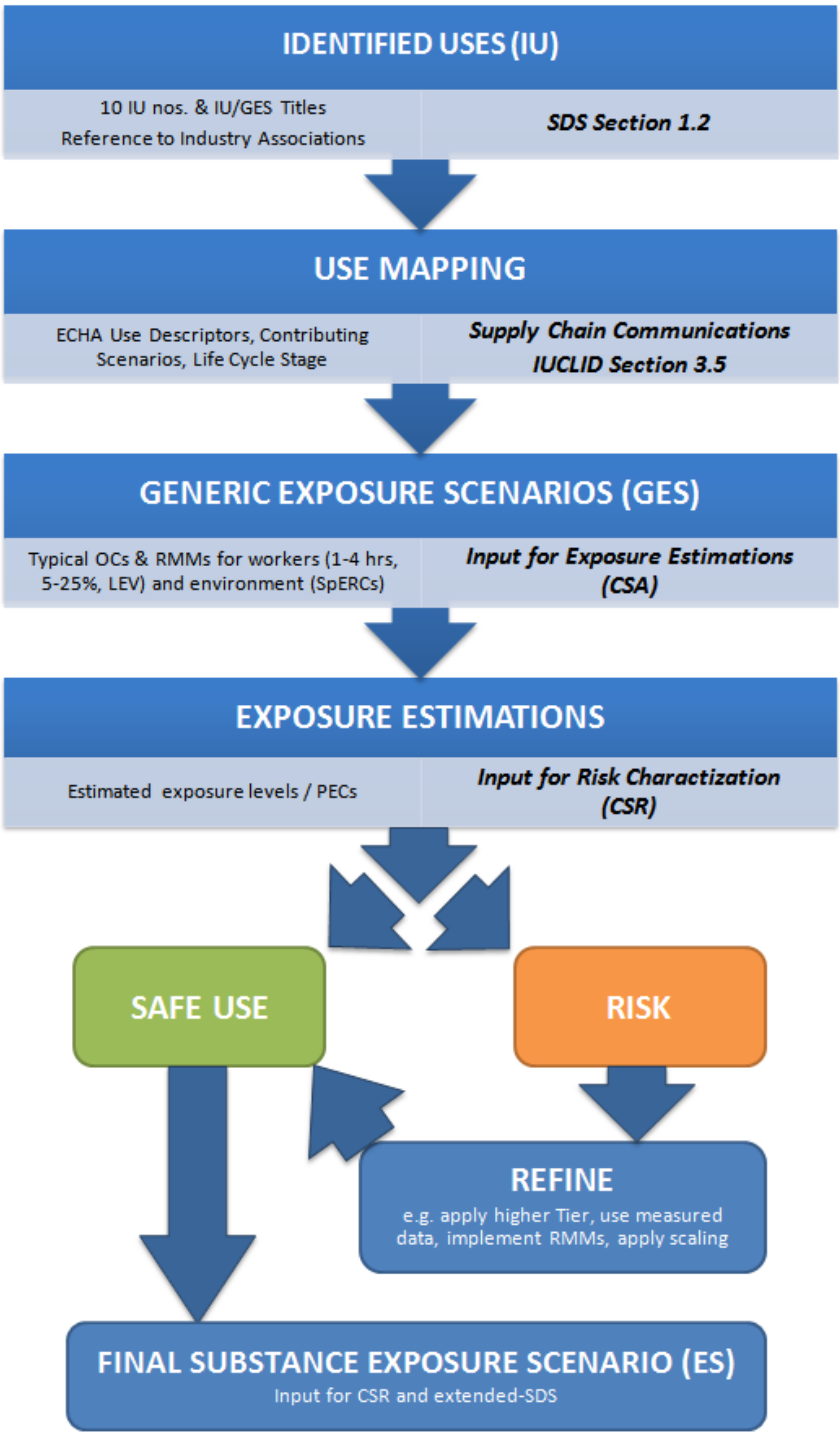


Figure 1: Stepwise Process to prepare Exposure Scenarios for a fragrance substance

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Abbreviations:

CSA	:	Chemical Safety Assessment
CSR	:	Chemical Safety Report
DNEL	:	Derived No Effect Level
DU	:	Downstream User
ECETOC	:	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	:	European Chemicals Agency
EEA	:	European Economic Area (Member States of the European Union (EU) as well as Norway, Iceland and Liechtenstein where the REACH Regulation is also in force)
EFFA	:	European Flavour and Fragrance Association
ERC	:	Environmental release category
ES	:	Exposure scenario
e-SDS	:	Extended Safety Data Sheet
EUSES	:	European Union Substance Evaluation System
GES	:	Generic exposure scenario
HERA	:	Human and Environmental Risk Assessment
IFRA	:	International Fragrance Association
mg/m3	:	milligram per cubic metre, concentration unit
M/I	:	Manufacturer or importer
OCs	:	Operational conditions
PBT	:	Persistent and Bioaccumulative and Toxic substance
PC	:	Preparation category
PEC	:	Predicted exposure concentration
PNEC	:	Predicted no effect concentration
PPE	:	Personal Protection Equipment
Ppm	:	Parts per million, concentration units
PROC	:	Process category
QC	:	Quality Control
QSAR	:	Quantitative Structure Activity Relationships
RCR	:	Risk Characterisation Ratio
RIFM	:	Research Institute for Fragrance Materials
RMM	:	Risk management measures
spERC	:	Specific environmental release category
STP	:	Sewage Treatment Plant
SU / SoU	:	Sector of use
TRA	:	Targeted Risk Assessment
vPvB	:	Very Persistent and Very Bioaccumulative substance
WWTP	:	Wastewater treatment plant

Glossary:

Fragrance substance (synonym Fragrance material; Fragrance ingredient)	:	Individual substance as defined in REACH (EC) No 1907/2006, Article 3.1 and used in fragrance compounds as defined below
Fragrance compound (synonym Fragrance preparation; Fragrance mixture; compound oil; fragrance oil; perfume oil)	:	Mixture as defined in REACH (EC) No 1907/2006, Article 3.2. A mixture of several individual fragrance substances, which can also contain stabilizers and solvents to enhance the function of the compound
Fragranced end-product (synonym Fragrance product; End product; Final product; Consumer product; end-use preparation)	:	End product used by consumers and/or workers (usually a mixture of a fragrance compound with, i.e. denatured alcohol or water and other functional ingredients).
Compounding (syn. Compounding process)	:	Action of producing a fragrance compound, i.e. mixing several individual fragrances
Compounding site	:	Site where individual fragrances are mixed together to obtain a fragrance compound
Identified Use	:	means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user
Industrial use	:	Uses of substances as such or in preparations* at industrial sites
Institutional (syn. professional)	:	Public domain (administration, education, entertainment, services, craftsmen)
Consumer uses	:	Private households (= general public = consumers)
Exposure scenario	:	The set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate. *(REACH (EC) No 1907/2006, Article 3.37)*
Generic exposure scenario	:	In the context of this document, sets of determinants of exposure which cover all individual activities included in one use of fragrance substances or products containing these substances. The conditions represented by the determinants cover a broad range of specific uses and are therefore generic.
Chemical Safety Assessment (CSA)	:	A chemical safety assessment of a substance includes the following steps: (a) human health hazard assessment; (b) physicochemical hazard assessment; (c) environmental hazard assessment;

		(d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.
Chemical Safety Report (CSR)	:	A report that documents the chemical safety assessment
Extended Safety Data Sheet (eSDS)	:	A safety data sheet that contains in annex the relevant exposure scenarios (including use and exposure categories where appropriate
Downstream user (DU)	:	Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user *(REACH (EC) No 1907/2006, Article 3.13)*
Use descriptors	:	System that standardises the description of the use of substances. This facilitates: the identification of uses to be provided in the registration dossiers; the building of an ES by suppliers, based on communication up and down the supply chain; and the building of short titles for exposure scenarios
Operational Conditions (OCs)	:	Operational conditions consist of a set of actions, tools, parameters such as amount of substance, process temperature and pH, duration and frequency of release, type of use (e.g. indoor or outdoor), containment of process (open or closed), continuous or batch process (leading to an intermittent release), capacity of surroundings, etc. having, as a side effect, an impact on the release and the exposure.
Risk Management Measures (RMMs)	:	Risk management measures consist of technologies and procedures aimed at either reducing the releases and/or preventing a release pathway.
Local exhaust ventilation (LEV)		Technical conditions and measures to control dispersion from source towards the worker
Personal Protection Equipment (PPE)	:	Individual protection of worker or user, e.g. gloves or a suit.
Environmental Release Category (ERC)	:	Describes the broad conditions of use from the environmental perspective
spERC (specific ERC)	:	Describes the more specific conditions of use than in the ERC, from the environmental perspective
Process Category (PROC)	:	Describes the application techniques or process types defined from the occupational perspective
Chemical product category (PC) (synonym Preparation category)	:	Describes in which types of chemical products (= substances as such or in mixtures)* the substance is finally contained when it is supplied to end-uses (by industrial, professional or consumer users) *The term chemical product covers both substances as such or in a preparation (mixture)
Article Category (AC)	:	Describes the type of article into which the substance has

eventually been processed. This also includes mixtures in their dried or cured form (e.g. dried printing ink in newspapers; dried coatings on various surfaces)

1 INTRODUCTION

The REACH Chemical Safety Assessment (CSA) process consists of a hazard assessment, an exposure assessment and a risk characterisation and is reported in the Chemical Safety Report (CSR) format as defined in REACH Annex I. In this report the focus will be on exposure assessment and the development of REACH Exposure Scenarios for the different life cycle steps of fragrance substances.

Spread across many technical guidance documents published by ECHA, registrants can find much information on how a REACH CSA should be performed. In practice however, differences in interpretation of the guidance and different tools/models used by registrants have resulted in a high variability of CSRs and Exposure Scenarios in terms of content and layout. This is also true for substances used in the fragrance industry, even though this industry has many common practices. This IFRA guidance document aims at documenting industry common practices using standardized terminology in order to better align the CSAs and resulting Exposure Scenarios and CSRs for fragrance substances.

Normally exposure assessment starts at Tier 1. In this Tier the exposure is estimated using conservative models, taking worst-case default values as input information for the different exposure parameters.

The aim of this guidance is to provide registrants of fragrance substances with a standard methodology of describing Identified Uses and preparing Exposure Scenarios for the entire life cycle. By including the provided Identified Uses and related Use Mapping information in their registration dossiers, registrants will cover all the important uses of fragrance substances and should meet the needs of their Downstream Users in nearly all cases. Consistent use of this information in extended-SDSs will greatly facilitate compliance checks and will ultimately enable an efficient preparation of Exposure Scenarios for fragrance compounds. By applying the included Generic Exposure Scenarios as the basis for their CSRs, registrants can start straight away with a Tier 1.5 exposure assessment based on validated industry-specific data and will not have to rely on the worst-case defaults that are used in a Tier 1 approach.

In the context of this document the GES is a set of determinants of exposure which cover all individual activities included in one use of fragrance substances or products containing these substances. The conditions represented by the determinants cover a broad range of specific uses and are therefore generic.

If industry-specific data do not lead to safe use, a Tier 2 exposure assessment can be performed using detailed site-specific information, measured data, or specialized models. This IFRA guidance only provides the information for a more generic Tier 1.5 approach. Tier 2 assessments are beyond the scope of the present document and will need to be performed by specialists substance-by-substance.

In preparation for the 2010 submissions under REACH, the fragrance industry collaborated on the first version of this guidance document (finalized 3 February 2010). It was written by industry experts from the IFRA REACH Task Force and RIFM with the support of external service provider Royal Haskoning. It provided the information needed to complete substance specific CSAs following the latest guidance available at that time from ECHA and affected industry associations (e.g. Cefic, AISE, ECETOC).

The IFRA REACH Task Force felt strongly that with each new deadline the guidance document should be reviewed against both the experiences of the membership from previous CSA preparation exercises and any revised or new guidance from ECHA and other industry associations. Since the publication of the previous version, indeed registrants have gained a wealth of experience in preparing Exposure Scenarios and running risk assessments and also many new or updated guidance documents, tools and models have become available. It was therefore decided to update this guidance accordingly, which took place during October 2011 – March 2012, this time with the support of service provider CEHTRA, which has resulted in the current version presented here.

This first revision of the IFRA Guidance document is reflective of the Work Group's best understanding of the latest available information at the time of publication. It expresses the collective experience through the 2010 submission process of the Work Group and its contracted consultant, CEHTRA. It is meant to serve, as did the previous version as step-by-step guidance on the preparation of Exposure Scenarios.

Chapter 2 is intended to explain the complex process of chemical safety assessment (including exposure & risk assessment) to relative non-experts. It describes the different life cycle steps of a typical fragrance substance, the process of hazard assessment (deriving DNELs and PNECs), how to do Use Mapping, the contents of an Exposure Scenario, calculating Exposure Estimations, performing risk characterization (deriving RCRs), and communication to Downstream Users.

Chapter 3 is presenting the ten main Identified uses (IUs) specifically for the fragrance industry. As has been discussed above manufacturing is not in scope. The Use Mapping within the life cycle steps formulation of fragrance compounds, formulation of fragranced end-products, industrial and professional end-uses has been done in much more detail for worker and the environment compared to the previous version of the IFRA guidance document. Information from AISE and Cosmetic Europe has been used when applicable for fragrances to stay in full alignment with our Downstream Users. Generic Exposure Scenarios (GESs) have been included for each identified use including spERCs for many uses. For consumer end-use it was decided to remove a number of PCs and ACs that were included in the previous version. This was done because for most fragrance substances these uses will fall under one or more of the exemptions from REACH Article 37.4, due to the low dosage levels and/or relatively low volumes used. Also for most of these uses no standardized Use Mapping tables have been made available by industry associations.

Chapter 4 provides a high level guidance on how to use the GESs to perform Exposure Estimations using the different tools available. Exposure estimations for a typical generic fragrance substance have been included as illustrative example.

2 CHEMICAL SAFETY ASSESSMENT

2.1 Introduction to the Chemical Safety Assessment

With the introduction of REACH Regulation ((EC) No 1907/2006), information requirements were set for substances manufactured in or imported into Europe. A technical dossier has to be submitted for substances manufactured or imported at a volume of ≥1 ton/year per Legal Entity in the EEA[1]. In addition, a Chemical Safety Assessment (CSA) is required for all substances imported or manufactured in quantities of ≥10 tons/year ((EC) No 1907/2006, Article 14). The CSA requires inclusion of an exposure assessment and risk characterization when the substance is classified as hazardous to human health, the environment or presents a physicochemical hazard or is assessed as a PBT or vPvB substance. The CSA is to be reported in the format of the Chemical Safety Report (Annex I of REACH). A schematic overview of the CSA process is presented in Figure 2.

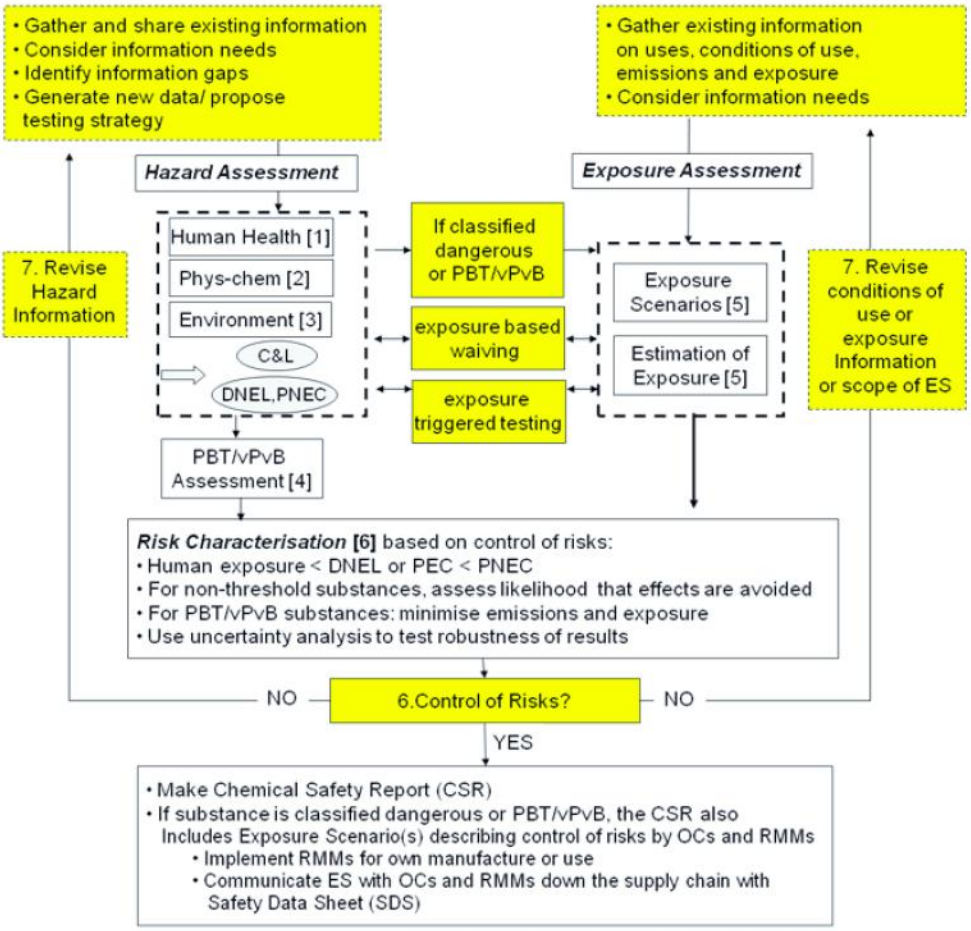

Figure 2: Chemical Safety Assessment Framework

As a first step in the CSA, also referred to as a Tier 0 assessment, the hazards of the substance are rated based on the hazard classification according to the former Dangerous Substance Directive (DSD, Directive 67/548/EEC) and the current CLP (Regulation (EC) 1272/2008). This assessment can result in one of the following conclusions:

[1] EEA stands for European Economic Area and includes the 27 EU Member States plus Iceland, Liechtenstein and Norway

1. The substance is not classified as hazardous or as PBT/vPvB. Exposure and Risk assessment are not required and the CSR includes only the section on Hazard Assessment.
2. The substance meets the criteria for classification as hazardous or is assessed to be a PBT or vPvB, the CSA shall include the following steps (Article 14.4 of the REACH Regulation):
    a. Exposure assessment including the generation of Exposure Scenarios (or the identification of relevant uses and exposure categories if appropriate) and exposure estimation;
    b. Risk characterisation.

The aim of the CSA is to demonstrate the safe use of a substance for workers, consumers and the environment during each life cycle step of a substance. The relevant stages within the life cycle of a substance can be found in the ECHA guidance document: "Guidance on information requirements and chemical safety assessment Part D: Exposure Scenario Building" (v1.1, May 2008). The relevant life cycle stages for the fragrance industry can be found in Figure 3.

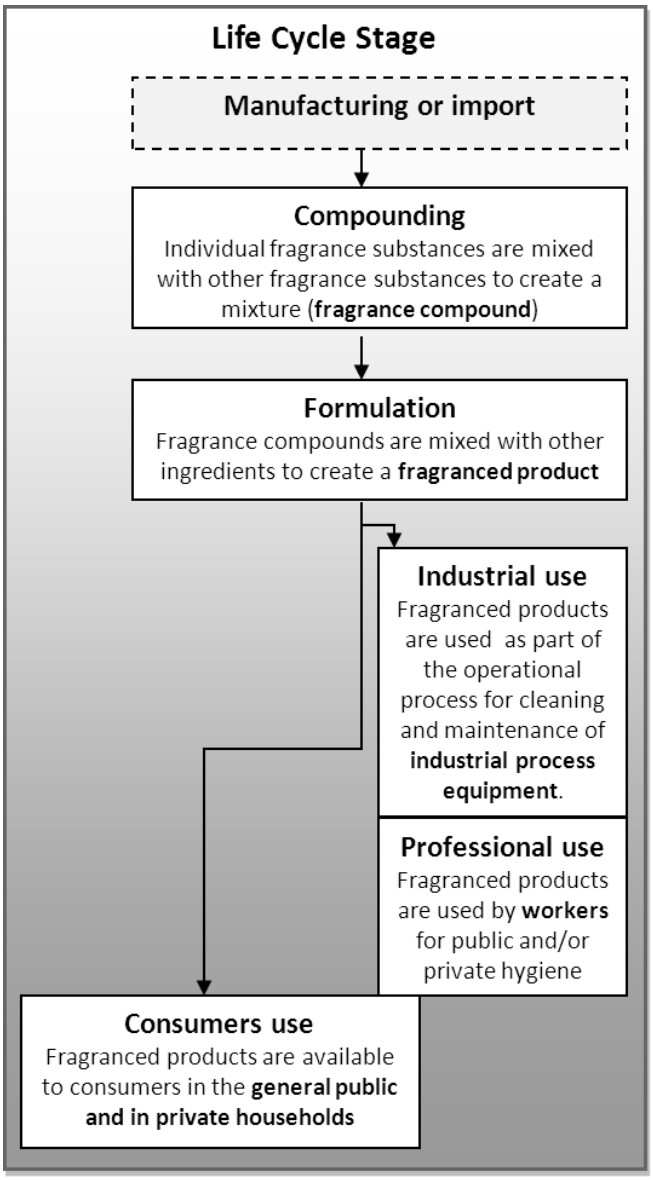

Figure 3: Relevant life-cycle stages for the fragrance industry

2.1.1 The CSA framework

In this report the steps as presented in Figure 3 will be further discussed in the following order:

1. Hazard assessment, including classification and deriving safe limit values, not in scope of this document. However, a short introduction is presented in 2.2 because of its relevance for deriving safe use.
2. Exposure assessment (see 2.3)
    - Use Mapping (see 2.3.2)
    - Exposure Scenarios (see 2.3.3)
        - Workers (see 2.3.3.1)
        - Consumers (see 2.3.3.2)
        - Environment (see 2.3.3.3)
    - Exposure Estimates (see 2.3.3.4)
        - Workers
        - Consumers
        - Environment
3. Risk characterization (see 2.4).

The CSA is an iterative or Tiered process that continues until conditions have been identified which lead to the adequate control of exposure. This reiteration either on creating new hazard data or exposure data should lead to conditions that allow a safe use. Normally this process starts by refining the exposure data.

The final exposure scenarios (see 2.5), resulting from this refinement, are reported in the Chemical Safety Report. The Chemical Safety Report can be created using the CHESAR tool developed by ECHA (current version 1.2, updated version 2 expected in Q3 of 2012), which runs under IUCLID. With CHESAR it is possible to report the Exposure scenarios in an automated and harmonized way allowing maximum alignment between registrants and therefore it is strongly advised to all registrants of fragrances to use this tool. Alternatively, the CSR can be reported in a Word document (.rtf file) and the template can be found at http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats. The format is available as a .dot file which can be opened with Microsoft Word. Drawback of this way for reporting the CSR is that all data forming the exposure scenario will have to be entered manually in the template. Guidance on the CSR format is available in the ECHA guidance document: “Guidance on information requirements and chemical safety assessment Appendix to Part F CSR Template with explanation” (v1, July 2008).

In the Annex to the SDS (extended-SDS) those Exposure Scenarios are communicated to the DU (see 2.6). Additionally, guidance to the DU is presented in section 2.7 on how to handle in case the OCs described in an exposure scenario that they have received are different from their own specific situation.

2.2 Hazard assessment

The first steps of the CSA are the human health and environmental hazard assessment of the substance based on a variety of human health endpoints and ecotoxicological endpoints described in Annex VII-Annex X of the REACH Regulation. Based on this hazard information classification and labelling is proposed and safe limit values are derived (DNELs and PNECs), which should not be exceeded during exposure.

2.2.1 Selection of safe limit values (DNELs and PNECs)

For workers and consumers the significant routes of exposure need to be defined and the safe limit value appropriate to that route is to be selected. The safe limit value for human exposure is the derived no effect level (DNEL), for the environment it is the predicted no effect concentration (PNEC).

Relevant exposure routes for workers in industrial and professional settings are via the dermal and inhalatory route. For the general public (consumers) the routes are via inhalation, dermal and oral. It has to be noted that for fragranced end-products (except for those used in cosmetics e.g. mouth care), the oral route is not considered to be a standard exposure route. Indirect exposure of e.g. residues on plates from dishwashing products is possible but considered to be minimal. Therefore, fragrance exposure via the oral route is considered to be not significant compared with the dermal and inhalation routes.

From a practical perspective it is advised to finalise the DNELs and PNECs before starting on the exposure estimation because any further changes to these values will need to be taken into account for each exposure scenario.

2.2.1.1 Safe limit values for human exposure

The process of deriving a DNEL is described in the ECHA guidance document: "Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health" (v2, December 2010). ECETOC developed a more refined approach for derivation of the DNEL (Technical report 110, 2010 freely available from the ECETOC website http://www.ecetoc.org/index.php). It is advised to compare both methods when setting the final DNEL. The choice of either method has to be scientifically justified in the CSR.

The basis for the DNEL can be a no observed adverse effect level (NOAEL) established with appropriate information from *in vitro* tests and/or tests in animals and/or information from epidemiological studies, or in rare cases from QSARs. A series of assessment factors (AF) are used in the derivation process. Assessment factors are used to account for uncertainties, for example, in extrapolation between and within species (inter-species and intra-species factor). By default for workers in industrial and professional settings and for consumers DNELs will be derived for the inhalatory and dermal route for systemic long-term exposure. If a substance is classified for acute and/or local effects DNELs have to be derived for these routes in addition.

For skin and eye corrosion/irritation no method is yet available to derive safe limit values. In case classification and labelling is required for these endpoints, a qualitative approach has to be followed. This means that the Risk Management Measures (RMM) need to be implemented such as goggles, face shields or gloves. For substances that are classified for skin sensitisation a similar approach can be chosen. However when a "DNEL induction" can be derived for skin sensitisation (when results available from a LLNA), a residual risk based approach can also be followed estimating the residual exposure wearing gloves by the worker. For the consumer, no personal protective equipment is anticipated and therefore, no fragranced end-products are classified as skin sensitiser.

2.2.1.2 Safe limit values for environmental exposure

The derivation of a PNEC is described in detail in the ECHA guidance document: "Guidance on information requirements and chemical safety assessment Chapter R.10: Characterisation of dose [concentration]-response for environment" (v1, May 2008).

As with the derivation of the DNEL, assessment factors are also applied to the ecotoxicological endpoints (L(E)C50/NOEC values) used to derive the final PNEC. The PNECs that are derived for the environmental endpoints are: aquatic (freshwater and marine), sediment (freshwater and marine), soil (terrestrial), secondary poisoning and the sewage treatment plant.

2.3 Exposure Assessment

2.3.1 Introduction

In this IFRA guidance document, Generic Exposure Scenarios (GES) for the fragrance industry are described consisting of the typical operational conditions (OCs) for the fragrance industry for each life-cycle step. Each GES contains several Contributing Scenarios which describe the handling activities of the substance within one life cycle step. A 'final' substance ES describes the conditions under which the use of a specific substance within one life cycle step is considered safe.

Following the ECHA Use Descriptor system, OCs for workers can be categorised in Process Categories (PROCs) to be able to relate them to exposure doses and concentrations. For consumers this can be either the Product Category (PC) or the Article Category (AC). For the environment those conditions are described by means of Environmental Release Categories (ERCs).

Industry associations have defined typical operational conditions for workers, consumers and the environment. For the formulation of fragrance compounds, typical OCs for workers and the environment have been defined by IFRA and are presented in chapter 3. For the other life-cycle stages those were taken from AISE and Cosmetics Europe. For the environment these typical OCs are defined within a Specific Environmental Release Category (spERC) and can be used for the CSA when documented in a factsheet. IFRA spERCs have been developed for the formulation of fragrance compounds and are documented in a factsheet in Annex 4 to this report. For other life-cycle steps, spERCs from AISE and Cosmetics Europe have been used. More details on these spERCs are provided in Chapter 3.

In some instances the typical operational conditions defined will not lead to safe use e.g. for highly toxic substances or substances used in very high volumes. In those cases registrants will need to modify the GES data and additional risk management measures (RMMs) may be required to ensure safe use, for example Personal Protection Equipment (PPE). Once the conditions for safe use have been established, the final Exposure Scenarios are documented in a Chemical Safety Report (CSR). The Exposure Scenarios are communicated down the supply chain by annexing them to the Safety Data Sheet (SDS), i.e. the extended Safety Data Sheet (ext-SDS).

2.3.2 Mapping uses

2.3.2.1 Gathering information

Under the REACH Regulation use is defined as "any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation" (Article 3.24). The registrant's own use "means an industrial or professional use by the registrant" (Article 3.25). An identified use is "a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user" (Article 3.26). Identified Uses are described by using the ECHA Use Descriptor System.

The Use Descriptor System was developed by ECHA:

1. To describe a use in general terms in the context of REACH Annex VI;
2. For use identification/communication from DU to supplier;
3. For naming exposure scenarios in a systematic way.

Communication on Identified Uses of a substance between the manufacturer/importer (M/I) and downstream user (DU) is essential in preparing a Chemical Safety Assessment for the whole life cycle of a substance.

The M/I lists all of their uses and includes in this list the uses of the Downstream Users that they are aware of and can support. Subsequently the M/I communicates this list of uses with the downstream users to check whether their uses are covered.

A template for the communication of identified uses is developed by DUCC (the Downstream Users of Chemicals Coordination Group) and is available here: http://cefic.org/files/Downloads/Final_Template_09_03_09.xls.

In this IFRA guidance document the Identified Uses for the fragrance industry are included. Other uses can be added substance by substance by the registrant.

The downstream user can ask the M/I to add uses to the list. The DU must describe the use (not only including the use descriptors but also describing the actual handling activity/task) and include the relevant information (i.e. OCs) in order for the M/I to include it as an Identified Use and take it into account for the CSA.

If the M/I decides to support the new use, it will be included in the use mapping. If the registrant decides not to support the use he has to provide reasoning to the DU. In that case the downstream user has to prepare a DU CSA for his use, based on the hazard data supplied by his M/I (unless they are exempted by REACH Article 37.4).

2.3.2.2 Selecting Use Descriptors

For all identified uses the registrant selects the use descriptors as presented in the ECHA guidance document: "Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system" (v2, March 2010). The following use descriptors are included:

- **Sector of Use (SU)** which describes the sector of the economy where the substance is used. This includes the manufacturing of the fragrance substance in the chemical industry (SU8/9), formulation of fragrance compounds/end-products (SU10), end-use in an industrial setting (SU3), professional setting (SU22) and by consumers (SU21). The SU's only purpose is to define the sector of economy and has no relevance for exposure estimation. For the fragrance industry is was decided to use only the above mentioned SU codes and not further specify those in subsectors of use.
- **the process category (PROC)** describes the technical process or application in which the substance is used from an occupational perspective. PROCs are defined for workers only.
- **the product category (PC)** describes the type of preparations (mixtures) containing the substance on end-use. These PCs have to be used for consumer products and for transparency should also be assigned to industrial and professional end-uses to distinguish between the many different end-products that contain fragrance substances.
- **the article category (AC)** describes the type of article into which the substance has eventually been processed. These are only applicable for consumer end use.
- **the environmental release category (ERC)** describes the broad conditions of use and emission from the environmental perspective.

The applicable use descriptors which should be assigned to the different life cycle stages are presented in Table 2.

Table 2: Relevance of the ECHA Use Descriptors in the different life-cycle stages

Life-cycle stage	SU	PROC	PC	AC	ERC
Manufacturing	+	+	NA	NA	+
Formulation of fragrance compounds	+	+	NA	NA	+
Formulation of fragranced end-products	+	+	NA	NA	+
Industrial end-use	+	+	+	NA	+
Professional end-use	+	+	+	NA	+
Consumer end-use	+	NA	+	+	+

NA = not applicable

2.3.2.3 Selection of the appropriate Use Descriptors for the fragrance industry

Fragrance substances are used in a wide range of products. The IFRA list of identified uses for fragrance ingredients can be found in Chapter 3. The following sources of information have been used to identify the uses and thus the use descriptors of fragrance substances.

- AISE use mapping tables, which contain a long list of uses including formulation and professional/industrial use of cleaning and maintenance products as well as use of consumer products (available from: http://www.aise.eu/reach/?page=exposureass_sub2);
- the Cosmetics Europe list reports uses in the cosmetics industry. The uses are reported according to the UseR format as developed by DUCC (the Downstream Users of Chemicals Coordination Group). They cover most uses of substances in the manufacturing of cosmetic products and their end use. The Cosmetics Europe list is available from: http://www.cosmeticseurope.eu/safety-and-science-cosmetics-europe/reach-and-chemicals/use-and-exposure-information.html.

EDANA also has provided use mapping tables for their uses, which can be found here: http://www.edana.org/Content/Default.asp?PageID=498. Out of these, only the tables for absorbent hygiene products (AHP) and wet wipes contain uses that are considered relevant for the fragrance industry. Wet wipes may contain a fragranced lotion, which is considered a preparation/mixture and not an article. Consumer and professional uses of wipes for cleaning purposes are included in the AISE use mapping tables and are therefore included as Identified Uses in this guidance. Fragranced absorbent hygiene products are considered articles with intended release. Although the use of fragrances in AHPs can occur, this Identified Use is not further considered in this guidance document, because most fragrance substances will be present in concentrations below the applicable concentration limit of REACH Article 14.2.

2.3.3 Exposure Scenario

REACH Article 3.37 defines an Exposure Scenario as: "the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment". These exposure scenarios may cover one specific process or use or several processes or uses as appropriate."

2.3.3.1 Exposure Scenario for workers

The registrant starts out to document the handling activities/tasks performed with the substance during each life cycle step. These handling activities can be e.g. transfer from one container to another, mixing, storage, washing of containers and equipment and sampling. This is the process description and each of these activities can be a Contributing Scenario (CS) in the Exposure Scenario for each life-cycle step (e.g. storage (CS) during manufacturing (ES)). Such a description should contain the Operational Conditions during the identified process e.g. exposure time and concentration of substance in the mixture. The process description is captured in process categories (PROCs). The operational conditions are defined per PROC per life-cycle stage. These PROCs and defined operational conditions are used as input in software tools such as ECETOC TRA to estimate exposure doses or concentrations for workers. In the current version of ECETOC (version 2) for dermal exposure the exposure estimate is solely PROC depending. For inhalation exposure the exposure estimate is depending on the physical form and vapour pressure range. Furthermore exposure refinements can be made by adjusting exposure time and concentrations of the substance in the product. In March 2012 a new version of ECETOC will be released (version 3). Some changes to the current version are implemented and will be further described in Chapter 3.

2.3.3.2 Exposure Scenario for consumers

All end-products containing fragrance substances are identified using Product Categories (PC) based on the ECHA Use descriptor system. These PCs are used together with the physico-chemical properties of the substance as input for software tools such as ECETOC TRA to estimate exposure doses (by dermal and/or oral routes) or concentrations (by inhalation). In March 2012 a new version of ECETOC will be released (version 3). As for the worker, some changes to the current version are implemented and will be further described in Chapter 3.

2.3.3.3 Exposure Scenario for the environment

As minimum input for a Tier 1 exposure assessment, the physico-chemical properties of the substance, the EU Tonnage and Fraction of EU tonnage used in region (1 or 0.1), the appropriate ERC and whether the use of a WWTP is assumed have to be defined.
For most IFRA GESs one or several spERCs are available. The appropriate spERC and industry sector can be selected and the Tier 1 inputs from the ERC will be replaced by inputs that are more specific for the fragrance industry (Tier 1.5 assessment).

2.3.4 Exposure Estimation

At first exposure is estimated using models. Tier 1 exposure estimation normally starts with a worst case estimation meaning default operational conditions (such as 8 hour exposure time per working day and pure substance for workers) and no RMMs (LEV, respiratory protection, gloves). For the fragrance industry default worst case operational conditions can be replaced by typical ones (realistic worst case) which can be entered into a Tier 1 exposure estimation tool and can be considered a refined Tier 1 approach (for workers) or a Tier 1.5 approach (for consumers and environment).

ECETOC has developed a Targeted Risk Assessment (TRA) tool for the estimation of exposure for worker, consumers and environment, based on the identified exposure scenarios, which is available upon registration here or here: http://www.ecetoc.org/tra (select download integrated tool). Prior to the ECETOC TRA model, the Joint Research Centre of the European Commission had developed EUSES. Regarding environmental risk assessment, ECETOC TRA and EUSES are based exactly on the same equations, so they are equivalent and can both be used for Tier 1 environmental assessments. The only difference is that the ERC and spERC system have not been implemented in EUSES, so default inputs have to be set manually (see section 4.3 for more details).

By running the models in the ECETOC TRA, for each contributing scenario an exposure estimate is generated (Predicted exposure concentration (PEC) for the environment and the predicted exposure level (PEL) for workers/consumers).

2.4 Risk Characterisation

2.4.1 Risk Characterisation for worker and consumer exposure

In order to characterise the risk of a scenario in which human exposure occurs, the exposure is compared to the appropriate DNEL, i.e. derived according to the route of exposure (oral, dermal or inhalation), the time of exposure (acute or long-term exposure) and the type of effect (local and/or systemic effect). The risk of a scenario is determined by calculating the Risk Characterisation Ratio (RCR) for each human exposure route according to the following equation

RCR_{human} = concentration or dose (PEL) / DNEL

If in a scenario more than one route of exposure applies (i.e. both inhalation and dermal exposure) then the RCR's are aggregated.

2.4.2 Risk Characterisation for environment

In order to characterise the risk of a scenario in which emission to the environment occurs, the predicted environmental concentration (PEC) is compared to the safe limit value for the environmental compartment of interest (PNEC). The risk of an exposure scenario is determined by calculating the Risk Characterisation Ratio (RCR) for each environmental compartment according to the following equation:

$RCR_{environment} = PEC / PNEC$

2.4.3 Determining whether a use is safe

If the RCR is below 1 for all relevant scenarios, the use is considered safe. If the same target is exposed to one substance through various routes (which are part of the supply chain of the registrant) the RCRs have to be added up. This combined RCR should also be below 1.

If the RCR is above 1, the use cannot be considered as safe and in principle should not be incorporated into a CSR and needs to be further refined or in rare cases the particular use is to be advised against. For refinement the following options are available (however not discussed further here):

- refinement of the exposure scenario:
  - performing a more precise exposure estimation (using higher Tier models);
  - adapting the operational conditions and risk management measures;
  - carry out measurements to define exposure;
- refinement of the hazard assessment (in order to derive a higher safe limit value).

2.5 Completion of the Exposure Scenario

The defined operational conditions, the results of the exposure models, the estimated exposure concentrations for workers and consumer exposure as well as the predicted environmental concentrations in various compartments that lead to safe use can be put down in the final exposure scenario. This can be done either in CHESAR or the CSR template in Microsoft Word.
ECHA has provided some guidance on how the title section of the Exposure Scenario for communication should be built up. The title of the Exposure Scenario is meant to indicate for which life cycle stages and main user groups, types of products, technical processes/operations/activities or sectors of industry the ES is applicable. As a minimum (also referred to as the 'short title') the title of an exposure scenario should contain the life cycle stage and sector of use followed by the product category. These minimum requirements have been followed for building the titles of the exposure scenarios described in this document.

2.6 Supply Chain Communication of information on hazards and safe use

The information on the safe use of a substance is communicated to the Downstream User through the Safety Data Sheet (SDS). For all substances for which a CSA is required and Exposure Scenarios have been developed an extended Safety Data Sheet (ext-SDS) has to be communicated. The relevant Exposure Scenarios including OC's and RMM's are attached to the SDS and the content of several of the 16 chapters of the main body of the SDS have to be brought in line with the content of the CSR.

The ECHA guidance document: "Guidance on information requirements and chemical safety assessment Part G: Extending the SDS" (v1.1, May 2008) contains more

information concerning the ext-SDS. Table G.2 of the guidance document referred to above indicates where the information of the CSA should be placed in the chapters of the ext-SDS.

2.7 Actions for DU after receiving the Exposure Scenarios

Downstream Users must pass on Exposure Scenarios further down the supply chain where relevant. DUs have to verify whether the Exposure Scenarios that are received via an ext-SDS describe the conditions for their applicable uses on-site. First a check needs to be done to see if the Identified Uses of the DU are included (ES titles, use descriptors, main exposure determinants). Then a check to see if all recommended OCs and RMMs are in place. If the DU is in compliance with the conditions in the relevant Exposure Scenario(s), this needs to be documented and DUs must be able to show this information to the authorities in case of inspections.

If DUs do not operate according to the conditions of an Exposure Scenario, several options are available for consideration:

- Implementation of the recommended RMMs and OCs
- Communication to the supplier of the on-site conditions the DU has in place with a request to update the relevant Exposure Scenario accordingly
- Preparation of a DU CSA
- Scaling: recalculate exposure & risk using modelling tools using the on-site conditions

Cefic and DUCC have been very active in the fields of DU CSA and scaling and have done several presentations on these topics recently (Q4 2011, Q1 2012).

Normally exploring these options further will eventually result in safe use, which again needs to be documented and made available to authorities during inspections. In exceptional cases where no safe use can be demonstrated, the use will need to be advised against.

3 GENERIC EXPOSURE SCENARIOS FOR FRAGRANCE SUBSTANCES

3.1 Introduction

For the assessment of the potential exposure to a substance, all stages of its life-cycle must be considered and both human and environmental exposure must be taken into account (figure 4). The life-cycle of a fragrance substance starts with the manufacturing, i.e. synthesis or extraction of the substance. The next step is the mixing of fragrance substances into a fragrance compound (formulation of fragrance compounds) followed by the formulation of the compound into a fragranced end-product (formulation of a fragranced end-product). The number of “compounding” sites in the EU is limited (fragrance houses and some downstream users who mix their own fragrances) whereas the number of fragranced end-product sites that formulate compounds into fragranced end-products is much larger and the formulating operations are potentially more varied.

Fragranced end-products are used in industry, by professionals and/or consumers. They can be used for cleaning and maintenance of industrial process equipment, are available for public hygiene, and are available to consumers in private households. Figure 4 contains a schematic overview of the life-cycle of a typical fragrance substance and contains links to the corresponding chapters where further information is provided on the exposure occurring during each stage.

For each life cycle stage one or more Identified Uses can be described to which ECHA use descriptors can be assigned following a Use Mapping process. For each Identified use a Generic Exposure Scenario (GES) can be generated, which will then form the basis for calculating exposure estimations and assessing risk. This process is depicted in Figure 5 and will be described in detail in Chapters 3 and 4.

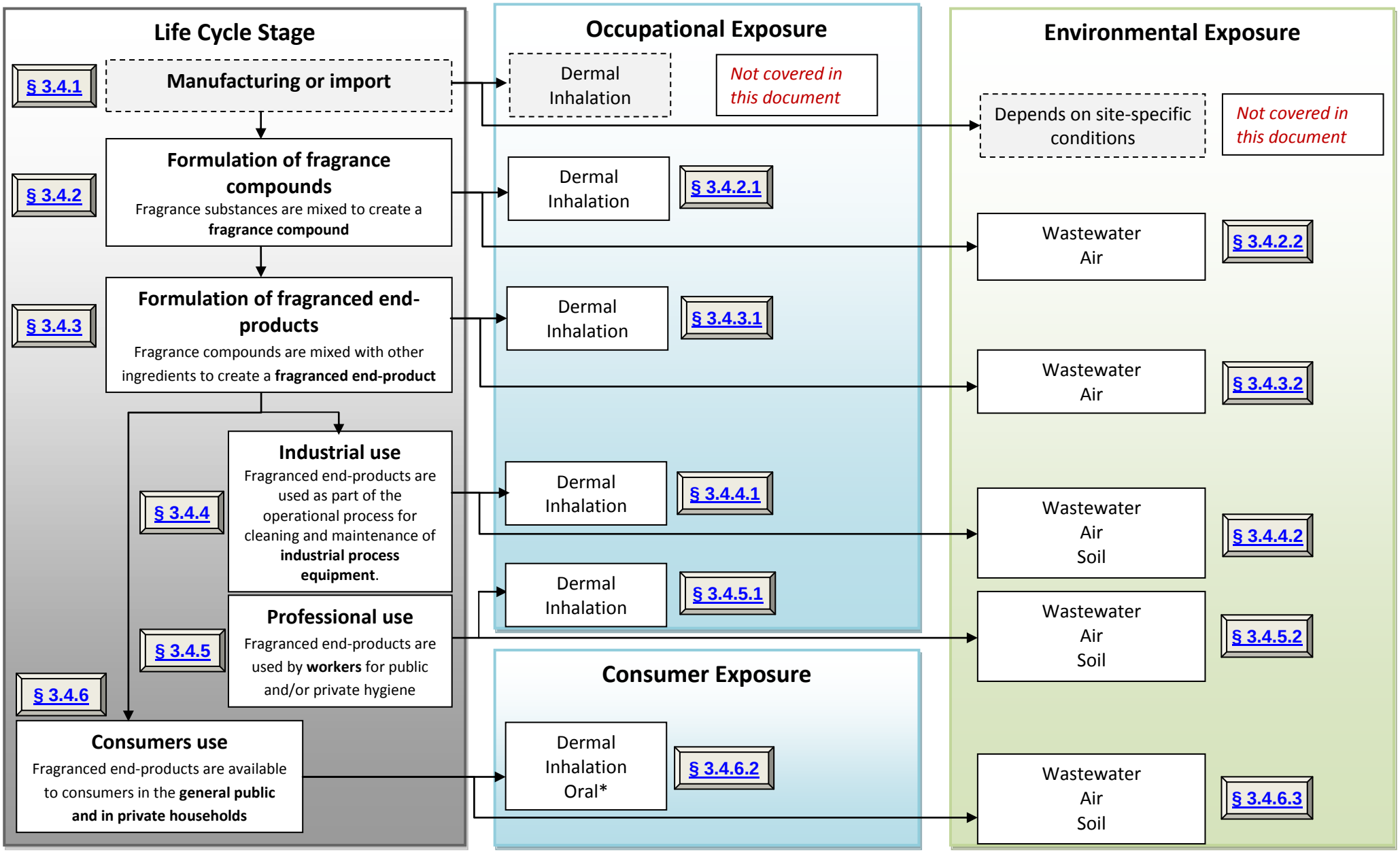

Figure 4: Overview of life-cycle stages with Tier 1 and Tier 1.5 assessment ** Only in Tier 1.5 consumer exposure assessment (considering indirect contact by oral)*

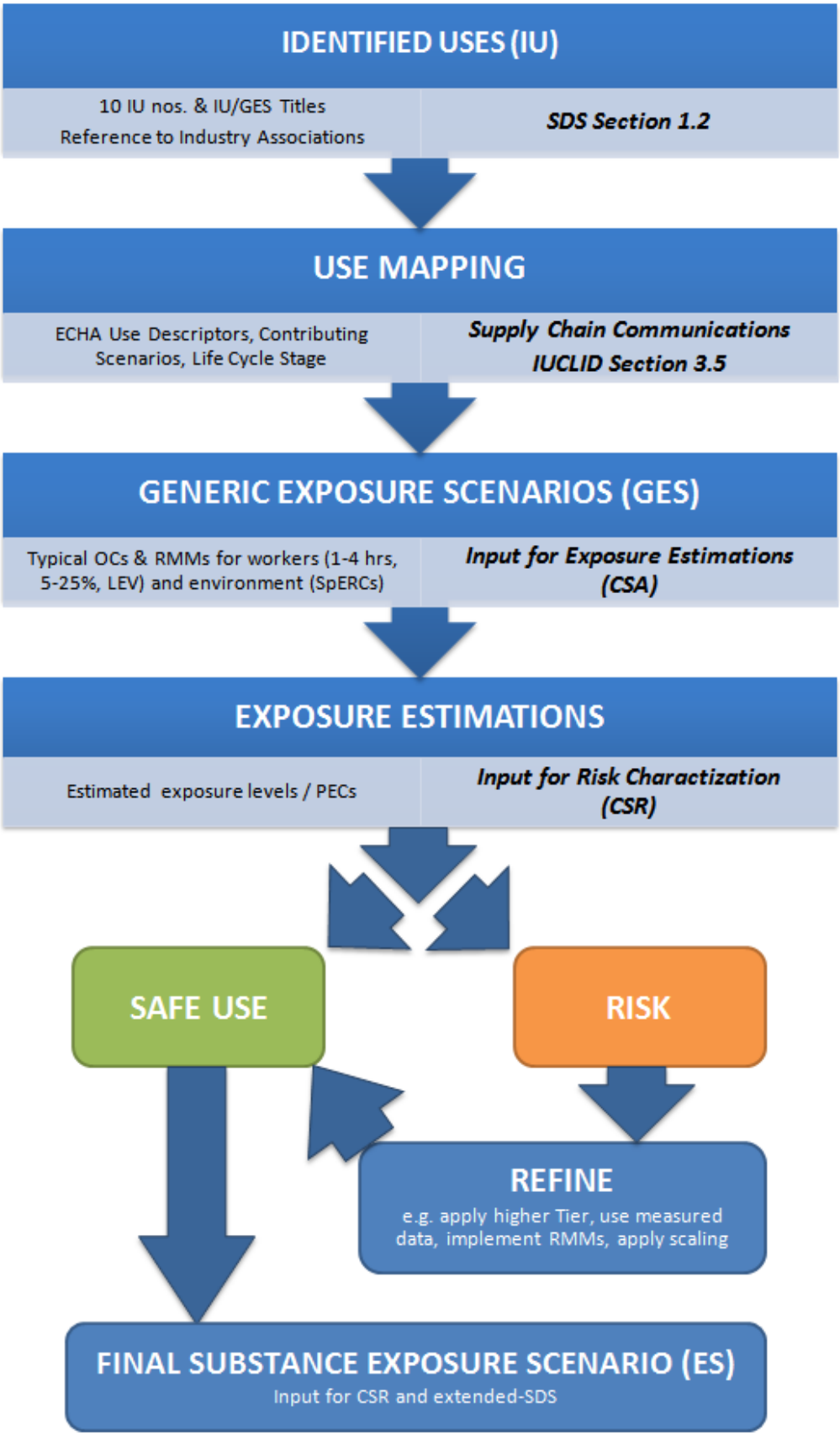

Figure 5: Stepwise Process to prepare Exposure Scenarios for a fragrance substance

3.2 Identified uses

IDENTIFIED USES (IU)	
10 IU nos. & IU/GES Titles Reference to Industry Associations	***SDS Section 1.2***

Ten main Identified Uses (IU) have been identified by IFRA as uses of fragrance substances in specific industrial, professional or consumer settings (see Table 3), which IFRA strongly recommends registrants of fragrance substances to include in their REACH registrations as a minimum. IFRA members and their suppliers are advised to adhere to these exact IU numbers and titles in order to maximize industry alignment when reporting them in their dossiers or in section 1.2 of the ext-SDS.

IU 1, Formulation of fragrance compounds, is specific to the fragrance industry and the Use Mapping and GES have been developed by experts from IFRA member companies for inclusion in this Guidance document. All other Identified Uses are based on the use mapping and GES data provided by Downstream User (DU) Associations (AISE, Cosmetics Europe). Manufacturing is another Identified Use but will not be described in a GES because this is always substance and site specific and also does not apply to substances that are imported.

Fragrance substances may occasionally also occur in products that are not included in the list of Identified Uses in Table 3, such as paints, fuels or inks (PC9a-c, 13, 18). The same is true for scented articles, such as clothes, erasers, toys and CDs (AC31, 32, 34, 36). The rationale for this omission is that the concentration of a fragrance substance in these products is considered to be lower than the applicable concentration limit as listed in REACH Article 14.2 (in practice this usually means <1% or <0.1% for substances classified as N,R50/53 or N,R51/53). In this case an Exposure Scenario for this end-use would not be required. Individual Registrants can of course always decide to include additional Identified Uses to the dossier of a given substance, for example when these have been specifically requested by a DU and/or when the substance is present in an end-product above the applicable concentration limit.

For scented paper articles (AC35), DU Association EDANA has provided Use Mapping tables that were reviewed by IFRA experts. Out of the EDANA use mapping tables, only the tables for absorbent hygiene products (AHP) and wet wipes contain uses that are considered relevant for the fragrance industry. Wet wipes may contain a fragranced lotion, which is considered a mixture and not an article. Consumer and professional uses of wipes for cleaning purposes are included in the AISE use mapping tables and are therefore included as Identified Uses in this guidance. Fragranced absorbent hygiene products are considered articles with intended release. Although the use of fragrances in AHPs can occur, this Identified Use is not included in this guidance document, because most fragrance substances will be present in concentrations below the applicable concentration limit of REACH Article 14.2. However, this should always be reviewed carefully on a substance specific basis and if conclusive information is available about the concentration levels above the limit, an Exposure Scenario for this end-use should be included in the registration dossier, which should be based on the use mapping provided by EDANA (http://www.edana.org/Content/Default.asp?PageID=498).

Table 3: Identified Uses (IU) and Generic Exposure Scenarios (GES) for fragrance substances

IU n°	IU Title	Reference
IU 0	Manufacturing of fragrance substances *	**Site specific**
IU 1	GES1 - Formulation of fragrance compounds (mixing of fragrance substances into fragrance compounds)	**IFRA**
IU 2	GES2 - Formulation of fragranced end-products (mixing of fragrance compounds into fragranced end-products)	**AISE / Cosm. Eur.**
IU 3	GES3 - Industrial end-use of washing and cleaning products	**AISE**
IU 4	GES4 - Professional end-use of washing and cleaning products	**AISE**
IU 5	GES5 - Professional end-use of polishes and wax blends	**AISE**
IU 6	GES6 - Consumer end-use of washing and cleaning products	**AISE**
IU 7	GES7 - Consumer end-use of air care products	**AISE**
IU 8	GES8 - Consumer end-use of biocides	**AISE**
IU 9	GES9 - Consumer end-use of polishes and wax blends	**AISE**
IU 10	GES10 - Consumer end-use of cosmetics **	**Cosm. Eur.**

** No GES for manufacturing (site specific)*

*** Only includes environmental exposure, assessment of human exposure is exempt from REACH*

3.3 Use Mapping

USE MAPPING	
ECHA Use Descriptors, Contributing Scenarios, Life Cycle Stage	***Supply Chain Communications IUCLID Section 3.5***

The Use Mapping for IU 1-10 is provided below in Tables 4 to 10. The Use Mapping for manufacturing of fragrance substances is not included because this information needs to be generated by the manufacturers themselves.

Each IU is based on specific activities/processes which are named Contributing Scenarios (CS+n° in table use mapping).
For the Industrial & Professional end-use of washing and cleaning products and the Professional end-use of polishes and wax blends (IU 3-5) the AISE Use Mapping based on the DUCC UseR template was used, however only those activities/processes (i.e. Contributing Scenarios) that are applicable to fragranced end-products have been included, therefore not all AISE numbers (P-XXX) are included.

Regarding the use of fragranced end-products by consumers (IU 6-10), the AISE and Cosmetics Europe information was taken over without significant changes to the content. Please note that a CSR does not need to include consideration of the risks to human health from cosmetic end-use (IU 10), so therefore only the environmental risk needs to be considered (Article 14.5(b) of the REACH Regulation).

The information from the Use Mapping tables can be used to complete Chapter 3.5 of IUCLID.

Table 4: Use mapping for Formulation of fragrance compounds (IU 1)

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 1 - Formulation of fragrance compounds												
	X					CS1	Uploading/unloading	PROC8b	SU10	–	–	ERC2
						CS2	Sampling of received goods	PROC2				
						CS3	Q control of received goods	PROC15				
						CS4	Storage	PROC1				
						CS5	Closed system mixing including filling process equipment	PROC3				
						CS6	Batch mixing with significant contact including filling process equipment	PROC5				
						CS7	Cleaning and maintenance	PROC8a				
						CS8	Sampling of compound	PROC2				
						CS9	Q control of compound	PROC15				
						CS10	Charging/discharging from/to vessels/large containers (dedicated facilities)	PROC8b				
						CS11	Transfer into small containers (dedicated filling line, including weighing)	PROC9				

Table 5: Use mapping for Formulation of fragranced end-products (IU 2)

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 2 - Formulation of fragranced end-products												
	X					CS1	Uploading/unloading	PROC8b	SU10	_	_	ERC2
						CS2	Sampling of received goods	PROC2				
						CS3	Q control of received goods	PROC15				
						CS4	Storage	PROC1				
						CS5	Closed system mixing including filling process equipment	PROC3				
						CS6	Batch mixing with significant contact including filling process equipment	PROC5				
						CS7	Cleaning and maintenance	PROC8a				
						CS8	Sampling of compound	PROC2				
						CS9	Q control of compound	PROC15				
						CS10	Charging/discharging from/to vessels/large containers (dedicated facilities)	PROC8b				
						CS11	Transfer into small containers (dedicated filling line, including weighing)	PROC9				
						CS12	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	PROC14				

Table 6: Use mapping for Industrial end-use of washing and cleaning products (IU 3)

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 3 - Industrial end-use of washing and cleaning products												
		X				CS1a	Use of laundry detergents and conditioners (softener/starch); automatic process (AISE-P101, AISE-P104) - preparatory phase	PROC8b	SU3	PC35	_	ERC4
						CS1b	Use of laundry detergents and conditioners (softener/starch); automatic process (AISE-P101, AISE-P104) - use phase	PROC2				
						CS2a	Use of laundry aid (gasing and non-gasing); automatic process (AISE-P107, AISE-P110) - preparatory phase	PROC8b				
						CS2b	Use of laundry aid (gasing and non-gasing); automatic process (AISE-P107, AISE-P110) - use phase	PROC2				
						CS3a	Use of train and aeroplane cleaners, car wash products and dewaxing products; semi-automatic process (AISE-P707, AISE-P708, AISE-P709, AISE-P712)- preparatory phase	PROC8a				
						CS3b	Use of train and aeroplane cleaners, car wash products and dewaxing products; semi-automatic process (AISE-P707, AISE-P708, AISE-P709, AISE-P712)- use phase	PROC4				
						CS4a	Use of car wash products and boat cleaners in spray and rinse processes and spray and wipe manual processes (AISE-P710, AISE-P711, AISE P714)- preparatory phase	PROC8a				
						CS4b	Use of car wash products and boat cleaners in spray and rinse processes and spray and wipe manual processes (AISE-P710, AISE-P711, AISE P714)- use phase	PROC7				
						CS5a	Use of boat cleaners; manual process (AISE-P713)- preparatory phase	PROC8a				
						CS5b	Use of boat cleaners; manual process (AISE-P713)- use phase	PROC10				
						CS6	Use of food process cleaner; cleaning in place (CIP) process (AISE-P801); preparatory phase only	PROC8b				
						CS7a	Use of food process cleaner; semi closed cleaning process (AISE-P802)- preparatory phase	PROC8b				
						CS7b	Use of food process cleaner; semi closed cleaning process (AISE-P802)- use phase	PROC4				

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 3 - Industrial end-use of washing and cleaning products												
						CS8a	Use of chain maintenance product; automatic spray process (AISE-P803)- preparatory phase	PROC8a				
						CS8b	Use of chain maintenance product; automatic spray process (AISE-P803)- use phase	PROC7				
						CS9a	Use of chain maintenance product; automatic drip and brush process (AISE-P804)- preparatory phase	PROC8a				
						CS9b	Use of chain maintenance product; automatic drip and brush process (AISE-P804)- use phase	PROC13				
						CS10	Use of defoaming product; automatic process (AISE-P805); preparatory phase only	PROC8b				
						CS11a	Use of a foam cleaner; semi-automatic with and without venting process (AISE-P806, AISE-P807)- preparatory phase	PROC8a				
						CS11b	Use of a foam cleaner; semi-automatic with and without venting process (AISE-P806, AISE-P807)- use phase	PROC7				
						CS12a	Use in animal housing care and disinfection products; semi-automatic processes (AISE P809, AISE P810)- preparatory phase	PROC8a				
						CS12b	Use in animal housing care and disinfection products; semi-automatic processes (AISE P809, AISE P810)- use phase	PROC10				
						CS13a	Use in disinfection products; fogging and gassing semi-automatic processes (AISE P811)- preparatory phase	PROC8a				
						CS13b	Use in disinfection products; fogging and gassing semi-automatic processes (AISE P811)- use phase	PROC7				
						CS14a	Use of façade/surface cleaning products (AISE P906, AISE P907)- preparatory phase	PROC8a				
						CS14b	Use of façade/surface cleaning products (AISE P906, AISE P907)- use phase	PROC7				
						CS15a	Use of metal cleaner (degreaser, descaler, etch) manual process (AISE P1004)- preparatory phase	PROC8a				
						CS15b	Use of metal cleaner (degreaser, descaler, etch) manual process (AISE P1004)- use phase	PROC10				

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 3 - Industrial end-use of washing and cleaning products												
						CS16a	Use of metal cleaner (degreaser, descaler, etch) semi-automatic process (AISE P1005)- preparatory phase	PROC8b				
						CS16b	Use of metal cleaner (degreaser, descaler, etch) semi-automatic process (AISE P1005)- use phase	PROC4				
						CS17a	Use of metal cleaner (degreaser, descaler, etch) automatic process (AISE P1006)- preparatory phase	PROC8b				
						CS17b	Use of metal cleaner (degreaser, descaler, etch) automatic process (AISE P1006)- use phase	PROC2				

Table 7: Use mapping for Professional end-use of washing and cleaning products (IU 4)

Manufacture	Formulation	End Use			Service Life (for article)		IU description	Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 4 - Professional end-use of washing and cleaning products												
			X			CS1	Professional use of laundry products; laundry detergent and conditioners, semi-automatic process (AISE P102, AISE P105); preparatory phase only	PROC8a	SU22	PC35	_	ERC8a (ERC8d, only for CS28a+b)
						CS2	Professional use of laundry products; laundry detergent and conditioners, manual process (AISE P103, AISE P106); preparatory phase only	PROC8a				
						CS3	Professional use of laundry products; laundry aid (gasing), semi-automatic and manual process (AISE P108, AISE P109); preparatory phase only	PROC8a				
						CS4	Professional use of laundry products; laundry aid (non-gasing), semi-automatic process (AISE P111); preparatory phase only	PROC8a				
						CS5	Professional use of laundry products; laundry aid (non-gasing), manual process (AISE P112); preparatory phase only	PROC8a				
						CS6	Professional use of laundry products; prespotter/stain remover, manual process (AISE P113)	PROC11				
						CS7a	Professional use of dishwash products; manual process (AISE P201) - preparatory phase	PROC8a				
						CS7b	Professional use of dishwash products; manual process (AISE P201) - use phase	PROC10				
						CS8a	Professional use of dishwash and rinse products; automatic process (AISE P202, AISE P204) - preparatory phase	PROC8b				
						CS8b	Professional use of dishwash and rinse products; automatic process (AISE P202, AISE P204)- use phase	PROC2				
						CS9	Professional use of dishwash products; semi-automatic process (AISE P203); preparatory phase only	PROC8a				
						CS10a	Professional use of general purpose cleaner, sanitary cleaner, glass cleaner and metal cleaning agent, manual process (AISE P301, AISE P305, AISE P312, AISE P316) - preparatory phase	PROC8a				
						CS10b	Professional use of general purpose cleaner, sanitary cleaner, glass cleaner and metal cleaning agent, manual process (AISE P301, AISE P305, AISE P312, AISE P316)- use phase	PROC10				
						CS11a	Professional use of general purpose cleaner, sanitary cleaner, glass cleaner, descaling agent and metal cleaning agent, spray and wipe manual process (AISE P302, AISE P306, AISE P308, AISE P313, AISE P315)- preparatory phase	PROC8a				

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 4 - Professional end-use of washing and cleaning products												
						CS11b	Professional use of general purpose cleaner, sanitary cleaner, glass cleaner, descaling agent and metal cleaning agent, spray and wipe manual process (AISE P302, AISE P306, AISE P308, AISE P313, AISE P315)- use phase	PROC11				
						CS12a	Professional use of kitchen cleaners; manual process (AISE P303)- preparatory phase	PROC8a				
						CS12b	Professional use of kitchen cleaners; manual process (AISE P303)- use phase	PROC10				
						CS13a	Professional use of kitchen cleaners; spray and wipe manual process (AISE P304)- preparatory phase	PROC8a				
						CS13b	Professional use of kitchen cleaners; spray and wipe manual process (AISE P304)- use phase	PROC11				
						CS14	Professional use of descaling agent; manual process (AISE P307); use phase only	PROC11				
						CS15	Professional use of descaling agent; dipping process (AISE P309); use phase only	PROC13				
						CS16	Professional use of oven/grill cleaner; manual process (AISE P310); use phase only	PROC10				
						CS17	Professional use of oven/grill cleaner; spray and wipe manual process (AISE P311); use phase only	PROC11				
						CS18a	Professional use of surface disinfectant; manual process (AISE P314)- preparatory phase	PROC8a				
						CS18b	Professional use of surface disinfectant; manual process (AISE P314)- use phase	PROC10				
						CS19	Professional use of wet wipes; manual process (AISE P317); use phase only	PROC10				
						CS20a	Professional use of floor cleaners; manual and semi-automatic process (AISE P401, AISE P403)- preparatory phase	PROC8a				
						CS20b	Professional use of floor cleaners; manual and semi-automatic process (AISE P401, AISE P403)- use phase	PROC10				
						CS21a	Professional use of floor cleaners; spray and wipe manual process (AISE P402)- preparatory phase	PROC8a				

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 4 - Professional end-use of washing and cleaning products												
						CS21b	Professional use of floor cleaners; spray and wipe manual process (AISE P402)- use phase	PROC11				
						CS22a	Professional use of floor strippers and carpet cleaners; manual and semi-automatic process (AISE P404, AISE P405, AISE P409, AISE P410)- preparatory phase	PROC8a				
						CS22b	Professional use of floor strippers and carpet cleaners; manual and semi-automatic process (AISE P404, AISE P405, AISE P409, AISE P410)- use phase	PROC10				
						CS23	Professional use of carpet cleaners; spray and brush manual process (AISE P411); use phase only	PROC11				
						CS24	Professional use of drain cleaners; manual process (AISE P607); use phase only	PROC8a				
						CS25a	Professional use of car wash and dewaxing products; semi-automatic process (AISE P701, AISE P704)- preparatory phase	PROC8a				
						CS25b	Professional use of car wash and dewaxing products; semi-automatic process (AISE P701, AISE P704)- use phase	PROC4				
						CS26a	Professional use of car wash products and boat cleaners; spray and rinse process and spray and wipe manual process (AISE P702, AISE P703, AISE P706)- preparatory phase	PROC8a				
						CS26b	Professional use of car wash products and boat cleaners; spray and rinse process and spray and wipe manual process (AISE P702, AISE P703, AISE P706)- use phase	PROC11				
						CS27a	Professional use of boat cleaners; manual process (AISE P705)- preparatory phase	PROC8a				
						CS27b	Professional use of boat cleaners; manual process (AISE P705)- use phase	PROC10				
						CS28a	Professional use of façade/surface cleaner; high and medium pressure process (AISE P901, AISE P902)- preparatory phase	PROC8a				
						CS28b	Professional use of façade/surface cleaner; high and medium pressure process (AISE P901, AISE P902)- use phase	PROC11				
						CS29a	Professional use of medical devices; semi-automatic process (AISE P1101)- preparatory phase	PROC8a				
						CS29b	Professional use of medical devices; semi-automatic process (AISE P1101)- use phase	PROC4				

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 4 - Professional end-use of washing and cleaning products												
						CS30a	Professional use of medical devices; dipping process (AISE P1102)- preparatory phase	PROC8a				
						CS30b	Professional use of medical devices; dipping process (AISE P1102)- use phase	PROC13				
						CS31a	Professional use of medical devices; manual process (AISE P1103)- preparatory phase	PROC8a				
						CS31b	Professional use of medical devices; manual process (AISE P1103)- use phase	PROC10				
						CS32a	Professional use of medical devices; spray process (AISE P1104)- preparatory phase	PROC8a				
						CS32b	Professional use of medical devices; spray process (AISE P1104)- use phase	PROC11				

Table 8: Use mapping for Professional end-use of polishes and wax blends (IU 5)

Manufacture	Formulation	End Use			Service Life (for article)	IU description		Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer								
IU 5 - Professional use of polishes and wax blends												
			X			CS1	Professional use of floor care products; polish/impregnating agent (manual or semi-automatic process); use phase only (AISE P406 and AISE P407)	PROC10	SU22	PC31	_	ERC8a
						CS2	Professional use of floor care products; polish/impregnating agent (spray and wipe manual process); use phase only (AISE P408)	PROC11				
						CS3	Professional use of maintenance products; furniture and leather care products (manual process); use phase only (AISE P601 and AISE P603)	PROC10				
						CS4	Professional use of maintenance products; furniture and leather care products (spray and wipe manual process); use phase only (AISE P602 and AISE P604)	PROC11				
						CS5a	Professional use of maintenance products; leather care product (automatic process) (AISE P605) - preparation phase	PROC8a				
						CS5b	Professional use of maintenance products; leather care product (automatic process) (AISE P605) - use phase	PROC2				
						CS6	Professional use of maintenance products; drain unblocker (manual process, use phase only); AISE P606	PROC8a				
						CS7	Professional use of maintenance products; stainless steel care; manual process (use phase only); AISE P608	PROC10				
						CS8	Professional use of maintenance products; stainless steel care; spray and wipe manual process (use phase only); AISE P609	PROC11				

Table 9: Use mapping for Consumer end-use of washing and cleaning products (IU 6)

Manufacture	Formulation	End Use			Service Life (for article)	IU description	Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer							
IU 6 - Consumer end-use of washing and cleaning products*											
				X		CS1 Laundry and dish washing products a) laundry regular (powder, liquid); AISE C1 b) laundry compact (powder, liquid/gel, tablet); AISE C2 c) fabric conditioners (liquid regular, liquid concentrate); AISE C3 d) Laundry additives (powder bleach, liquid bleach, tablet); AISE C4 e) Hand dishwashing (liquid regular, liquid concentrate); AISE C5 f) Machine dishwashing (powder, liquid, tablet); AISE C6 g) Laundry aids (ironing aids-starch spray, ironing aids-other); AISE C12 CS2 Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners) a) surface cleaners (liquid, powder, gel neat) AISE C7 b) Toilet cleaners (powder, liquid, gel, tablet) AISE C8 c) Carpet cleaners (liquid) AISE C11 d) Wipes (bathroom, kitchen, floor) AISE C15 e) High pressure washers/cleaners AISE C21 f) Automotive care (liquid) AISE C22 CS3 Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners) a) surface cleaners (spray neat) AISE C7 b) Oven cleaners (trigger spray) AISE C10 c) Carpet cleaners (spray,) AISE C11 d) Automotive care (spray) AISE C22	–	SU21	PC35	–	ERC8a ERC8d

*For some end-products (e.g. washing and cleaning end-products / PC 35) both type of formulations, i.e. liquids and sprays, are not applicable (e.g., wipes or oven cleaners) as addressed in the consumer target risk assessment. Therefore, some differences can be observed from the original AISE tables.

Table 10: Use mapping for Consumer end-use of air care products (IU 7), biocides (IU 8), polishes and wax blends (IU9) and cosmetics (IU10)

Manufacture	Formulation	End Use			Service Life (for article)	IU description	Process category (PROC)	Sector of use (SU)	Product category (PC)	Article category (AC)	Environment release category (ERC)
		Industrial	Professional	Consumer							
IU 7 - Consumer end-use of air care products											
				X		CS1 Air care, instant action (aerosol sprays): Air fresheners aerosol (aqueous, non-aqueous, concentrated (mini-aerosol, timed-release aerosols)); AISE C17 CS2 Air care continuous action (solid & liquid): Air fresheners non aerosol (perfume in/on solid substrate (gel), candles, diffusers (heated); AISE C18	_	SU21	PC3	_	ERC8a
IU 8 - Consumer end-use of biocides											
				X		CS1 Insecticides (liquid electric, spray neat) and repellents; AISE C19	_	SU21	PC8	_	ERC8a ERC8d
IU 9 -Consumer end-use of polishes and wax blends											
				X		CS1 Polishes, wax/cream (floor, furniture, shoes) CS2 Polishes, spray (furniture, shoes)	_	SU21	PC31	_	ERC8a
IU 10 - Consumer end-use of cosmetics											
				X		End-use of cosmetic products ; COLIPA U1 Note: only the environmental risk needs to be considered according to REACH Article 14.5(b)	_	SU21	PC39 PC28	_	ERC8a

3.4 Generic Exposure Scenarios for Fragrance Substances

GENERIC EXPOSURE SCENARIOS (GES)	
Typical OCs & RMMs for workers (1-4 hrs, 5-25%, LEV) and environment (SpERCs)	***Input for Exposure Estimations (CSA)***

3.4.1. Manufacturing

Fragrance substances can either be extracted from natural sources or manufactured via chemical synthesis. For each manufacturing site, an exposure scenario must be put together to assess the risks for workers and the local environment. The manufacturing process for each substance is specific per manufacturing site and cannot be described in a generic way. **Therefore this Identified Use is outside the scope of this document and no GES is included.**

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3.4.2 Formulation of fragrance compounds: GES 1

Individual fragrance substances are mixed with other fragrance substances to create a mixture (fragrance compound). Dosing, mixing and filling may be a completely automated process for larger batches whereas the small batches may be processed automatically (e.g. via robot) or manually.

Stabilizers and solvents may also be added to enhance the function of the compound. The final concentration of a fragrance substance in the mixture can range from parts per million up to 20% w/w [2]. On average a fragrance compound contains 40-60 different fragrance substances, but fragrances containing up to 300 substances (e.g. due to the use of complex sub-formulas) are no exception.

In many cases combinations of automated and manual dosing and mixing will occur. After each batch the equipment will be cleaned with water in a closed system or by spraying, sometimes using detergents, or with steam. In some cases alcohol or other solvents are used for cleaning instead of water.

The majority of the fragrance substances are liquids, but some are solids. Vapour pressure is an important parameter to assess worker exposure. Most fragrance substances have a VP < 500 Pa (Table 12), and are categorized as low volatility substances in exposure estimation tools. Fragrance compounds are always liquids.

The various steps of the general compounding process are shown in Figure 6. Worker exposure can occur during these steps and therefore for each step a Contributing Scenario (CS) is derived. Losses of the substance and subsequently potential release to the environment, is indicated by the blue lines of Figure 6.

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[2] *OECD, 2010.* ***EMISSION SCENARIO DOCUMENT ON THE BLENDING OF FRAGRANCE OILS INTO COMMERCIAL AND CONSUMER PRODUCTS,*** *ENV/JM/MONO(2010)38.*

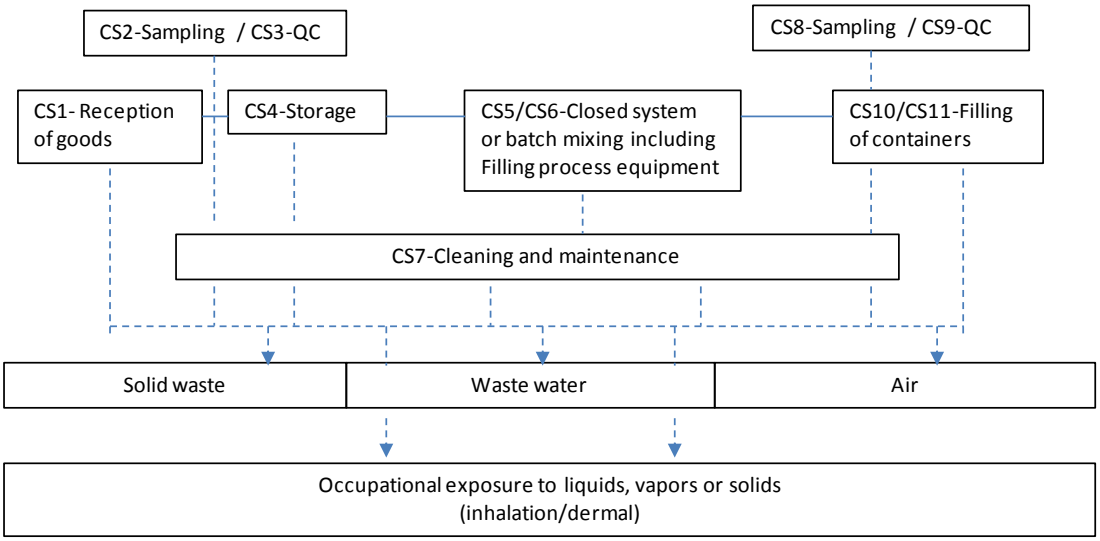

Figure 6: Operations during formulation of fragrance compounds and exposure routes (CS: contributing scenario, QC: Quality Control)

The operations and Contributing Scenarios in Figure 6 are also considered to be applicable to the production of encapsulated fragrances and to the formulation of flavour compounds for end-products not exempt from REACH (i.e. end-uses other than in food/feeding stuffs or medicinal products, see REACH Article 2.6)

3.4.2.1 Occupational exposure during compounding

As shown in Figure 6 and in the CS of Table 11 there are numerous points for where potential contact of workers with the fragrance substances or the mixture may occur and thus workers may be exposed. The likely exposure routes are dermal uptake and inhalation, resulting from:

- exposure to liquids, solids or vapours during unloading from transport containers and transfer to storage containers (CS1, CS10);
- exposure to liquids, vapours, and solids during dosing into the mixing vessels and during mixing process (CS5, CS6);
- exposure to liquids, solids and vapours during sampling and quality controls (CS2, CS3, CS8, CS9);
- exposure to liquids, vapours and aerosols during container and equipment cleaning (CS7);
- exposure to liquids and vapours during the packaging of compounds and storage (CS11, CS4).

For a first tier quantitative worker exposure estimation by inhalatory and dermal routes, the ECETOC TRA model can be used. The handling activities during compounding are related to use descriptors. The typical OCs and RMMs to refine Tier 1 TRA inputs for these activities in the fragrance industry are given in Table 11.

The exposures during these handling activities are grasped into 11 Contributing Scenarios to which PROCs are assigned.
For each PROC a default dermal and inhalation exposure estimate is available. For inhalation exposure this default depends on the vapour pressure of the substance. In

case the vapour pressure is < 500 Pa (most cases) the low volatility default value can be selected. For the final mixture the < 500 Pa can also be used because the partial vapour pressure of the substance in the mixture is < 500 Pa.

For each PROC the typical OCs are presented for exposure duration and substance in preparation (Table 11). The exposure duration for each handling is estimated by experts in the fragrance compounding industry based on common industrial practices. For batch mixing (CS6) significant contact and an exposure duration of 1-4 hours is assumed. It is anticipated that this PROC 5 in a compounding facility may be a worst case estimate. Still the PROC5 has been included because mixing is the key process during compounding. When needed, on-site refinements can be made (Specific ES).

In fragrance compounding in the first four contributing scenarios (CS1-CS4), a first step is to apply the “substance in preparation: NO” TRA input as the worker is exposed to the neat substance. For CS5 and CS6 (mixing processes) a TRA default value of >25% is used as the process is started with neat substances which will be mixed with other substances to form a compound that has an end-concentration of the substance <25%. For the five last steps an appropriate realistic worst case use level would be 5 to 25% (TRA default value) as the substance would be part of a mixture during these steps.

The use of Risk Management Measures (e.g. LEV, skin and respiratory protection) are not included in this GES because under REACH these RMMs are driven by the hazard classification or risk characterisation of the specific substance. In addition, it has to be noted that the activities during compounding are considered to be indoor but this should be determined for each site individually.

Using the OCs described and subsequently the exposure reduction efficiencies as listed in Table 11, the exposure assessor can perform a refined Tier 1 assessment. These typical refined Tier 1 TRA inputs (duration, percentage in the mixture), define the initial GES for the formulation of fragrance compounds. If the conditions described in the initial GES do not result in safe use, the downstream user can refine these conditions for its own situation (see Chapter 4).

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Table 11: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES 1 Formulation of fragrance compounds

GES n°	GES title	Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier1 ECETOC TRA V2			
					duration	substance in preparation	indoor without LEV	respiratory protection
1	GES1 - Formulation of fragrance compounds	CS1	Uploading/unloading	PROC8b	15 min to 1 hour	no	x	not use
		CS2	Sampling of received goods	PROC2	< 15 min	no	x	not use
		CS3	Q control of received goods	PROC15	< 15 min	no	x	not use
		CS4	Storage	PROC1	15 min to 1 hour	no	x	not use
		CS5	Closed system mixing including filling process equipment	PROC3	1 to 4 hours	yes at >25%	x	not use
		CS6	Batch mixing with significant contact including filling process equipment	PROC5	1 to 4 hours	yes at >25%	x	not use
		CS7	Cleaning and maintenance	PROC8a	1 to 4 hours	yes at 5 - 25 %	x	not use
		CS8	Sampling of compound	PROC2	< 15 min	yes at 5 - 25 %	x	not use
		CS9	Q control of compound	PROC15	< 15 min	yes at 5 - 25 %	x	not use
		CS10	Charging/discharging from/to vessels/large containers (dedicated facilities)	PROC8b	15 min to 1 hour	yes at 5 - 25 %	x	not use
		CS11	Transfer into small containers (dedicated filling line, including weighing)	PROC9	15 min to 1 hour	yes at 5 - 25 %	x	not use

3.4.2.2 Environmental exposure during compounding

Fragrance substances or fragrance compounds that are lost during the compounding process by washing, cleaning or spillage are collected in the wastewater and discharged to a water treatment system (Figure 6).

According to ECHA Guidance R.16 on Environmental Exposure Estimation the default Environmental Release Category for the formulation of preparations is ERC2. Table R.16-23 in the ECHA Guidance presents the default values used for the ERCs. ERC2 presents a worst-case default scenario that assumes a release to waste water of 2% of the use volume and 2.5% to air and 0.01% to soil during 10 days per year (see Guidance Table R.16-23).

However, this default scenario is concluded to be not applicable to fragrances. Such release values lead to unrealistically high exposure estimates compared to what is measured in practice and should not be used. IFRA has collected specific data for releases to air, soil and water which have been used to define spERCs for large/medium and small sites [3].

Water

More detailed information on fragrance release to water has been collected by the fragrance industry and is available. Indeed, in 2008 RIFM initiated a study that aimed to deliver an evidence-based Emission Scenario Document using qualitative and quantitative information on the operational conditions, environmental exposure scenarios and emission factors. The project was limited to emissions to wastewater.
Information on operating conditions and practices within participating companies was obtained by means of an inquiry sent to RIFM members and clients. Following the results of this study, a recommended scenario for the formulation of fragrance compounds was proposed. In this scenario, the release factor to waste water (prior to any RMM such as oil skimmer and on site STP) during the compounding process is not more than 0.5% of the use volume for smaller compounding sites, whereas for the large/medium sites it is 0.2%. All surveyed compounding sites are operating during at least 250 days per year[4].

Air

The default release factor to air in ERC2 is 2.5% and is based on highly volatile substances (>1000 Pa).
Regarding air emissions control and factor, not enough specific data is available to date to derive a specific release factor for compounding sites, even though it seems obvious that the default release factor of 2.5% overestimates the emission to air.
Vapour pressures (measured values) of almost a thousand fragrances substances were analysed, showing that most of them are below 1000 pa and even 500 Pa (Table 12).
Even though these data are insufficient to refine a lower release factor to air, IFRA is gathering more information and may propose an update of this factor at a later time. For the time being the default value of 2.5% release to air can be used. In a sensitivity

[3] Review and evaluation of environmental emission scenarios for fragrance substances Environmental exposure from the formulation of products (9S3975.01/R0002/Nijm), Royal Haskoning 2009

[4] Review and evaluation of environmental emission scenarios for fragrance substances Environmental exposure from the formulation of products (9S3975.01/R0002/Nijm), Royal Haskoning 2009

analysis it has been shown that this default release has limited impact on the risk characterisation for water and soil (see Annex 5).

This sensitivity analysis has shown that although emissions to air do have a contribution to soil exposure, this contribution is negligible in regards to other source of exposure (e.g. via sludge application to soil). Therefore the worst case value of ERC 2, which corresponds to compounding and formulation ES, should be used in the spERC development for compounding ES, i.e. 2.5%.
The major contribution to soil exposure, as calculated by ECETOC TRA, comes from the application of sludge residues from WWTP to natural soils. This condition is systematically assumed by the model in tier 1 assessment as a worst case. It can be changed to the contrary (no sludge to soil) if there is enough justification for it.
Furthermore, the exposure to local soil increases when vapour pressure of the substance decreases, due to higher redeposition.

Table 12: analysis of vapour pressure of 971 chemicals used in fragrance products

n =	971	substances
>10000 Pa	3	substances
<10000 Pa	968	substances
>1000 Pa	24	substances
<1000 Pa	947	substances
>500 Pa	43	substances
<500 Pa	928	substances
min =	0.00008	Pa
max =	73030	Pa
median =	2.76	Pa
99-percentile =	3016	Pa
97.5-percentile =	990.2	Pa
95-percentile =	417.5	Pa
90-percentile =	152.9	Pa

Soil
The typical release to soil for compounding facilities is 0%, as most compounding processes are done indoor and have impermeable floors[5].

Defining the IFRA spERCs for water, air and soil
These data have been integrated in the development of two specific ERCs (spERCs) for compounding of fragrance compounds, taking into account differences between smaller and larger/medium compounding sites - spERC codes (as according to CEFIC guidance)

- IFRA 2.1a.v1 (large/medium sites) and
- IFRA 2.1b.v1 (small sites).

These spERCs and their inputs are described in the document “SPERC fact sheet – Compounding of fragrance compounds” available in Annex 4 of this document as well as on the IFRA website.

These spERCs can be used instead of ERC2 as a refinement. The list of these spERCs is presented in the Table 13 below.

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[5] Review and evaluation of environmental emission scenarios for fragrance substances Environmental exposure from the formulation of products (9S3975.01/R0002/Nijm), Royal Haskoning 2009

Table 13: List of IFRA spERCs for compounding for a Tier 1.5 assessment

SPERC Name	Specifies ERC	Fraction used at main source	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	spERC Code	SPERC description	Glossary text
IFRA 1	2	1	250	yes	0.025	0.002	0	18000	-	-	-	IFRA 2.1a.v1	IFRA - Formulation of fragrance compounds at large/medium sites	Fragrance compound: A blend of fragrance substances, representing a specific fragrance formula.
IFRA 2	2	1	250	yes	0.025	0.005	0	18000	-	-	-	IFRA 2.1b.v1	IFRA - Formulation of fragrance compounds at small sites	Fragrance compound: A blend of fragrance substances, representing a specific fragrance formula.

3.4.3 Formulation of fragranced end-products: GES 2

In the formulation stage the fragrance compound is combined with other ingredients to make a fragranced end-product. Fragranced end-products can be found in many product categories (PCs). The formulation of these products is discussed in this section. The focus will be on the formulation of the main PCs: washing and cleaning (PC35), air care (PC3), biocides (PC8), waxes and polishes (PC 31) and cosmetics (PC 39 & PC 28). In the emission scenario document of the OECD report of 2010 descriptions of these processes are available.

AISE and Cosmetics Europe have Uses done a Use Mapping and established Generic Exposure Scenarios which have been used when relevant for fragrance substances.

AISE and Cosmetic Europe have also identified emission scenarios for all Identified Uses which will be used when relevant for fragrance substances. For workers the contributing scenarios as established by AISE will be used for fragrance substances.

3.4.3.1 Occupational exposure during formulation of fragranced end-products

As shown in figure 6, there are numerous points for where potential contact of workers with mixtures containing fragrance substances may occur and thus workers may be exposed. The likely exposure routes are dermal uptake and inhalation, resulting from:

- exposure to liquids and vapours during unloading from transport containers and transfer to storage containers (CS1, CS10);
- exposure to liquids and vapours during dosing into the mixing vessels and during mixing process (CS5, CS6);
- exposure to liquids and vapours during sampling and quality controls (CS2, CS3, CS8, CS9);
- exposure to liquids, vapours and aerosols during container and equipment cleaning (CS7);
- exposure to solids during tableting and compression of compact detergents (CS12);
- exposure to liquids and vapours during the packaging of fragrance end-products and storage (CS11, CS4).

As for GES1, for a first tier quantitative worker exposure estimation by inhalatory and dermal routes, the ECETOC TRA model can be used. The handling activities during formulation of end-products are related to use descriptors. The typical OCs and RMMs to refine Tier 1 TRA inputs for these activities in the fragrance industry are given in Table 14.

The main difference between GES1 compounding and GES2 formulation of end-products is the CS12 “PROC14 - production of preparations of articles by tabletting, compression, extrusion, pelletisation”. This CS12 covers the production of compact detergents.

The exposures during these handling activities are grasped into 12 Contributing Scenarios to which PROCs are assigned.
For each PROC a default dermal and inhalation exposure estimate is available. For inhalation exposure this default depends on the vapour pressure of the substance. In case the vapour pressure is < 500 Pa (most cases) the low volatility default value can be selected. For the final fragrance end-product the < 500 Pa can also be used because the partial vapour pressure of the substance in the end-product is < 500 Pa.

For each PROC the typical OCs are presented for exposure duration and substance in preparation (Table 14). The exposure duration for each handling is estimated by experts in the formulation of fragrance end-products industry based on common industrial practices. For batch mixing (CS6) significant contact and an exposure duration of 1-4 hours is assumed. It is anticipated that this PROC 5 in a formulation facility may be a worst case estimate. Still the PROC5 has been included because mixing is the key process during formulation. When needed, on-site refinements can be made (Specific ES).

In fragrance formulation of end-products, in the first six contributing scenarios (CS1-CS6), an appropriate realistic worst case use level would be 5 to 25% (TRA default value) as the substance would be part of a mixture during these steps. For the 6 last steps of the formulation process (table 14, CS7 to CS12), the % value (corresponding with <1% TRA default value) is calculated from the maximum concentration of the fragrance compound (formulation) in the final product (see Table 21).

The use of Risk Management Measures (e.g. LEV, skin and respiratory protection) are not included in this GES because under REACH these RMMs are driven by the hazard classification or risk characterisation of the specific substance. In addition, it has to be noted that the activities during formulation of fragrance end-products are assumed to be indoor but this should be determined for each site individually.

Using the OCs described and subsequently the exposure reduction efficiencies as listed in Table 14, the exposure assessor can perform a refined Tier 1 assessment. These typical refined Tier 1 TRA inputs (duration, percentage in the mixture), define the initial GES for the formulation of fragrance end-products. If the conditions described in the initial GES do not result in safe use, the downstream user can refine these conditions for its own situation (see chapter 4).

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Table 14: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES2 Formulation of fragranced end-products

GES n°	GES title	Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier1 ECETOC TRA V2			
					duration	substance in preparation	indoor without LEV	respiratory protection
2	GES2 - Formulation of fragranced end-products	CS1	Uploading/unloading	PROC8b	15 min to 1 hour	yes at 5 - 25 %	x	not use
		CS2	Sampling of received goods	PROC2	< 15 min	yes at 5 - 25 %	x	not use
		CS3	Q control of received goods	PROC15	< 15 min	yes at 5 - 25 %	x	not use
		CS4	Storage	PROC1	15 min to 1 hour	yes at 5 - 25 %	x	not use
		CS5	Closed system mixing including filling process equipment	PROC3	1 to 4 hours	yes at 5 - 25 %	x	not use
		CS6	Batch mixing with significant contact including filling process equipment	PROC5	1 to 4 hours	yes at 5 - 25 %	x	not use
		CS7	Cleaning and maintenance	PROC8a	1 to 4 hours	yes at < 1 %	x	not use
		CS8	Sampling of compound	PROC2	< 15 min	yes at < 1 %	x	not use
		CS9	Q control of compound	PROC15	< 15 min	yes at < 1 %	x	not use
		CS10	Charging/discharging from/to vessels/large containers (dedicated facilities)	PROC8b	15 min to 1 hour	yes at < 1 %	x	not use
		CS11	Transfer into small containers (dedicated filling line, including weighing)	PROC9	15 min to 1 hour	yes at < 1 %	x	not use
		CS12	Production of preparations or articles by tabletting, compression, extrusion, pelletisation	PROC14	> 4 hours	yes at < 1 %	x	not use

3.4.3.2 Environmental exposure during formulation of fragranced end-products

The emission to waste water differentiates between the various fragranced end-products. For formulation ERC2 has a default release factor of 2% to waste water which will lead to substantial overestimation of the PEC for fragrance substances.
spERCs developed by A.I.S.E. (International Association for Soap, Detergents and Maintenance Products) and Cosmetics Europe (*ex* COLIPA) related to formulation apply to formulation of fragranced end-products and can be used to refine exposure assessment. These spERCs and associated Factsheets are available on A.I.S.E. website (http://www.aise.eu/reach/?page=exposureass_sub4) and Cosmetics Europe website (http://www.cosmeticseurope.eu/safety-and-science-cosmetics-europe/reach-and-chemicals/use-and-exposure-information.html). The list of these spERCs is reproduced in the Table 15 below.

Although all the spERC are presented here, the registrant or downstream user should select only applicable spERC based on knowledge of product type. Registrants who do not have any knowledge about in what end-products their substance is used are advised to include all spERCs. Also, it is possible to group some of these spERCs based on release fraction, number of emission days or specific RMM.

Cosmetics Europe has included some spERCs with release fractions higher than the default factors from the ECHA guidance. In these cases it is advised to use the maximum release fraction from ECHA (e.g. ERC2 default for release fraction to water of 2%) for fragrance substances.

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Table 15: List of AISE and Cosmetics Europe spERCs for formulation of fragranced end-products for a Tier 1.5 assessment

SPERC Name	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	SpERC Code	SPERC description
AISE 1	2	220	yes	0.0002	0.0001	0	18000	Filtration / Scrubbing	0.99	16700	AISE SPERC 2.1.a.v1	AISE - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (large scale)
AISE 2	2	220	yes	0.0002	0.001	0	18000	Filtration / Scrubbing	0.99	4500	AISE SPERC 2.1.b.v1	AISE - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (medium scale)
AISE 3	2	20	yes	0.0002	0.002	0	18000	Filtration / Scrubbing	0.99	10	AISE SPERC 2.1.c.v1	AISE - Formulation of Detergents/Maintenance Products: Granular Detergent -Regular (small scale)
AISE 4	2	220	yes	0.0002	0.00001	0	18000	Filtration / Scrubbing	0.99	16700	AISE SPERC 2.1.d.v1	AISE - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (large scale)
AISE 5	2	220	yes	0.0002	0.0001	0	18000	Filtration / Scrubbing	0.99	4500	AISE SPERC 2.1.e.v1	AISE - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (medium scale)
AISE 6	2	20	yes	0.0002	0.0002	0	18000	Filtration / Scrubbing	0.99	10	AISE SPERC 2.1.f.v1	AISE - Formulation of Detergents/Maintenance Products: Granular Detergent -Compact (small scale)
AISE 7	2	220	yes	0	0.0001	0	18000	-	-	16700	AISE SPERC 2.1.g.v1	AISE - Formulation of liquid Detergents/Maintenance Products: Low Viscosity (large scale)

SPERC Name	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	SpERC Code	SPERC description
AISE 8	2	220	yes	0	0.001	0	18000	-	-	4500	AISE SPERC 2.1.h.v1	AISE - Formulation of liquid Detergents/Maintenance Products: Low Viscosity (medium scale)
AISE 9	2	20	yes	0	0.002	0	18000	-	-	10	AISE SPERC 2.1.i.v1	AISE - Formulation of liquid Detergents/Maintenance Products: Low Viscosity (small scale)
AISE 10	2	220	yes	0	0.001	0	18000	-	-	16700	AISE SPERC 2.1.j.v1	AISE - Formulation of liquid Detergents/Maintenance Products: High Viscosity (large scale)
AISE 11	2	220	yes	0	0.002	0	18000	-	-	4500	AISE SPERC 2.1.k.v1	AISE - Formulation of liquid Detergents/Maintenance Products: High Low Viscosity (medium scale)
AISE 12	2	20	yes	0	0.004	0	18000	-	-	10	AISE SPERC 2.1.l.v1	AISE - Formulation of liquid Detergents/Maintenance Products: High Viscosity (small scale)
COLIPA 1	2	220	yes	0	0.001	0	18000	-	-	16700	COLIPA SPERC 2.1.a.v1	COLIPA - Formulation of low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (large scale)
COLIPA 2	2	220	yes	0	0.002	0	18000	-	-	4500	COLIPA SPERC 2.1.b.v1	COLIPA - Formulation of low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (medium scale)
COLIPA 3	2	220	yes	0	0.004	0	18000	-	-	10	COLIPA SPERC 2.1.c.v1	COLIPA - Formulation of low viscosity liquids (Shampoo, hair conditioner, shower gel, foam bath) (small scale)

SPERC Name	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	SpERC Code	SPERC description
COLIPA 4	2	220	yes	0	0.015	0	18000	-	-	4500	COLIPA SPERC 2.1.d.v1	COLIPA - Formulation of Fine Fragrances - Cleaning with Water (medium scale)
COLIPA 5	2	220	yes	0	0.03	0	18000	-	-	10	COLIPA SPERC 2.1.e.v1	COLIPA - Formulation of Fine Fragrances - Cleaning with Water (small scale)
COLIPA 6	2	220	yes	0	0.01	0	18000	-	-	4500	COLIPA SPERC 2.1.f.v1	COLIPA - Formulation of Medium Viscosity Body Care Products (medium scale)
COLIPA 7	2	220	yes	0	0.02	0	18000	-	-	10	COLIPA SPERC 2.1.g.v1	COLIPA - Formulation of Medium Viscosity Body Care Products (Small scale)
COLIPA 8	2	220	yes	0	0.01	0	18000	-	-	16700	COLIPA SPERC 2.1.h.v1	COLIPA - Formulation of Non-liquid Creams, high viscosity Products (large scale)
COLIPA 9	2	220	yes	0	0.02	0	18000	-	-	4500	COLIPA SPERC 2.1.i.v1	COLIPA - Formulation of Non-liquid Creams, high viscosity Products (medium scale)
COLIPA 10	2	220	yes	0	0.04	0	18000	-	-	10	COLIPA SPERC 2.1.j.v1	COLIPA - Formulation of Non-liquid Creams, high viscosity Products (small scale)
COLIPA 11	2	220	yes	0	0	0	18000	-	-	16700	COLIPA SPERC 2.2.a.v1	COLIPA - Formulation of cosmetic products involving cleaning with Organic Solvents (Varnish / Removers, Decorative Cosmetics, Spray, Lacquer, Fine Fragrance, Solar oil, solid products - (large scale)

SPERC Name	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	SpERC Code	SPERC description
COLIPA 12	2	220	yes	0	0	0	18000	-	-	4500	COLIPA SPERC 2.2.b.v1	COLIPA - Formulation of cosmetic products involving cleaning with Organic Solvents (Varnish / Removers, Decorative Cosmetics, Spray, Lacquer, Fine Fragrance, Solar oil, solid products - (medium scale)
COLIPA 13	2	220	yes	0	0	0	18000	-	-	10	COLIPA SPERC 2.2.c.v1	COLIPA - Formulation of cosmetic products involving cleaning with Organic Solvents (Varnish / Removers, Decorative Cosmetics, Spray, Lacquer, Fine Fragrance, Solar oil, solid products - (small scale)
COLIPA 14	2	220	yes	0	0.0005	0	18000	-	-	16700	COLIPA SPERC 2.3.a.v1	COLIPA - Formulation of body care soap (large scale)
COLIPA 15	2	220	yes	0	0.001	0	18000	-	-	4500	COLIPA SPERC 2.3.b.v1	COLIPA - Formulation of body care soap (medium scale)
COLIPA 16	2	20	yes	0	0.002	0	18000	-	-	10	COLIPA SPERC 2.3.c.v1	COLIPA - Formulation of body care soap (small scale)

3.4.4 Industrial end-use of fragranced end-products (GES 3)

This chapter introduces the following GES, based on information provided by AISE:

- GES 3 Industrial end-use of washing and cleaning products

Fragranced end-products are used in an industrial setting for cleaning and maintenance of industrial process equipment. Thus industrial users use the products as part of the operational process.

The concentration of a fragrance substance in washing and cleaning end-products may be lower than the applicable concentration limit as listed in REACH Article 14.2 (in practice this usually means <1% or <0.1% for substances classified as N,R50/53 or N,R51/53). In this case an Exposure Scenario for this end-use would not be required. However, this should always be reviewed carefully on a substance specific basis and if insufficient or inconclusive information is available about the concentration levels of a fragrance substance for Industrial end-use of washing and cleaning products, an Exposure Scenario for this end-use should be included in the registration dossier by default.

3.4.4.1 Occupational exposure during industrial use of fragranced end-products

For the preparation and use of these products, the operators will dose and mix the products in water and use them in liquid form with rollers, brushes or sprays. In other applications they may treat articles by dipping, pouring or immersion.

For a first tier quantitative industrial worker exposure estimation by inhalatory and dermal routes, the ECETOC TRA model can be used. AISE provided information on the use descriptors and refined Tier 1 TRA inputs for the GES 3.
Please note that dermal Protective Personal Equipment (gloves) is not a parameter that can be chosen in the ECETOC TRA V2 model and thus the use of this PPE must be considered as an extended TRA approach depending on the dermal risk and/or hazard classification of a substance (out of scope of this guidance). However the users of the present guidance must be aware that in an updated version of ECETOC TRA (version V3, released April 2012) gloves have been added as a refined Tier 1 input parameter with a specific percentage of efficiency.

The Contributing Scenarios and refine Tier 1 TRA inputs for GES 3 are given in table 16. A condensed approach has been followed to decrease the numbers of contributing scenarios following from the AISE tables that have to be assessed. For this, the uses as defined by AISE and identified by their P number, have been grouped based on their similarity in activity. The similarity is shown by the activity description, same PROC code, duration of exposure, concentration in end-product and RMMs. As shown in table 16 the contributing scenarios CS1b and CS2b (covering AISE uses P101, P104, P107 and P110) could for example be assessed together in a first assessment. If the typical OCs and RMMs as defined would not lead to safe use the activities have to be assessed individually.

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Table 16: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES3 Industrial end-use of washing and cleaning products

GES3 - Industrial end-use of washing and cleaning products									Industrial activity
Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier 1 ECETOC TRA V2						Extra Tier 1 exposure modifier
			duration	%	outdoor	indoor		respiratory protection	dermal protection
						without LEV	with LEV		
CS1b	Use of laundry detergents and conditioners (softener/starch); automatic process (AISE-P101, AISE-P104) – use phase	PROC2	< 15 min	< 1 %		x		not use	not use
CS2b	Use of laundry aid (gasing and non-gasing); automatic process (AISE-P107, AISE-P110) – use phase								
CS18b	Use of metal cleaner (degreaser, descaler, etch) automatic process (AISE P1006) – use phase	PROC2	> 4 hours	< 1 %			x	not use	gloves
CS3b	Use of train and aeroplane cleaners, car wash products and dewaxing products; semi-automatic process (AISE-P707, AISE-P708, AISE-P709, AISE-P712) – use phase	PROC4	> 4 hours	< 1 %	x			not use	gloves
CS7b	Use of food process cleaner; semi closed cleaning process (AISE-P802) – preparatory phase – use phase	PROC4	> 4 hours	< 1 %		x		not use	not use
CS17b	Use of metal cleaner (degreaser, descaler, etch) semi-automatic process (AISE P1005) – use phase	PROC4	> 4 hours	< 1 %			x	not use	gloves
CS4b	Use of car wash products and boat cleaners in spray and rinse processes and spray and wipe manual processes (AISE-P710, AISE-P711, AISE P714) – use phase	PROC7	15 min to 1 hour	< 1 %	x			not use	gloves
CS8b	Use of chain maintenance product; automatic spray process (AISE-P803) – use phase	PROC7	> 4 hours	< 1 %		x		not use	not use
CS11b	Use of a foam cleaner; semi-automatic with venting process (AISE-P806) – use phase	PROC7	< 15 min	< 1 %			x	not use	gloves
CS12b	Use of a foam cleaner; semi-automatic without venting process (AISE-P807) – use phase	PROC7	< 15 min	< 1 %		x		half mask	gloves
CS14b	Use in disinfection products; fogging and gassing semi-automatic processes (AISE P811) – use phase								
CS15b	Use of façade/surface cleaning products (AISE P906, AISE P907) – use phase	PROC7	> 4 hours	< 1 %		x		half mask	gloves

GES3 - Industrial end-use of washing and cleaning products

Industrial activity

Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier 1 ECETOC TRA V2						Extra Tier 1 exposure modifier
			duration	%	outdoor	indoor		respiratory protection	dermal protection
						without LEV	with LEV		
CS3a	Use of train and aeroplane cleaners, car wash products and dewaxing products; semi-automatic process (AISE-P707, AISE-P708, AISE-P709, AISE-P712) – preparatory phase	PROC8a	15 min to 1 hour	< 1 %	x			not use	gloves
CS4a	Use of car wash products and boat cleaners in spray and rinse processes and spray and wipe manual processes (AISE-P710, AISE-P711, AISE P714) – preparatory phase								
CS5a	Use of boat cleaners; manual process (AISE-P713) – preparatory phase								
CS11a	Use of a foam cleaner; semi-automatic with venting process (AISE-P806) – preparatory phase	PROC8a	15 min to 1 hour	< 1 %			x	not use	gloves
CS12a	Use of a foam cleaner; semi-automatic without venting process (AISE-P807) – preparatory phase	PROC8a	15 min to 1 hour	< 1 %		x		not use	gloves
CS13a	Use in animal housing care and disinfection products; semi-automatic processes (AISE P809, AISE P810) – preparatory phase								not use
CS8a	Use of chain maintenance product; automatic spray process (AISE-P803) – preparatory phase	PROC8a	< 15 min	< 1 %		x		not use	gloves
CS9a	Use of chain maintenance product; automatic drip and brush process (AISE-P804) – preparatory phase								
CS14a	Use in disinfection products; fogging and gassing semi-automatic processes (AISE P811) – preparatory phase								
CS15a	Use of façade/surface cleaning products (AISE P906, AISE P907) – preparatory phase								
CS16a	Use of metal cleaner (degreaser, descaler, etch) manual process (AISE P1004) – preparatory phase	PROC8a	< 15 min	< 1 %			x	not use	gloves

GES3 - Industrial end-use of washing and cleaning products

Industrial activity

Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier 1 ECETOC TRA V2						Extra Tier 1 exposure modifier
			duration	%	outdoor	indoor		respiratory protection	dermal protection
						without LEV	with LEV		
CS1a	Use of laundry detergents and conditioners (softener/starch); automatic process (AISE-P101, AISE-P104) – preparatory phase.	PROC8b	< 15 min	< 1 %		x		not use	gloves
CS2a	Use of laundry aid (gasing and non-gasing); automatic process (AISE-P107, AISE-P110) – preparatory phase								
CS6	Use of food process cleaner; cleaning in place (CIP) process (AISE-P801); preparatory phase only								
CS7a	Use of food process cleaner; semi closed cleaning process (AISE-P802) – preparatory phase								
CS10	Use of defoaming product; automatic process (AISE-P805); preparatory phase only								
CS17a	Use of metal cleaner (degreaser, descaler, etch) semi-automatic process (AISE P1005) – preparatory phase	PROC8b	< 15 min	< 1 %			x	not use	gloves
CS18a	Use of metal cleaner (degreaser, descaler, etch) automatic process (AISE P1006) – preparatory phase								
CS5b	Use of boat cleaners; manual process (AISE-P713) – use phase	PROC10	> 4 hours	< 1 %	x			not use	gloves
CS13b	Use in animal housing care and disinfection products; semi-automatic processes (AISE P809, AISE P810) – use phase	PROC10	> 4 hours	< 1 %		x		not use	not use
CS16b	Use of metal cleaner (degreaser, descaler, etch) manual process (AISE P1004) – use phase	PROC10	> 4 hours	< 1 %			x	not use	gloves
CS9b	Use of chain maintenance product; automatic drip and brush process (AISE-P804) – use phase	PROC13	> 4 hours	< 1 %		x		not use	not use

3.4.4.2 Environmental emission during industrial end-use of fragranced end-products

After use, the water containing the cleaning products is normally discharged to the sewer to go to an industrial or municipal wastewater treatment plant. In some cases residues of products may remain on the hard surfaces or are released to air or soil. The applicable ERC for this Industrial end use is considered to be ERC4 as the emissions are coming forward from industrial sources which are considered to be point sources. It has to be noted however that with respect to an environmental exposure assessment the use of cleaning products in industrial settings is similar to the end-use of cleaning products in professional settings and by private households, although these are considered to be wide-dispersive sources. Instead of breaking up the volumes going to either of these uses it could be considered to assess the total volume going to these uses, as in practice it is almost impossible to identify how much of a substance will go to either of these uses. If such an approach is followed in the CSA it should be thoroughly explained.

The spERC for Industrial Use of Water Borne Processing Aids developed by A.I.S.E. (spERC 4.1.v1, detailed below in Table 17) applies to industrial use of fragranced end-products and can be used to refine environmental exposure assessment for industrial end-use of fragranced end-products (ERC4).

Table 17: AISE spERC for Industrial Use for a Tier 1.5 assessment

SPERC Name	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	SpERC Code	SPERC description
AISE 13	4	220	yes	0	1	0	18000	-	-	50	AISE SPERC 4.1.v1	AISE - Industrial Use of Water Borne Processing Aids - no RMM

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3.4.5 Professional end-use of fragranced end-products (GES 4-5)

This chapter introduces the following two GESs, based on information provided by AISE:

- GES 4 Professional end-use of washing and cleaning products
- GES 5 Professional end-use of polishes and wax blends

In a professional setting the products are used by workers for public and/or private hygiene. Workers may be, for example, specialised cleaners that use similar products frequently on a daily basis. Thus their exposure is in general not comparable to that of the regular consumer.

The concentration of a fragrance substance in washing and cleaning end-products or polishes and wax blends may be lower than the applicable concentration limit as listed in REACH Article 14.2 (in practice this usually means <1% or <0.1% for substances classified as N,R50/53 or N,R51/53). In this case an Exposure Scenario for this end-use would not be required. However, this should always be reviewed carefully on a substance specific basis and if insufficient or inconclusive information is available about the concentration levels of a fragrance substance, Exposure Scenarios for these end-uses should be included in the registration dossier by default.

3.4.5.1 Occupational exposure during professional end-use of fragranced end-products

For the preparation and use of these products, the operators will dose and mix the products in water and use them in liquid form with rollers, brushes or sprays. In other applications they may treat articles by dipping, pouring or immersion.

For quantitative professional worker exposure estimation by inhalatory and dermal routes, ECETOC TRA V2 Tier 1 model tool is used. AISE provided information on the use descriptors and refine Tier 1 TRA inputs for the two GESs (4 and 5).
Also here dermal Protective Personal Equipment (gloves) is not considered a typical OC for this GES. Also it is not a default value of Tier 1 ECETOC TRA V2 model and thus the use of this PPE must be considered as an extended TRA Tier approach depending on the dermal risk and/or hazard classification of a substance (out of scope of this guidance). However the users of the present guidance must be aware that in the future version of ECETOC TRA (version V3, expected March 2012) gloves will be probably added as a Tier 1 input parameter with a specific percentage of efficiency.

The contributing scenarios and refine Tier 1 TRA inputs for GES4 and GES5 are given in the following tables 18 and 19. A condensed approach has been followed to decrease the numbers of contributing scenarios following from the AISE tables that have to be assessed. For this, the uses as defined by AISE and identified by their P number, have been grouped based on their similarity in activity. The similarity is shown by the activity description, same PROC code, duration of exposure, concentration in end-product and RMMs. As shown in Table 18 the contributing scenarios CS25a, CS26a and CS27a (covering AISE uses P701-P706) could for example be assessed together in a first assessment. If the typical OCs and RMMs as defined would not lead to safe use the activities have to be assessed individually.

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Table 18: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES4 Professional end-use of washing and cleaning products

GES4 – Professional end-use of washing and cleaning products									Professional activity
Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier 1 ECETOC TRA V2						Extra Tier 1 exposure modifier
			duration	%	outdoor	indoor		respiratory protection	dermal protection
						without LEV	with LEV		
CS8b	Professional use of dishwash and rinse products; automatic process (AISE P202, AISE P204) – use phase	PROC2	< 15 min	< 1 %		x		not use	not use
CS25b	Professional use of car wash and dewaxing products; semi-automatic process (AISE P701, AISE P704) – use phase	PROC4	> 4 hours	< 1 %	x			not use	gloves
CS29b	Professional use of medical devices; semi-automatic process (AISE P1101) – use phase	PROC4	1 to 4 hours	< 1 %			x	not use	gloves
CS1	Professional use of laundry products; laundry detergent and conditioners, semi-automatic process (AISE P102, AISE P105); preparatory phase only	PROC8a	< 15 min	< 1 %		x		not use	gloves
CS4	Professional use of laundry products; laundry aid (non-gasing), semi-automatic process (AISE P111); preparatory phase only								
CS9	Professional use of dishwash products; semi-automatic process (AISE P203); preparatory phase only								
CS11a	Professional use of general purpose cleaner, sanitary cleaner, glass cleaner, descaling agent and metal cleaning agent, spray and wipe manual process (AISE P302, AISE P306, AISE P308, AISE P313, AISE P315) – preparatory phase								
CS18a	Professional use of surface disinfectant; manual process (AISE P314) – preparatory phase								
CS7a	Professional use of dishwash products; manual process (AISE P201) – preparatory phase								not use
CS12a	Professional use of kitchen cleaners; manual process (AISE P303) – preparatory phase								
CS13a	Professional use of kitchen cleaners; spray and wipe manual process (AISE P304) – preparatory phase								
CS24	CS24 Professional use of drain cleaners; manual process (AISE P607); use phase only								
CS32a	Professional use of medical devices; spray process (AISE P1104) – preparatory phase								

GES4 – Professional end-use of washing and cleaning products										Professional activity
Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier 1 ECETOC TRA V2							Extra Tier 1 exposure modifier
			duration	%	outdoor	indoor		respiratory protection		dermal protection
						without LEV	with LEV			
CS2	Professional use of laundry products; laundry detergent and conditioners, manual process (AISE P103, AISE P106); preparatory phase only	PROC8a	15 min to 1 hour	< 1 %		x		not use		gloves
CS3	Professional use of laundry products; laundry aid (gasing), semi-automatic and manual process (AISE P108, AISE P109) – preparatory phase									
CS5	Professional use of laundry products; laundry aid (non-gasing), manual process (AISE P112); preparatory phase only									
CS21a	Professional use of floor cleaners; spray and wipe manual process (AISE P402) – preparatory phase									
CS22a	Professional use of floor strippers and carpet cleaners; manual and semi-automatic process (AISE P404, AISE P405, AISE P409, AISE P410) – preparatory phase									
CS10a	Professional use of general purpose cleaner, sanitary cleaner, glass cleaner and metal cleaning agent, manual process (AISE P301, AISE P305, AISE P312, AISE P316) – preparatory phase									not use
CS20a	Professional use of floor cleaners; manual and semi-automatic process (AISE P401, AISE P403) – preparatory phase									
CS31a	Professional use of medical devices; manual process (AISE P1103) – preparatory phase									
CS25a	Professional use of car wash and dewaxing products; semi-automatic process (AISE P701, AISE P704) – preparatory phase	PROC8a	15 min to 1 hour	< 1 %	x			not use		gloves
CS26a	Professional use of car wash products and boat cleaners; spray and rinse process and spray and wipe manual process (AISE P702, AISE P703, AISE P706) – preparatory phase									
CS27a	Professional use of boat cleaners; manual process (AISE P705) – preparatory phase									
CS28a	Professional use of façade/surface cleaner; high and medium pressure process (AISE P901, AISE P902) – preparatory phase	PROC8a	< 15 min	< 1 %	x			not use		gloves
CS29a	Professional use of medical devices; semi-automatic process (AISE P1101) – preparatory phase	PROC8a	15 min to 1 hour	< 1 %			x	not use		gloves
CS30a	Professional use of medical devices; dipping process (AISE P1102)	PROC8a	< 15 min	< 1 %			x	not use		gloves

GES4 – Professional end-use of washing and cleaning products									Professional activity
Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier 1 ECETOC TRA V2						Extra Tier 1 exposure modifier
			duration	%	outdoor	indoor		respiratory protection	dermal protection
						without LEV	with LEV		
	– preparatory phase								
CS8a	Professional use of dishwash and rinse products; automatic process (AISE P202, AISE P204) – preparatory phase	PROC8b	< 15 min	< 1 %		x		not use	gloves
CS7b	Professional use of dishwash products; manual process (AISE P201) – use phase	PROC10	> 4 hours	< 1 %		x		not use	gloves
CS10b	Professional use of general purpose cleaner, sanitary cleaner, glass cleaner and metal cleaning agent, manual process (AISE P301, AISE P305, AISE P312, AISE P316) – use phase								not use
CS18b	Professional use of surface disinfectant; manual process (AISE P314) – use phase								
CS19	Professional use of wet wipes; manual process (AISE P317); use phase only								
CS20b	Professional use of floor cleaners; manual and semi-automatic process (AISE P401, AISE P403) – use phase								
CS22b	Professional use of floor strippers and carpet cleaners; manual and semi-automatic process (AISE P404, AISE P405, AISE P409, AISE P410) – use phase								
CS31b	Professional use of medical devices; manual process (AISE P1103) – use phase								
CS27b	Professional use of boat cleaners; manual process (AISE P705) – use phase	PROC10	> 4 hours	< 1 %	x			not use	gloves
CS12b	Professional use of kitchen cleaners; manual process (AISE P303) – use phase	PROC10	1 to 4 hours	< 1 %		x		not use	not use
CS16	Professional use of oven/grill cleaner; manual process (AISE P310); use phase only	PROC10	15 min to 1 hour	< 1 %		x		not use	gloves
CS6	Professional use of laundry products; prespotter/stain remover, manual process (AISE P113)	PROC11	15 min to 1 hour	< 1 %		x		not use	not use
CS21b	Professional use of floor cleaners; spray and wipe manual process (AISE P402) – use phase								gloves

GES4 – Professional end-use of washing and cleaning products										Professional activity
Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier 1 ECETOC TRA V2							Extra Tier 1 exposure modifier
			duration	%	outdoor	indoor		respiratory protection		dermal protection
						without LEV	with LEV			
CS11b	Professional use of general purpose cleaner, sanitary cleaner, glass cleaner, descaling agent and metal cleaning agent, spray and wipe manual process (AISE P302, AISE P306, AISE P308, AISE P313, AISE P315) – use phase	PROC11	< 15 min	< 1 %		x		not use		gloves
CS14	Professional use of descaling agent; manual process (AISE P307); use phase only									
CS17	Professional use of oven/grill cleaner; spray and wipe manual process (AISE P311); use phase only									
CS13b	Professional use of kitchen cleaners; spray and wipe manual process (AISE P304) – use phase									not use
CS23	CS23 Professional use of carpet cleaners; spray and brush manual process (AISE P411); use phase only									
CS32b	Professional use of medical devices; spray process (AISE P1104) – use phase									
CS26b	Professional use of car wash products and boat cleaners; spray and rinse process and spray and wipe manual process (AISE P702, AISE P703, AISE P706) – use phase	PROC11	15 min to 1 hour	< 1 %	x			not use		gloves
CS28b	Professional use of façade/surface cleaner; high and medium pressure process (AISE P901, AISE P902) – use phase	PROC11	> 4 hours	< 1 %	x			half mask		gloves
CS15	Professional use of descaling agent; dipping process (AISE P309); use phase only	PROC13	15 min to 1 hour	< 1 %		x		not use		gloves
CS30b	Professional use of medical devices; dipping process (AISE P1102) – use phase	PROC13	1 to 4 hours	< 1 %			x	not use		gloves

Table 19: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES5 Professional end-use of polishes and wax blends

GES5 - Professional end-use of polishes and wax blends										Professional activity
Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier 1 ECETOC TRA V2							Extra Tier 1 exposure modifier
			duration	%	outdoor	indoor		respiratory protection		dermal protection
						without LEV	with LEV			
CS5b	Professional use of maintenance products; leather care product (automatic process) (AISE P605) – use phase	PROC2	< 15 mins	< 1 %		x		not use		not use
CS5a	Professional use of maintenance products; leather care product (automatic process) (AISE P605) – preparatory phase	PROC8a	< 15 mins	< 1 %		x		not use		not use
CS6	Professional use of maintenance products; drain unblocker (manual process, use phase only); AISE P606	PROC8a	< 15 mins	< 1 %		x		half mask		gloves
CS1	Professional use of floor care products; polish/impregnating agent (manual or semi-automatic process); use phase only (AISE P406 and AISE P407)	PROC10	> 4 hours	< 1 %		x		not use		not use
CS3	Professional use of maintenance products; furniture and leather care products (manual process); use phase only (AISE P601 and AISE P603)	PROC10	1 to 4 hours	< 1 %		x		not use		not use
CS7	Professional use of maintenance products; stainless steel care; manual process (use phase only); AISE P608									
CS2	Professional use of floor care products; polish/impregnating agent (spray and wipe manual process); use phase only (AISE P408)	PROC11	< 15 mins	< 1 %		x		not use		not use
CS4	Professional use of maintenance products; furniture and leather care products (spray and wipe manual process); use phase only (AISE P602 and AISE P604)									
CS8	Professional use of maintenance products; stainless steel care; spray and wipe manual process (use phase only); AISE P609									

3.4.5.2 Environmental emission during professional end-use of fragranced end-products

In general, after use, the water containing the cleaning products is discharged to the sewer to go to an industrial or municipal wastewater treatment plant. In some cases residues of products may remain on the hard surfaces or are released to air or soil. The most common ERCs for professional use are ERC8a and ERC8d, which basically describe the same process with main difference that ERC8a is for the indoor situation and ERC8d for the outdoor situation[6].

spERCs developed by A.I.S.E. and Cosmetics Europe (*ex* COLIPA) related to professional and consumer end-use of fragranced end-products can be used to refine exposure assessment. The environmental release fractions and other relevant parameters as identified by AISE and Cosmetics Europe are presented in Table 20 below[7].

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[6] ECHA guidance R.12: Use descriptor system

[7] See A.I.S.E. website http://www.aise.eu/reach/?page=exposureass_sub4 and Cosmetics Europe website http://www.cosmeticseurope.eu/safety-and-science-cosmetics-europe/reach-and-chemicals/use-and-exposure-information.html

Table 20: AISE and Cosmetics Europe spERCs for Professional and Consumer end-use of fragranced end-products for Tier 1.5 assessment

SPERC Name	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	SpERC Code	SPERC description
AISE 16	8a	365	yes	0	1	0	18000	-	-		AISE SPERC 8a.1.a.v1	AISE - Wide Dispersive Use in 'Down the Drain' cleaning and maintenance products (Consumers and Professionals) - Fraction of EU tonnage to region: 0.04 (default: 0.1)
AISE 17	8a	365	yes	0	1	0	18000	-	-		AISE SPERC 8a.1.a.v1	AISE- Wide Dispersive Use in Aerosol products for cleaning and maintenance products (Non-Propellants) Fraction of EU tonnage to region: 0.04 (default: 0.1)
AISE 18	8a	365	yes	1	0	0	18000	-	-		AISE SPERC 8a.1.a.v1	AISE- Wide Dispersive Use in Aerosol products for cleaning and maintenance products (Propellants) Fraction of EU tonnage to region: 0.04 (default: 0.1)

SPERC Name	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	SpERC Code	SPERC description
COLIPA 17	8a	365	yes	0	1	0	18000	-	-		COLIPA SPERC 8a.1.a.v1	Colipa - Wide Dispersive Use in 'Down the Drain' products - hair and skin care products (Consumers and Professionals) Fraction of EU tonnage to region: 0.053 (default: 0.1)
COLIPA 18	8a	365	yes	1	0	0	18000	-	-		COLIPA SPERC 8a.1.b.v1	Colipa - Wide Dispersive Use of Aerosol products for hair and skin care (Propellants) Fraction of EU tonnage to region: 0.053 (default: 0.1)
COLIPA 19	8a	365	yes	0	1	0	18000	-	-		COLIPA SPERC 8a.1.c.v1	Colipa - Wide Dispersive Use of Aerosol products for hair and skin care (Non-Propellants) Fraction of EU tonnage to region: 0.053 (default: 0.1)

3.4.6 Consumer use of fragranced end-products: GES 6, 7, 8, 9 and 10

The following should be taken into account for the assessment of consumer exposure:

a) The human health aspects of cosmetics have already been assessed under the Cosmetics Directive and as such are not covered by REACH as indicated below:
Article 14, paragraph 5b stipulates that: "The chemical safety report need not include consideration of the risks to human health from the following end uses; (b) in cosmetic products within the scope of Directive 76/768/EEC". Please note that oral care products (e.g. toothpaste, mouthwash, etc.) also fall under the Cosmetic Directive.

b) The exposure assessment of substances classified as hazardous is not required in the CSA if the concentration of the substance in the mixture (*i.e.* professional formulations or consumer end-products) is less than the lowest of any of the following as listed in REACH Article 14.2:

- (a) the applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC;
- (b) the concentration limits given in Annex I to Directive 67/548/EEC;
- (c) the concentration limits given in Part B of Annex II to Directive 1999/45/EC;
- (d) the concentration limits given in Part B of Annex III to Directive 1999/45/EC.

In practice this usually means <1% for substances classified as skin sensitiser, for instance. In this case an Exposure Scenario for this end-use would not be required. However, this should always be reviewed carefully on a substance specific basis and if insufficient or inconclusive information is available about the concentration levels of a fragrance substance for the listed uses (IU 6-10), Exposure Scenarios for these end-uses should be included in the registration dossier by default.

3.4.6.1 Presentation of categories and articles for fragranced end-products

Fragranced end-products are available to consumers in the general public and in private households. They are grouped in Product Categories (PC).
A special case is the incorporation of fragrance compounds into fragranced articles. In the sense of REACH, the fragrance is a substance intended to be released from the article. However, articles containing fragrances are not considered in the IFRA guidance since the concentrations of fragrance substances in these articles are below the REACH regulatory limit of 0.1%.

In the IFRA guidance, fragranced end-product Categories (PC) are divided into five Generic Exposure Scenarios (GES) based on the Use Descriptor system of the ECHA guidance Chapter R.12 (2010) as described in Table 3 (see §3.2).

- GES 6 - Consumer end-use of washing and cleaning products (PC 35)
- GES 7 - Consumer end-use of air care products (PC 3)
- GES 8 - Consumer end-use of biocides (PC 8)
- GES 9 - Consumer end-use of polishes and wax blends (PC 31)
- GES 10 - Consumer end-use of cosmetics (PC 28 & PC 39)

The PCs identified by the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.) are also coded as "AISE CNo" and indicated in Table 9 and Table 10 (see §3.3). Regarding the biocidal products (PC8) in particular, AISE identified that the fragrances are mainly included in Insecticides and Repellents (AISE C19), not as active substances, but to mask the odour of the final product formulation.

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3.4.6.2 Estimation of consumer exposure: tiered exposure assessment methodology

The main exposure route for the consumer is the dermal route for washing and cleaning products (PC 35) polishes and waxes (PC31) and biocides (PC8). The inhalation route is mainly applicable for air care products (PC3) but as can be anticipated some inhalation exposure may also occur for PC31 and PC8.

AISE have specified the potential consumer exposure to their products on their website including the routes of exposure as described below:

Product Category	Product type	Form of delivery	Oral	Dermal	Inhalation
Fabric Washing	Heavy duty detergents	Powder	Accidental	Expected	Not expected
		Liquid	Accidental	Expected	Not expected
		Unit doses (caps, tabs)	Accidental	Expected	Not expected
	Light duty detergents	Powder	Accidental	Expected	Not expected
		Liquid	Accidental	Expected	Not expected
		Unit doses (caps, tabs)	Accidental	Expected	Not expected
	Fabric conditioners		Accidental	Expected	Not expected
Dish Cleaning	Hand dish		Expected	Expected	Not expected
	Machine dish		Expected	Not expected	Not expected
	Rinse aids		Expected	Not expected	Not expected
Hard Surface Cleaners	General purpose	Spray	Not expected	Expected	Expected
	Toilet rim blocks		Accidental	Accidental	Expected
Air Care Products	Air freshener sprays		Not expected	Accidental	Expected
	Electric diffusers		Accidental	Accidental	Expected

Note: Accidental exposure is indicated only for product stewardship reasons, not for Exposure Scenarios development.

Consumers may be exposed to fragrance substances directly *via* the use of fragranced end-products, *e.g.* washing and cleaning agents or air fresheners, but also indirectly by contact with residues on surfaces such as washed clothes. The oral route is potentially applicable for residues of dishwashing agents on plates but this will be a very minor exposure route. The oral route for consumers may be relevant for small children engaging in common habits of mouthing (*e.g.* plastic or wood articles as toys). However, an exposure assessment for toys is not needed because the fragrance substance concentrations in these articles are expected to be below 0.1%. Intentional human exposure from food and medicinal products is considered under other Directives/Regulations. Unintentional human exposure *via* food, drinking water and air is considered in the environmental section. For these reasons consumer exposure by oral route does not need to be assessed in these cases.

The evaluation of exposure for consumer refers to external exposure which is characterised by the amount of a substance that can be absorbed after inhalation, dermal contact or oral intake during indirect contact with residues (*e.g.* machine dishwashing). The aim of this evaluation is to generate information that can be compared to DNELs which are also expressed as external exposure values. Hence, the consumer exposure estimation will need to consider three separate routes (inhalation and dermal routes, oral route by indirect contact with residues).

Furthermore, a tiered exposure assessment methodology is applied to estimate the consumer exposure for fragranced end-products according to the AISE general figure as following:

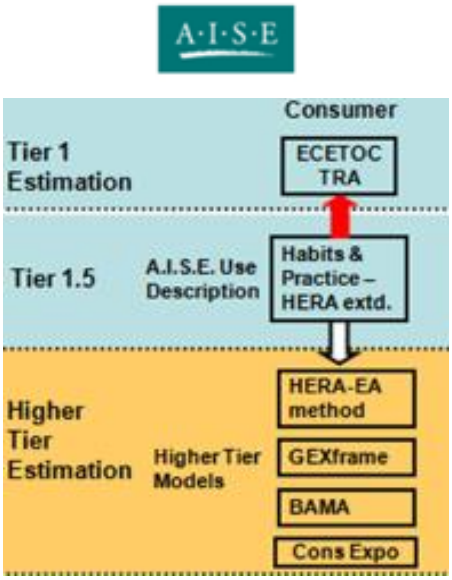

Figure 7: General picture of tiered Exposure Assessment according to AISE

Tier 1 assessment: Tier 1 assessment generates exaggerated exposure estimates that may exceed plausible levels. For several uses, basic use information (named use descriptions) are available from ECETOC TRA Consumer tool which lists default exposure parameters and relevant exposure routes for each product/article, together with subpopulation-specific (child, adult) default parameters (see Annex 1). Moreover, use description and mapping for cleaning and maintenance products (PC3, PC31 and PC35) are available from A.I.S.E as described in Table 9 and Table 10 (§3.1). These use descriptors are the input to perform the assessment using the ECETOC TRA exposure estimation consumer tool.

In general it is expected that the Tier 1 assessment will be skipped and that a Tier 1.5 assessment will be the starting point for fragrance substances.

Tier 1.5 assessments: To refine the Tier 1 exposure estimations, specific data on operational conditions such as duration/use or amount/use can be used to give more realistic refined screening exposure estimations. Hence, IFRA has collected data on the fraction of fragrance substance in fragranced end-products for all contributing scenarios of consumer generic exposure scenarios (GES) as described in Table 21 (see below). These concentrations are based on a high volume common fragrance substance and its typical concentration in these consumer end products (median value). These typical concentrations can be used as such in the exposure estimation tools of e.g. AISE. In the same way, AISE has collected additional information on PC3, PC31 and PC35 including refined exposure parameters such as amount in the fragranced end-product for event, duration and frequency of exposure (see Annex 2). This information has been collected among others as a part of the HERA project of AISE[8].

The overall information can be processed in the ECETOC TRA exposure assessment tool. However, AISE also provides a tool named A.I.S.E. Reach Exposure Assessment Consumer Tool or A.I.S.E. REACT which allows quantitative estimation of systemic consumer exposures to substances such as fragrances that are present in end-products used by consumers (see §4.2).
For PC8 fragranced insecticides, exposure estimations for consumer can only be approximated by the ECETOC TRA or AISE REACT for the air care products (PC3) assuming that the fragranced insecticides used against flies, mosquitoes and crawling insects are:

[8] **HERA**: Human and Environmental Risk Assessment project of AISE. This is a voluntary industry programme to carry out risk assessments on ingredients of household cleaning products.

- sprayed using a ready-to-use aerosol can or a ready-to-use trigger spray,
- evaporated slowly by heating using electrical evaporator.

Therefore, the Tier 1.5 scenario of aerosol air fresheners for neat spray and non-aerosol air fresheners for heated diffuser can be applied to Insecticides. For PC8 fragranced repellents, no Tier 1 or Tier 1.5 scenario is available to estimate or approximate the exposure. Therefore, only higher Tier tool such as ConsExpo tool can be used to estimate the exposure and to assess the risk for the consumer.

Higher-Tier assessments: To predict consumer exposure to end-products (biocidal product category, essentially), the Dutch National Institute for Public Health and the Environment (RIVM) has developed the software model ConsExpo based on mathematical estimations. This program is designed for the use by expert exposure assessors only. To enhance transparency and standardization for a number of PC, default parameter values have been compiled in several Fact Sheets available on their website. However, for fragrance substance included in repellents (biocidal products/PC8), as neither Tier 1 nor Tier 1.5 scenario is available**,** the registrant has to estimate the exposure using the Tier 2 ConsExpo tool and a specific scenario described in the Pest Control Products fact sheet.

Finally, there are numerous different types of products which could be considered when estimating consumer exposure to fragranced end-products, as outlined in the identified uses (Table 9 and Table 10). However, the majority of product types lead to only low levels of exposure due to low incorporation and release levels of fragrance substances. Therefore, it is unlikely that higher-Tier assessments have to be performed.

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Table 21: Overview of typical Tier 1.5 inputs for contributing scenarios of GES 6, 7, 8 and 9

GES no. and title / Product Category (PC)	Contributing Scenarios[1]	Fragrance compound in fragranced end-product (%)[2]	Fragrance substance in fragranced end-product (%)[3]
GES6 - Consumer end-use of washing and cleaning products / **PC 35**	**CS1 Laundry and dish washing products**		
	a) laundry regular (powder, liquid) ; AISE C1	1	0.05
	b) laundry compact (powder, liquid/gel, tablet) ; AISE C2	1	0.05
	c) fabric conditioners (liquid regular, liquid concentrate) ; AISE C3	**2**	**0.10**
	d) Laundry additives (powder bleach, liquid bleach, tablet) ; AISE C4	1	0.05
	e) Hand dishwashing (liquid regular, liquid concentrate) ; AISE C5	1	0.05
	f) Machine dishwashing (powder, liquid, tablet) ; AISE C6	1	0.05
	g) Laundry aids (ironing aids-starch spray, ironing aids-other) ; AISE C12	0.5	0.025
	CS2 Cleaners, liquids (all-purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners)		
	a) Surface cleaners (liquid, powder, gel neat) ; AISE C7	2	0.10
	b) Toilet cleaners (powder, liquid, gel, tablet) ; AISE C8	**6**	**0.30**
	c) Carpet cleaners (liquid) ; AISE C11	2	0.10
	d) Wipes (bathroom, kitchen, floor) ; AISE C15	2	0.10
	e) High pressure washers/cleaners (liquid) ; AISE C21	2	0.10
	f) Automotive care (liquid) ; AISE C22	5	0.25
	CS3 Cleaners, trigger sprays (all-purpose cleaners, sanitary products, glass cleaners)		
	a) Surface cleaners (spray neat) ; AISE C7	2	0.10
	b) Oven cleaners (trigger spray) ; AISE C10	2	0.10
	c) Carpet cleaners (spray) ; AISE C11	2	0.10
	d) Automotive care (spray) ; AISE C22	**5**	**0.25**
GES7 - Consumer end-use of air care products / **PC 3**	**CS1 Air fresheners aerosol** : aqueous, non-aqueous, concentrated (mini-aerosol, Timed release aerosol) ; AISE C17	**5**	**0.25**
	CS2 Air fresheners non aerosol: a) perfume in/on solid substrate (gel), diffusers (heated) ; AISE C18	**100**	**5**
	b) candles ; AISE C18	10	0.5
GES8 - Consumer end-use of biocides / **PC 8**	**CS1 Insecticides**: liquid electric, spray neat ; AISE C19	**20**	**1.00**
	CS2 Repellents ; AISE C19		
GES9 - Consumer end-use of polishes and wax blends / **PC 31**	**CS1 Furniture, floor & leather care (spray, liquid):** wax/cream; (floor, furniture, shoes) ; AISE C20	**2**	**0.10**
	CS2 Furniture, floor & leather care (spray, liquid): spray; (furniture, shoes) ; AISE C20		

[1]AISE C9 (water softeners / PC 36), AISE C13 (Drain products / PC35) and AISE C14 (Descalers / PC35) are not considered to be applicable for fragrance substances.

[2]Industrial Common Practices: upper limit percentages of fragrance compounds in fragranced end-products.

[3]Industrial Common Practices: calculated using a realistic percentage of 5% fragrance substance in fragrance compound.

3.4.6.3 Environmental exposure during consumer use of fragranced end-products

Some products will be completely discharged 'down the drain' (rinse-off cosmetics, laundry detergents) whereas others will not be discharged to the sewer (shoe polish, dry cleaning). By nature, air fresheners will end up in the air. The identified ERCs for consumer end use are ERC8a and 8d (indoor/outdoor).

spERCs developed by A.I.S.E. and Cosmetics Europe (*ex* COLIPA) related to professional and consumer end-use of fragranced end-products can be used to refine exposure assessment. The environmental release fractions and other relevant parameters as identified by AISE and Cosmetics Europe are presented in Table 20 above[9].

Back to Fig. 4

3.5 Applicable Risk Management Measures

Worker, consumer and environmental exposure depend on characteristics of substances, products, processes, tasks/work activities, conditions and RMMs used. In the ECETOC model there are several parameters which, when changed from the default value, will give a reduction in exposure. In Table 22 these parameters are shown and the applicable efficiencies related to inhalatory and dermal exposure are given. It has to be noted that the information listed in Table 22 is coming from the version 2 model of ECETOC TRA. In the newly released version 3 of ECETOC TRA (April 2012) there are some additional parameters now added such as gloves. Also taken up in version 3 of ECETOC TRA is a refinement of ventilation. In addition to Local Exhaust Ventilation (LEV), which was also included in version 2, now also 'basic' and 'enhanced' general ventilation can be chosen. Furthermore, as an optional function in version 3 it can now be chosen if LEV has to be taken into account for dermal exposure.

In order to communicate OCs and RMMs in a consistent way within industry, 'standard phraseology' can be assigned to the relevant OCs and RMMs. The OC and RMM phrases to write in an ES are directly linked to the model input parameters used for exposure calculation. The Tables 22, 23, 24 below present the principal OC and RMM phrases to be used when a Tier 1 exposure assessment is done. These phrases are standard phrases from the CEFIC RMM library. Cefic has published these phrases as the ESCom phrases which can be downloaded from the Cefic website at www.cefic.org. The ESCom catalogue contains phrases received from different industry associations. Below the phrases from the European Solvents Industry Group (ESIG) are given as an example only. Cefic is currently working on a new set of phrases which ideally would lead to a list with one unique phrase for each OC and RMM.

[9] See A.I.S.E. website http://www.aise.eu/reach/?page=exposureass_sub4 and Cosmetics Europe website http://www.cosmeticseurope.eu/safety-and-science-cosmetics-europe/reach-and-chemicals/use-and-exposure-information.html

Table 22: Tier 1 worker inputs and OC and RMM ESCOM standard phrases

worker tier 1 ECETOC TRA V2 inputs		efficiency of exposure reduction in		ESCom standard phrases OC and RMM (CEFIC RMM library)
		inhalation	dermal	
Duration	> 4 hours	0	none	*none*
	1 to 4 hours	40	none	Avoid carrying out activities involving exposure for more than 4 hours (ESIG, OC28)
	15 mins to 1 hour	80	none	Avoid carrying out activities involving exposure for more than 1 hour (ESIG, OC27)
	< 15 mins	90	none	Avoid carrying out activities involving exposure for more than 15 minutes (ESIG, OC26)
%	> 25 %	0	none	*none*
	5 to 25 %	40	none	Limit the substance content in the product to 25 % (ESIG, OC18)
	1 to 5 %	80	none	Limit the substance content in the product to 5 % (ESIG, OC17)
	< 1 %	90	none	Limit the substance content in the product to 1 % (ESIG, OC16)
outdoor		30	none	Outdoor (ESIG, OC9)
indoor				Indoor (ESIG, OC8) Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour) (ESIG, E11)
	indoor LEV no	0	none	*none*
	indoor LEV yes	75 to 97, depend on PROC n°	90 to 99, depend on PROC n°	Provide extract ventilation to points where emissions occur (ESIG, E54)
respiratory protection	half mask	90	none	Wear a respirator conforming to EN140 with Type A filter or better (ESIG, PPE22)
	full mask	95	none	Wear a full face respirator conforming to EN136 with Type A filter or better (ESIG, PPE24)

Table 23 presents the most typical standard OC and RMM phrases used for consumer exposure purpose. Those phrases are generally open phrases (with no specific value) and the registrant has to precise the relevant value link to default input used for exposure calculation (e.g. Covers concentration up to "*1%*"). It has to be noted that the given list is for example purposes only and that each registrant should assess individually which phrases should be assigned to the relevant OCs and RMMs. Ideally, the whole fragrance industry should use a standard set of phrases. However, as the work on the ESCom catalogue is not finished at this point in time it is not possible to define a final set of phrases that could be used within the fragrance industry.

Table 23: Tier 1 consumer inputs and OC and RMM ESCOM standard phrases

ESCom standard phrases OC and RMM	Codes	
Covers concentrations up to	ESIG	ConsOC1
For each use event, covers use amounts up to .	ESIG	ConsOC2
Covers skin contact area up to	ESIG	ConsOC5
Covers use under typical household ventilation.	ESIG	ConsOC8
Covers use in a one car garage (34 m3) under typical ventilation.	ESIG	ConsOC10
Covers use in room size of	ESIG	ConsOC11
Covers outdoor use.	ESIG	ConsOC12
Covers use at ambient temperatures.	ESIG	ConsOC15
See specific operational conditions below.	ESIG	ConsOC16
Avoid using at a product concentration greater than	ESIG	ConsRMM1
For each use event, avoid using a product amount greater than	ESIG	ConsRMM2
Avoid using product more than	ESIG	ConsRMM3
Avoid using without gloves.	ESIG	ConsRMM6
Avoid using in room with closed doors.	ESIG	ConsRMM7
Avoid using without an operating fan and open windows.	ESIG	ConsRMM9
Avoid using in rooms smaller than a garage - room volume of at least	ESIG	ConsRMM10
Avoid using in room size less than	ESIG	ConsRMM11
Avoid using indoors.	ESIG	ConsRMM12
For each use, avoid using for more than	ESIG	ConsRMM14
No specific risk management measure identified beyond those operational conditions stated	ESIG	ConsRMM15

Table 24 presents the most typical standard OC and RMM phrases used for environmental exposure purpose. Those phrases are generally open phrases (with no specific value) and the registrant has to precise the relevant value link to default, calculated or specific input used for exposure calculation (e.g. Annual site tonnage (tonne/year) (ESIG, A5): 150).

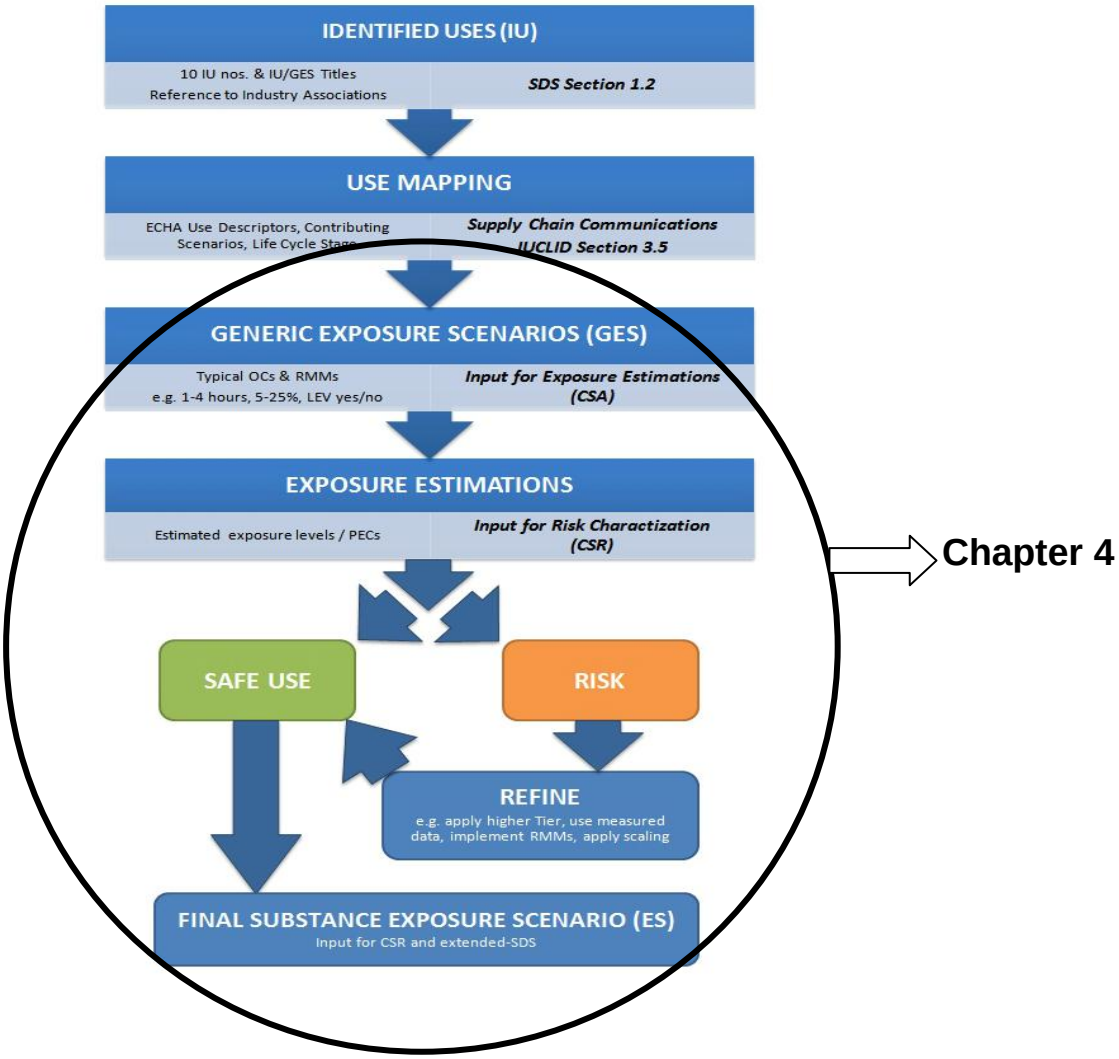
Table 24: Tier 1 environment inputs and OC and RMM ESCOM standard phrases

ENVIRO standard phrases (examples)		Source
Amounts used	Annual amount used in the EU (tonnes/year)	tier 1 ECETOC TRA inputs
	Fraction of EU tonnage used in region (ESIG, A1):	
	Regional use tonnage (tonnes/year) (ESIG, A2):	calculated (EU Tonnage*Fraction of EU tonnage used in region)
	Fraction of Regional tonnage used locally (ESIG, A3):	Tier 1: ERC - Default value depending on ERC n°
	Annual site tonnage (tonnes/year) (ESIG, A5):	calculated (Regional use tonnage*Fraction of Regional tonnage used locally)
	Maximum daily site tonnage (kg/day) (ESIG, A4):	calculated (Annual site tonnage*1000/Emission Days)
Emission type	Emission Days (days/year) (ESIG, FD4):	Tier 1: ERC - Default value depending on ERC n°
	Continuous release (ESIG, FD2).	Tier 1: Default (opposite is intermittent release)
	Local freshwater dilution factor (ESIG, EF1): 10 (default)	Tier 1: ERC - Default value
	Local marine water dilution factor (ESIG, EF2): 100 (default)	
	Receiving surface water flow is 18000 m3/d. (ESIG, EF3)(default)	
	Assumed domestic sewage treatment plant flow (m3/d) (ESIG, STP5): 2000 (default)	
Other given Operational Conditions of use affecting environmental exposure	Indoor use (ESIG, OOC2).	Set by user, depends on the ERC and the specific uses of the substances
	Indoor/Outdoor use (ESIG, OOC3).	
	Water-based process (ESIG, OOC12).	
	Release fraction to air from process (initial release prior to RMM) (ESIG, OOC4):	Tier 1: ERC - Default value depending on ERC n°
	Release fraction to wastewater from process (initial release prior to RMM) (ESIG, OOC5):	
	Release fraction to soil from process (initial release prior to RMM) (ESIG, OOC6):	
Technical conditions and measures at process level (source) to prevent release	Risk from environmental exposure is driven by freshwater (ESIG, TCR1a).	= the compartment with highest RCR (or lowest Msafe) Set by user, depends on risk assessment outputs
	Maximum allowable site tonnage (M_{Safe}) (kg/d) (ESIG, STP10):	tier 1 ECETOC TRA outputs (User should select the lowest Msafe)
Conditions and measures related to treatment of waste (including article waste)	If discharging to domestic sewage treatment plant, no onsite wastewater treatment required (ESIG, TCR9).	tier 1 ECETOC TRA inputs (equivalent to "STP=YES")
	Total efficiency of removal from wastewater after onsite and offsite (domestic treatment plant) RMMs (%) (ESIG, STP4):	tier 1 ECETOC TRA outputs
	Do not apply industrial sludge to natural soils (ESIG, OMS2).	RMM Equivalent to "SludgeToSoil?=NO" and considering that onsite wastewater treatment is systematic
	Sludge should be incinerated, contained or reclaimed (ESIG, OMS3).	RMM Equivalent to "SludgeToSoil?=NO" and considering that wastewater is treated either onsite or offsite

4 USING GES TO PERFORM EXPOSURE ESTIMATIONS

The aim of the chapter 4 is to provide a high level guidance on how to use the GESs to develop final exposure scenarios.
This chapter presents the principal steps of the guidance flow chart (figure 1, Executive summary) from GES to final substance exposure scenario (ES) for worker exposure assessment (chapter 4.1), consumer exposure assessment (chapter 4.2) and environmental exposure assessment (chapter 4.3). In each chapter the following will be discussed:

- a case showing **safe use** (RCR <1) using initial GES inputs
- a case showing **no safe use** (RCR>1) using initial GES inputs



For the following examples presented in chapter 4.1, 4.2 and 4.3, the characteristics of a fictitious but representative fragrance substance are used. The safe limit values are taken just for illustrative purposes. Ideally, band-widths of DNELs and PNECs should be considered. In this case for human exposure DNELs in the band-width 10-100 mg/kg/d or mg/m3 have been taken.

Table 25: Substance inputs used for the following examples in chapter 4.1, 4.2 and 4.3.

Physical-chemical properties of Substance X			
Molecular weight ($g.mol^{-1}$)	**200**		
Vapour pressure (Pa; temperature range 15-25°C)	**300**		
Water solubility ($mg.L^{-1}$; temperature range 15-25°C)	**6**		
Log Kow	**3.47**		
Biodegradability test result	**readily biodegradable**		
Log Koc ($L.kg^{-1}$)	**3.1**		
Safe limit values for human (DNEL)			
Long-term DNEL for systemic effect**	**Inhalation**	**Dermal**	**Oral**
Worker	60 mg/m^3	55 mg/kg bw/d	-
General population*	75 mg/kg bw/d***	25 mg/kg bw/d	25 mg/kg bw/d
Safe limit values for environment (PNEC)			
Reference value microorganisms STP ($mg.L^{-1}$)	100		
Reference value freshwater aquatic ($mg.L^{-1}$)	0.1		
Reference value freshwater sediment (mg $kgdwt^{-1}$)	12.36		
Reference value marine water (mg L^{-1})	0.01		
Reference value marine sediment (mg $kgdwt^{-1}$)	1.236		
Reference value terrestrial compartment (mg $kgdwt^{-1}$)	2.44		

*General population includes the consumer and the man exposed *via* the environment

** DNELS are fairly high because chronic data were available and substance or another explanation.

*** DNEL expressed in mg/kg bw/d using an inhalation rate of 1.37 m^3/h for 24h exposure to be consistent with ECETOC TRA and a body weight of 60 kg (R8 ECHA guidance).

4.1 Worker exposure assessment for industrial use

ECETOC TRA V2 for worker exposure via the dermal and inhalatory route is a Tier 1 model tool. The inputs used by the tool for exposure calculation are: Physical state of the substance (solid or liquid), Vapor pressure (for liquids) or dustiness (for solids), Molecular weight, Industrial or professional setting, Process category (PROC), Duration, Fraction of the substance in product, Local exhaust ventilation (LEV) and Personal protective equipment for inhalation (PPE).

4.1.1 First case – safe use identified (RCR <1) with initial refined Tier 1 GES default inputs

In this example we will take one contributing scenario ("Use of metal cleaner (degreaser, descaler, etc.) semi-automatic process (AISE P1005) - use phase" CS7b) from the GES 3 - industrial end use of washing and cleaning products.

Conclusion: in this case the default input parameters taken from the GES for a substance having an inhalation DNEL of 60 mg/m3 and a dermal DNEL of 55 mg/kg/d lead to safe use and thus the GES can be used as final exposure scenario without any additional modifications (OCs and/or RMMs).

Industrial use of washing and cleaning: initial refined Tier 1 ECETOC TRA V2 inputs based on GES 3 and CS7b (table 16):

setting	PROC	duration	% in the product	LEV	PPE
industrial	4	>4h	<1%[1]	no	no

[1] note that in ECETOC v2 the concentration in the end-product is not taken into account for dermal exposure

ECETOC TRA V2 exposure estimate results

Inhalation long term	Dermal long term
4.17 mg/m^3	6.86 mg/kg bw/d

RCR inhalation	RCR dermal	RCR total (inh+derm)
<1 (0.07)	**<1 (0.12)**	**<1 (0.19)**

SAFE USE

FINAL SUBSTANCE EXPOSURE SCENARIO (ES)

4.1.2 Second case – use not safe (RCR >1) with initial refined Tier 1 GES default inputs

In this example we will take one contributing scenario (CS8b, "Use of chain maintenance product; automatic spray process (AISE-P803) - use phase") from the GES 3 - industrial end use of washing and cleaning products) (see table 16).

Conclusion: in this case the default input parameters taken from the GES for a substance having an inhalation DNEL of 60 mg/m3 and a dermal DNEL of 55 mg/kg/d do not lead to safe use. The following options could be considered for refinement:

- Refinement of the initial GES (i.e. refinement of the OCs or introduce PPE);
- Use of a Tier 2 model (Stoffenmanager, Advanced Reach Tool) using site-specific data;
- Perform measurements to refine inhalation exposure.

Industrial use of washing and cleaning: Tier 1 ECETOC TRA V2 inputs based on GES 3, CS8b (table 16)

setting	PROC	duration	%	LEV	PPE
industrial	7	>4h	<1%	no	no

[1] note that in ECETOC v2 the concentration in the end-product is not taken into account for dermal exposure

Tier 1 ECETOC TRA V2 exposure results

Inhalation long term	Dermal long term
83.33 mg/m^3	42.86 mg/kg bw/d

RCR inhalation	RCR dermal	RCR total (inh+derm)
>1 (1.39)	<1 (0.78)	>1 (2.17)

RISK (use not safe)

REFINE until all RCR<1

SAFE USE

FINAL SUBSTANCE EXPOSURE SCENARIO (ES)

4.2 Consumer exposure estimations during the use of fragranced end-products

As for the worker, a “Tiered” approach (*i.e.* step-by-step) for consumer exposure assessment is recommended according to the ECHA Chapter R.15 Guidance (2010) as described in §3.7:

- Using the ECETOC Targeted Risk Assessment (ECETOC TRA) tool and Generic Exposure Scenarios as a first step.
- Often this Tier 1 is skipped and a first refinement of exposure estimation is carried out with Tier 1.5 tools such as AISE REACT. Also ConsEXPO contains Tier 1.5 models.
- In cases where safe use is not found with using these Tier 1.5 tools, higher Tier 2 models can be used. Also when the use is not covered in AISE, ConsEXPO can possibly be used (*e.g.* fragranced repellents).

The following table (Table 26) indicates the scenarios available at the different Tier levels for the fragranced end-products. Thereafter examples for consumer use of fragranced end-products are presented.

Table 26: The GES for Consumer Use and the exposure estimation tools available for fragranced end-products at the different tier levels

GES No.	GES title / Product Category (PC)	Contributing Scenarios	*Tier 1*	*Tier 1.5*		*Tier 2*
			ECETOC-TRA (default parameters)	AISE REACT[1]	ECETOC-TRA (refined parameters)[2]	ConsExpo
6	GES6 - Consumer end-use of washing and cleaning products / **PC 35**	**CS1 Laundry and dish washing products**				
		a) laundry regular (powder, liquid) ; AISE C1	x	x	x	x
		b) laundry compact (powder, liquid/gel, tablet) ; AISE C2	x	x	x	x
		c) fabric conditioners (liquid regular, liquid concentrate) ; AISE C3	x	x	x	x
		d) Laundry additives (powder bleach, liquid bleach, tablet) ; AISE C4	x	x	x	x
		e) Hand dishwashing (liquid regular, liquid concentrate) ; AISE C5	x	x	x	x
		f) Machine dishwashing (powder, liquid, tablet) ; AISE C6	x	x	x	x
		g) Laundry aids (ironing aids-starch spray, ironing aids-other) ; AISE C12	x	x	x	x
		CS2 Cleaners, liquids (all purpose cleaners, sanitary products, floor cleaners, glass cleaners, carpet cleaners, metal cleaners)				
		a) Surface cleaners (liquid, powder, gel neat) ; AISE C7	x	x	x	x
		b) Toilet cleaners (powder, liquid, gel, tablet) ; AISE C8	x	x	x	x
		c) Carpet cleaners (liquid) ; AISE C11	x	-	x	x
		d) Wipes (bathroom, kitchen, floor) ; AISE C15	x	x	x	x
		e) High pressure washers/cleaners ; AISE C21	x	-	x	x
		f) Automotive care (liquid) ; AISE C22	x	-	x	x
		CS3 Cleaners, trigger sprays (all purpose cleaners, sanitary products, glass cleaners)				
		a) Surface cleaners (spray neat) ; AISE C7	x	x	x	x
		b) Oven cleaners (trigger spray) ; AISE C10	x	-	x	x
		c) Carpet cleaners (spray) ; AISE C11	x	-	x	x
		d) Automotive care (spray) ; AISE C22	x	-	x	x
7	GES7 - Consumer end-use of air care products / **PC 3**	**CS1 Air fresheners aerosol** : aqueous, non aqueous, concentrated (mini-aerosol, Timed release aerosol) ; AISE C17	x	x	x	x
		CS2 Air fresheners non aerosol: a) perfume in/on solid substrate (gel), diffusers (heated) ; AISE C18	x	x	x	x
		b) candles ; AISE C18	x	x	x	x
8	GES8 - Consumer end-use of biocides / **PC 8**	**CS1 Insecticides**: liquid electric, spray neat; AISE C19	-	x[3]	x[3]	x
		CS2 Repellents ; AISE C19	-	-	-	x[4]
9	GES9 - Consumer end-use of polishes and wax blends / **PC 31**	**CS1 Furniture, floor & leather care** (spray, liquid): wax/cream ; (floor, furniture, shoes); AISE C20	x	-	x	x
		CS2 Furniture, floor & leather care (spray, liquid): spray; (furniture, shoes) ; AISE C20	x	x	x	x

[1]See Table 21 (§ 3.4.6.2) for the fraction (%) of fragrance substance in fragranced end-product as input

[2]See Annex 2 for refined inputs

[3]Air fresheners for neat spray and non-aerosol air fresheners for heated diffuser can be applied to the fragranced Insecticides

[4]Use the scenario "Pest control products / Insect repellents / Repellent, insects / application adult scenario" for the fragranced repellents

4.2.1 *ECETOC TRA Tool for consumer exposure estimation: Tier-1 assessment*

ECETOC TRA uses default values (see Annex 1) and it is largely based on the Tier 1 algorithms documented in Section R.15.3 from the ECHA guidance.

EXAMPLE showing safe use (RCR <1)

In this example, the contributing scenario "Air freshener non aerosol" and the subcategories "candles" from the GES 7 - consumer end use of air care products is considered.
In Tier1 ECETOC TRA V2 consumer assessment, the only input that the registrant has to choose is the PC n°. All the others inputs (frequency, amount, exposure time, etc) are automatic default parameters depending on PC No. choice.

Conclusion: in this case the default input parameters linked to the PC3 (GES7) for a substance having an inhalation DNEL of 75 mg/kg bw/d and a dermal DNEL of 25 mg/kg bw/d lead to safe use.
Thus the GES can be used as final exposure scenario without any additional modifications (OCs only as no RMMs used for consumer).

Tier 1 ECETOC TRA V2 inputs based on GES 7:

setting	PC / AISE	Default parameters (see Annex 1)
Private households	PC 3 / AISE C18	Product substance: 0.1 g/g Frequency: 1 event/day Skin surface contact area: 35.7 cm^2 Amount product/event: 50 g Room volume: 20 m^3 Exposure time: 8 h

Tier 1 ECETOC TRA V2 exposure results

-	Inhalation long term	Dermal long term
Exposure	**45.7 mg/kg bw/d**	**0.59 mg/kg bw/d**

RCR inhalation	RCR dermal	RCR total (inh+derm)
<1 (0.61)	**<1 (0.024)**	**<1 (0.63)**

Safe use

FINAL SUBSTANCE EXPOSURE SCENARIO (ES)

EXAMPLE showing no safe use (RCR >1)

In this example, the contributing scenario “Cleaners, liquids” and the subcategories “Surface cleaners” from the GES 6 - consumer end use of washing and cleaning products” is considered.
In Tier1 ECETOC TRA V2 consumer assessment, the only input that the registrant has to choose is the PC n°. All the others inputs (frequency, amount, exposure time, etc) are automatic default parameters depending on PC n° choice.

Conclusion: in this case the default input parameters linked to the PC35 (GES6) for a substance having an inhalation DNEL of 75 mg/kg bw/d and a dermal DNEL of 25 mg/kg bw/d lead to an unsafe use.
The next step to consider for a registrant would be to use a Tier 1.5 model (AISE REACT or Tier 1 ECETOC TRA with refined parameters)

Tier 1 ECETOC TRA V2 inputs based on GES 6:

setting	PC / AISE	Default parameters (see Annex 1)
Private households	PC 35 / AISE C7	Product substance: 0.5 g/g Frequency: 1 event/day Skin surface contact area: 857.5 cm^2 Amount product/event: 250 g Room volume: 20 m^3 Exposure time: 0.33 h

Tier 1 ECETOC TRA V2 exposure results

-	Inhalation long term	Dermal long term
Exposure	**47.6 mg/kg bw/d**	**71.5 mg/kg bw/d**

RCR inhalation	RCR dermal	RCR total (inh+derm)
<1 (0.63)	**>1 (2.9)**	**>1 (3.5)**

RISK (use not safe)

REFINE until all RCRs<1

Safe use

FINAL SUBSTANCE EXPOSURE SCENARIO (ES)

4.2.2 AISE REACT for consumer exposure estimation: Tier-1.5 assessment

The AISE REACT Consumer Tool allows quantitative estimation of systemic consumer exposures to substances that are present in fragranced end-products used by consumers. This consumer estimation is also considered as a Tier 1.5 assessment.

EXAMPLE showing safe use risk (RCR < 1) at Tier 1.5

In this example, the contributing scenario "Cleaners, liquids" and the subcategories "Surface cleaners" from the GES 6 - consumer end use of washing and cleaning products" is considered. Risks are identified using a Tier 1 risk assessment as described above and therefore refinement using a Tier 1.5 assessment is done.

Conclusion: in this case, using the Tier 1.5 AISE REACT default input parameters linked to PC35 (GES 6) and with the relevant fraction of fragrance substance (0.10%), for a substance having an inhalation DNEL of 75 mg/kg bw/d and a dermal DNEL of 25 mg/kg bw/d lead to safe use.

Tier 1.5 AISE REACT inputs based on GES 6 Table 14:

setting	PC / AISE	Refined parameters (see Table 14)
Private households	PC 35 / AISE C7	Fraction of fragrance substance in fragranced end-product: 0.10%

Tier 1.5 AISE REACT exposure results

-	Inhalation long term	Dermal long term
Exposure	**0.0012 mg/kg bw/d**	**0.143 mg/kg bw/d**

RCR inhalation	RCR dermal	RCR total (inh+derm)
<1 (0.000016)	**<1 (0.0057)**	**<1 (0.0057)**

Safe use

FINAL SUBSTANCE EXPOSURE SCENARIO (ES)

4.3 Environmental exposure assessment

The ECETOC TRA version 2 Integrated tool is used for Tier 1 exposure assessment. This model is based on equations documented in Section R.16 from the ECHA guidance. EUSES can also be used as it is equivalent to ECETOC TRA and is based on the same equations, with the difference that ERC and spERC are not available in EUSES, so default inputs have to be set manually.
As a first step the basic inputs are defined for Tier 1 assessment, starting with physico-chemical properties, the safe limit values (PNECs) and for each ES the EU Tonnage and Fraction of EU tonnage used in region (1 or 0.1), the appropriate ERC and whether the use of a WWTP is assumed or not. Other inputs come directly from the selected ERC or spERC.

4.3.1 First case: Consumer end use – acceptable RCR results with Tier 1 GES default inputs

In this example ERC8d related to the GES 6 – consumer end use of washing and cleaning products is considered.
The calculations have been done using ECETOC TRA version 2 with ERC approach.

Conclusion: in this case, with Tier 1 ERC default input parameters and an EU tonnage of 500 tpa the model predicts a safe use.

Tier 1 ECETOC TRA inputs set by user:

Description of use	GES 6 – consumer end use of washing and cleaning products
EU Tonnage (t/y)	500
Fraction of EU tonnage to region	0.1
Fraction at the local source	0.002
Release days (d/y)	365
Fraction at the local source	0.002
Use ERC or spERC for release estimation	ERC
ERC	ERC8d
Release fraction to air	1
Release fraction to waste water	1
Release fraction to soil	0.2
STP	yes
STP capacity (m^3/d)	2,000 (default)
River flow rate (m^3/d)	18,000 (default)
Sludge To Soil?	Yes (default)

Tier 1 ECETOC TRA V2 exposure results

PEC* in STP (mg.l-1)	4.87E-03
PEC for local freshwater (mg.l-1)	6.11E-04
PEC for local freshwater sediment (mg.kgdwt-1)	7.55E-02
PEC for local soil (mg.kgdwt-1)	2.33E-02
PEC for local marine water (mg.l-1)	5.92E-05
PEC for local marine sediment (mg.kgdwt-1)	7.32E-03

*PEC: Predicted Environmental Concentration

Risk characterisation ratios (RCRs)

RCR in STP (-)	**<1 (4.87E-05)**
RCR for local freshwater (-)	**<1 (6.11E-03)**
RCR for local freshwater sediment (-)	**<1 (6.11E-03)**
RCR for local terrestrial environment (-)	**<1 (9.57E-03)**
RCR for local marine water (-)	**<1 (5.92E-03)**
RCR for local marine sediments (-)	**<1 (5.92E-03)**

SAFE USE

FINAL SUBSTANCE EXPOSURE SCENARIO (ES)

4.3.2 *Second case: industrial end use – unacceptable RCR results with Tier 1 GES default inputs*

In this example ERC4 related to the GES3 – industrial end use of washing and cleaning products is considered. For this case it seems appropriate to start directly with a Tier 1.5 assessment using the spERC approach.
The calculations have been done using ECETOC TRA version 2 with spERC approach.

Conclusion: in this case, with Tier 1.5 spERC approach, using the spERC AISE 13 input parameters and an EU tonnage of 100 tpa the model does not predict a safe use for the local terrestrial environment only. This is probably the result of sludge application to agricultural soil.
The registrant should refine some parameters in ECETOC TRA to get the soil RCR < 1 or do a site-specific assessment with the focus on sludge application to soil.

Tier 1.5 ECETOC TRA inputs set by user

Description of use	GES3 – industrial end use of washing and cleaning products
EU Tonnage (t/y)	100
Fraction of EU tonnage to region	1
Fraction of the local source	Back-calculated from MspERC
Release days (d/y)	220
Fraction of the local source	Back-calculated from MspERC
Use ERC or spERC for release estimation	spERC
ERC	ERC4
spERC	AISE13 - Industrial Use of Water Borne Processing Aids
STP	yes
Release fraction to air	0
Release fraction to waste water	1
Release fraction to soil	0
STP	yes
STP capacity (m^3/d)	2,000 (default)
River flow rate (m^3/d)	18,000 (default)
Sludge To Soil?	Yes (default)

Tier 1.5 ECETOC TRA V2 exposure results

PEC* in STP (mg.l-1)	8.89E-01
PEC for local freshwater (mg.l-1)	8.88E-02
PEC for local freshwater sediment (mg.kgdwt-1)	1.10E+01
PEC for local soil (mg.kgdwt-1)	4.26E+00
PEC for local marine water (mg.l-1)	8.88E-03
PEC for local marine sediment (mg.kgdwt-1)	1.10E+00

*PEC: Predicted Environmental Concentration

Risk characterisation ratios (RCRs)

RCR in STP (-)	<1 (8.89E-03)
RCR for local freshwater (-)	<1 (8.88E-01)
RCR for local freshwater sediment (-)	<1 (8.88E-01)
RCR for local terrestrial environment (-)	>1 (1.75E+00)
RCR for local marine water (-)	<1 (8.88E-01)
RCR for local marine sediments (-)	<1 (8.88E-01)

RISK (use not safe)

REFINE all RCRs until <1

Once Safe use is demonstrated

FINAL SUBSTANCE EXPOSURE SCENARIO (ES)

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http://chesar.echa.europa.eu/

ANNEX 1

Use Descriptors and Tier 1 inputs for consumer exposure assessment

GES No.	GES title / Product Category (PC)	Product sub Category Sentinels	Product substance (g/g)	adult / child			Product is spray? (S)	frequency (events per day)	Skin surface contact area (cm^2)	Amount swallowed (g)	Amount product per event (g)	room volume (m^3)	exposure time (hr)
				d	o	i							
6	GES6 - Consumer end-use of washing and cleaning products / **PC 35**	AISE C1 - Laundry regular AISE C2 - Laundry compact AISE C3 - Fabric conditioners AISE C4 - Laundry additives AISE C5 - Hand dishwashing AISE C6 - Machine dishwashing AISE C12 - Laundry aids	0.6	A	-	A	-	1	857.5	-	50	20	1
		AISE C7 - Surface cleaners AISE C8 - Toilet cleaners AISE C11 - Carpet cleaners AISE C15 – Wipes AISE C21 - High pressure washers/cleaners AISE C22 - Automotive care	0.5	A	-	A	-	1	857.5	-	250	20	0.33
		AISE C7 - Surface cleaners AISE C10 - Oven Cleaners AISE C11 - Carpet cleaners AISE C22 - Automotive care	0.2	A	-	A	-	1	857.5	-	35	20	4
7	GES7 - Consumer end-use of air care products / **PC 3**	AISE C17 - Air fresheners aerosol as aqueous, non-aqueous, concentrated (mini-aerosol, Timed release aerosol)	0.5	-	-	A	S	4	-	-	10	20	0.25
		AISE C18 - Air fresheners non aerosol as perfume in/on solid substrate (gel), diffusers (heated)	0.1	A	-	A	-	1	35.7	-	50	20	8
8	GES8 - Consumer end-use of biocides / **PC 8**	AISE C19 - Air fresheners aerosol for Insecticides spray neat	0.01*	-	-	A	S	4	-	-	10	20	0.25
		AISE C19 - Air fresheners non-aerosol for Insecticides electric liquid	0.01*	A	-	A	-	1	35.7	-	50	20	8
9	GES9 - Consumer end-use of polishes and wax blends / **PC 31**	AISE C20 - Furniture floor and leather care - non spray wax/cream ; (floor, furniture, shoes)	0.5	A	-	A	-	1	857.5	-	550	20	4
		AISE C20 - Furniture floor and leather care - spray - (spray, liquid): spray; (furniture, shoes) ;	0.5	A	-	A	S	1	857.5	-	135	20	4

* Insecticides: fraction of fragrance substance in fragranced end-product indicated in Table 21 (see §3.4.6.2)

ANNEX 2

Table of habits and practices for consumer products in Western Europe developed by AISE (amended 2009) within the HERA project 2002

Product categories	Grams/Task			Use Frequency: # Tasks per week			Duration of Task (min)			Other intended uses of category
	Min.	Max.	Typ.	Min.	Max.	Typ.	Min.	Max.	Typ.	
LAUNDRY REGULAR										
Powder	55	290	150	1	18	5	Machine wash: < 1 min.			Laundry pretreatment: 10 min. / task, 50-60% paste (powder); neat liquid
Liquid	78	230	150	1,8	10	4	Hand wash (b): 10 min.			
LAUNDRY COMPACT										
Powder	20	200	75	1	21	5	Machine wash: < 1 min.			Laundry pretreatment: 10 min. / task, 50-60% paste (powder); neat liquid
Liquid/gel	40	140	90	2,8	10	4	Hand wash (b): 10 min.			
Tablet	45	135	90	3	10	4				
FABRIC CONDITIONERS										
Liquid Regular	50	140	135	3,3	10	4	Machine: < 1 min.			Not applicable
Liquid Concentrate	11	90	44				Hand wash (b): 10 min.			
LAUNDRY ADDITIVES										
Liquid Bleach (ml)	40	100	70	1,5	4	3	Hand wash (b): 5 - 10 min.			Laundry pretreatment liquid (neat)
Tablet	20	30	25							
HAND DISHWASHING										
Liquid Regular (a)	3	10	--	3	21	14	10	45	30	Not applicable
Liquid Concentrate (a)	2	5	--				10	45	30	
MACHINE DISHWASHING										
Powder	20	46	--							
Liquid	20	40	--	3	7	5	< 1 min.			Not applicable
Tablet	20	50	--							
SURFACE CLEANERS										
Liquid (a)	30	110	60							
Powder (a)	20	40	--	1	7	2	10	20	--	Not applicable

Product categories	Grams/Task			Use Frequency: # Tasks per week			Duration of Task (min)			Other intended uses of category
	Min.	Max.	Typ.	Min.	Max.	Typ.	Min.	Max.	Typ.	
Gel (neat)	20	40	--							
Spray (neat)	5	30	--				2	10	--	
TOILET CLEANERS										
Powder	15	30	20							
Liquid (ml)			30	1	2	1		< 1 min.		Not applicable
Gel	20	35	25							
Tablet	25	50	35							
LAUNDRY AIDS										
Ironing Aids	1	20	10	1	5	2	5	20	60	-
INSECTICIDES										
Liquid Electric	0,4	0,6	0,5	5,5	5,7	5,6	7,6	8,6	8,1	Units are grams/day in first column
Spray (neat)	9,5	10,75	10,1	2,5	2,7	2,6	3,9	4,4	4,2	
WATER SOFTENERS										
Powder (a)	22	88	44	1	4,5	2	<1min			-
Liquids (ml)	50	83	60	1	4,5	2	<1min			
Tabs(tab)	1tab	1tab	1tab	1	4,5	2	<1min			
MAINTENANCE PRODUCTS										
Spray	2	60	30	1	3	1	5	60	20	Furniture care, shoes, leather.
WIPES										
Bathroom			1g			7	1	10	5	based on a total weight weight of 7g
Kitchen			1g			3,5	2	10	5	based on total weight weight of 7g
Floor			26g			2	2	10	5	Wet weight not determined

Product categories	Grams/Task			Use Frequency: # Tasks per week			Duration of Task (min)			Other intended uses of category
	Min.	Max.	Typ.	Min.	Max.	Typ.	Min.	Max.	Typ.	
DRAIN GRANULES	70	70	70	0	1	<1	5	15	10	Single Unit
HIGH PRESSURE WASHERS/CLEANERS	1,16	320,83	50	0,02	1	0,23	60	600	300	Use frequency counted on a year
AUTOMOTIVE CARE (SPRAY/LIQUID)	50	500	200	0,02	2	0,5	200	600	300	Use frequency counted on a year
Product categories	**Discharge Rate (Grams/Sec)**			**Use Frequency: # Tasks per week**			**Duration of spraying (s)**			**Other intended uses of category**
	Min.	**Max.**	**Typical**	**Min.**	**Max.**	**Typical**	**Min.**	**Max.**	**Typical**	
AIR FRESHENERS										
1. Aerosol i) aqueous	1	1.8	1.4	1	37	8	1	15	6	
1. Aerosol ii) non-Aqueous	0.6	1.5	0.9	1	37	7	1	15	6	
2. Perfume in/on solid substrate (gel)	1.3 E-6	8.1 E-5	2.9 E-5	Continuous			Continuous			
3. Diffusers (heated + electrical)	6.9 E-6	1.4 E-5	1.2 E-5	1	7	3,5	Continuous			

ANNEX 3

Summary of generic exposure scenarios for environmental risk assessment

IU n°	0	1	2	3	4, 5, 6, 7, 8, 9, 10	4. 6. 8
Exposure scenario title	Manufacturing of fragrance (**site-specific**)	Formulation of fragrance compounds	Formulation of fragranced end-products	Industrial end-use of washing and cleaning products	- Professional end-use of washing and cleaning products - Consumer end-use of washing and cleaning products - Consumer end-use of air care products - Consumer end-use of biocides - Professional use of polishes and wax blends - Consumer end-use of polishes and wax blends - Consumer end-use of cosmetics	- Professional end-use of washing and cleaning products - Consumer end-use of washing and cleaning products - Consumer end-use of biocides
Life cycle stage	Manufacturing	Formulation	Formulation	Processing	Professional/consumer end-use	Professional/consumer end-use
ERC	ERC1	ERC2	ERC2	ERC4	ERC8a	ERC8d
List of possible spERCs	-	IFRA 2.1a.v1 IFRA 2.1b.v1	AISE SPERC 2.1.a.v1 AISE SPERC 2.1.b.v1 AISE SPERC 2.1.c.v1 AISE SPERC 2.1.d.v1 AISE SPERC 2.1.e.v1 AISE SPERC 2.1.f.v1 AISE SPERC 2.1.g.v1 AISE SPERC 2.1.h.v1 AISE SPERC 2.1.i.v1 AISE SPERC 2.1.j.v1 AISE SPERC 2.1.k.v1 AISE SPERC 2.1.l.v1 COLIPA SPERC 2.1.a.v1 COLIPA SPERC 2.1.b.v1 COLIPA SPERC 2.1.c.v1 COLIPA SPERC 2.1.d.v1 COLIPA SPERC 2.1.e.v1 COLIPA SPERC 2.1.f.v1 COLIPA SPERC 2.1.g.v1 COLIPA SPERC 2.1.h.v1 COLIPA SPERC 2.1.i.v1 COLIPA SPERC 2.1.j.v1 COLIPA SPERC 2.2.a.v1 COLIPA SPERC 2.2.b.v1 COLIPA SPERC 2.2.c.v1 COLIPA SPERC 2.3.a.v1 COLIPA SPERC 2.3.b.v1 COLIPA SPERC 2.3.c.v1	AISE SPERC 4.1.v1	AISE SPERC 8a.1.a.v1 (AISE 16, 17, 18)	-

ANNEX 4

spERC fact sheet – Formulation of fragrance compounds

IFRA SPERC INPUTS (ECETOC TRA format)

SPERC Name	Specifies ERC	Fraction used at main source	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to waste water	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m3/day)	Type of On-Site risk management measure implemented	Efficiency of On-Site risk management measure	M_{SPERC} (kg/d)	spERC Code	SPERC description	Glossary text
IFRA 1	2	1	250	yes	0.025	0.002	0	18000	-	-	-	IFRA 2.1a.v1	IFRA - Formulation of fragrance compounds at large/medium sites	Fragrance compound: A blend of fragrance substances, representing a specific fragrance formula.
IFRA 2	2	1	250	yes	0.025	0.005	0	18000	-	-	-	IFRA 2.1b.v1	IFRA - Formulation of fragrance compounds at small sites	Fragrance compound: A blend of fragrance substances, representing a specific fragrance formula.

General Information	
Title of Specific ERC	IFRA - Formulation of fragrance compound
Applicable ERC	2 – Formulation of preparations
spERC code	IFRA 2.1a.v1 IFRA - Formulation of fragrance compounds at large/medium sites IFRA 2.1b.v1 IFRA - Formulation of fragrance compounds at small sites
Responsible	IFRA
Version	V1
Scope	Usually, fragrance ingredients are formulated twice: - several ingredients are mixed together to make a fragrance compound: this is referred to as the "compounding" stage; - a fragrance compound is mixed with other ingredients to make a consumer product (e.g. a shampoo): this is referred to as the "formulation" stage. The scope of this fact sheet covers only the compounding stage. Formulation of fragranced end-products is covered by AISE and COLIPA spERCs Factsheets (http://www.aise.eu/reach/?page=exposureass_sub4 and http://www.cosmeticseurope.eu/safety-and-science-cosmetics-europe/reach-and-chemicals/use-and-exposure-information.html). *Substance Domain*: Applicable to individual fragrance substances, stabilizers and solvents that may also be added to enhance the function of the compound, used continuously during all days of the year. The final concentration of a fragrance substance in the fragrance compound can range from parts per million by mass up to 20% w/w. On average a fragrance compound contains 40-60 different fragrance substances. *Size of compounding sites*: compounding sites have been assigned to three relative sizes of operations, large, medium and small, based on quantity of fragrance compound produced per year on one compounding site (described below).

	<table><tr><th>Size of compounding sites</th><th>Quantity of fragrance compound produced per year on one site (t/y)</th></tr><tr><td>Small</td><td>< 1,000</td></tr><tr><td>Medium</td><td>1,000 - 10,000</td></tr><tr><td>Large</td><td>> 10,000</td></tr></table> Large and medium compounding sites have been aggregated in a single spERC as no major differences in operating conditions and environmental release were observed in an industry survey (Haskoning 2008). *Operations covered*: Mixing of individual fragrance substances with other fragrance substances, stabilizers and solvents to create a mixture (named fragrance compound), including reception of goods, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, filling process equipment, mixing of ingredients, filling of containers, large and small scale packing, sampling, cleaning, maintenance and associated laboratory activities.
Related use descriptors	Sectors of Use: SU3, SU10 Process Categories: PROC1: Use in closed process, no likelihood of exposure PROC2: Use in closed, continuous process with occasional controlled exposure (e.g. sampling) PROC3: Use in closed batch process (synthesis or formulation) PROC5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC15: Use as laboratory reagent

	Characteristics of specific ERC		Type of Input Information
Operational Conditions	IFRA 2.1a.v1	**spERC specific Operational Conditions** - The number and sizes of batches is variable (surveyed sites reported from 13 up to 140 batches per day). Naturally, small number of batches is produced in larger quantities; - Dosing is a mixture of automatic and manual dosing. **Operational Conditions common to both spERCs** - Compounding is carried out as a batch-wise process; - After each batch a number of mixing vessels will need to be cleaned; - The delivery area is a contained area so spills and contaminated rain is drained to the water treatment system; - Generally the empty containers are not cleaned but they are either dedicated containers or they are recycled by an external company; - Pumps may be cleaned with water and the water is discharged into the drains. Some minor losses may occur there. Estimated losses range from <<0.01% to 0.08%; - Mixing vessels and batch sizes span a large volume range, from a few litres to many cubic meters; - The main release occurs after the mixing process when containers, pumps and other equipment are cleaned with water, detergent and sometimes steam or alcohol. The average releases range from 0.015 to 0.1%, with higher estimates for small batches (< 60L) up to 0.3%. These results are based on measurements;	A survey was conducted in 2008 to obtain information on the emission to water during the compounding process[10]. Responses to the questionnaire were received from 7 compounding sites with varying size and varying degree of emission control. Typical emission fractions were derived from these data, including measurements.

[10] Royal Haskoning 2008. Review and evaluation of environmental emission scenarios for fragrance ingredients Environmental exposure from the formulation of products (9S3975.01/R0002/Nijm)

		- During the filling of all finished products, rinsing or cleaning procedures are directed towards avoiding emissions to wastewater. Estimated emissions are in the range of 0.01%; - Floors are mopped and the water is discharged to the sewer system; spills are absorbed and treated as chemical waste, although small spills may be washed down the drain.	
	IFRA 2.1b.v1	**spERC specific Operational Conditions** - The number and sizes of batches is variable (surveyed sites reported from <1 up to 15 batches per day). Naturally, small number of batches is produced in larger quantities; - Dosing is mainly a manual process. **Operational Conditions common to both spERCs** - Compounding is carried out as a batch-wise process; - After each batch a number of mixing vessels will need to be cleaned; - The delivery area is a contained area so spills and contaminated rain is drained to the water treatment system; - Generally the empty containers are not cleaned but they are either dedicated containers or they are recycled by an external company; - Pumps may be cleaned with water and the water is discharged into the drains. Some minor losses may occur there. Estimated losses range from <<0.01% to 0.08%; - Mixing vessels and batch sizes span a large volume range, from a few litres to many cubic meters; - The main release occurs after the mixing process when containers, pumps and other equipment are cleaned with water, detergent and sometimes steam or alcohol. The average releases range from 0.015 to 0.1%, with higher estimates for small batches	

		(< 60L) up to 0.3%. These results are based on measurements; - During the filling of all finished products, rinsing or cleaning procedures are directed towards avoiding emissions to wastewater. Estimated emissions are in the range of 0.01%; - Floors are mopped and the water is discharged to the sewer system; spills are absorbed and treated as chemical waste, although small spills may be washed down the drain.	
Obligatory onsite RMMs	No RMMs needed.		
Substance Use Rate	IFRA 2.1a.v1	No accurate substance maximum use rate in a typical operation can be determined	
	IFRA 2.1b.v1	No accurate substance maximum use rate in a typical operation can be determined	
Days Emitting	IFRA 2.1a.v1	250 days/year[11]	Equivalent to number of working days, based on 2002/2003 data and 2008 inquiry to compounders.[12]
	IFRA 2.1b.v1	250 days/year[2]	
Environmental Parameters for Fate Calculation	IFRA 2.1a.v1	Local freshwater dilution factor: 10 Local marine water dilution factor: 100 Receiving surface water flow is 18000 m3/d	Default values from REACH Guidance
	IFRA 2.1b.v1		

[11] This assumes that the release is continuous during all days of the year. If the specific fragrance ingredients is present only occasionally in the fragrance oils mixed into the end products, a correction needs to be made for the lower number of emissions days.
[12] ibid.

		Characteristics of Specific ERC		Justification
Emission Fractions (from the process)	*To air*	IFRA 2.1a.v1	0.025	Default conservative value from ERC2 Not enough specific data have been collected to derive a specific release factor for compounding sites, even though it is obvious that the default release factor of 2.5% overestimates the emission to air. Indeed, most fragrance substances present a moderate to low volatility, most of substances VP being < 500 Pa (see Table 4 below) while the default release factor of 2.5% is based on highly volatile substances (>1000 Pa).
		IFRA 2.1b.v1	0.025	

Table 4: analysis of vapour pressure of 998 chemicals used in fragrance products

n =	998	chemicals
>1000 Pa	25	chemicals
<1000 Pa	973	chemicals
min =	8.20E-05	Pa
max =	9.999E+04	Pa
median =	2.8	Pa
99-percentile =	3258	Pa
97.5-percentile =	999	Pa
95-percentile =	453	Pa
90-percentile =	156	Pa

	To Wastewater	IFRA 2.1a.v1	0.002	A survey was conducted in 2008 to obtain information on the emission to water during the compounding process[13]. Responses to the questionnaire were received from 7 compounding sites with varying size and varying degree of emission control. Most responses showed that the COD in wastewater was caused mainly by the presence of fragrances in the water. Based on indications of the COD and the production volumes, and assuming that the COD of most of the fragrance ingredients in wastewater = 3 mg O/mg substance it was possible to estimate the release of products to wastewater. This fraction, prior to any treatment, ranges from 0.2 to < 0.43 % for the small compounders whereas for the large compounders the estimates range from 0.01 to 0.15%.
		IFRA 2.1b.v1	0.005	
	To Soil	IFRA 2.1a.v1	0	All solid waste is collected. Used packaging which has been in contact with chemicals are recycled, collected by waste companies or incinerated. The delivery area as well as the mixing halls is in contained area, so all water is collected in dedicated sewers. This implies that there is no direct emission to the soil. Spills are cleaned with specific sorbing materials or cleaned with water that is collected in dedicated sewers along with the process water.
		IFRA 2.1b.v1	0	

[13] ibid.

				Spilled fragrances may be collected and recycled in the process[14].

	Type of RMM	Typical Efficiency
Optional risk management measures for iteration	***Water***	
	On-site physico-chemical treatment (before discharging into either a biological wastewater treatment plant on-site or in a municipal sewage treatment plant)	- It is common practice that the waste water is treated in a physical-chemical system before it is discharged into a biological wastewater treatment plant on-site or in a municipal sewage treatment plant.[15] The efficiency of this treatment depends on substance properties such as log Kow and should be considered with care. More especially the validity of this RMM is to be challenged for hydrophilic substances in oil/water separators. The survey of 7 operating plants reported removal efficiencies from 30 to 70%. Individual plants may vary and data collection will be needed to verify a particular treatment plant efficiency.
	On-site biological treatment (before discharging into a municipal sewage treatment plant)	- A biological treatment plants is often present on the larger industrial sites[6]. The efficiency of this RMM varies depending on the treatment technology and the properties of the substance as log Kow and the biodegradability. SimpleTreat is a conservative approach to estimate removal efficiency from biological treatment.

[14] ibid.
[15] ibid.

Narrative Description of specific ERC

Individual fragrance substances are potentially mixed with hundreds of other fragrance substances to create a fragrance compound. Stabilizers and solvents may also be added to enhance the function of the compound. This includes formulation, packing and re-packing of the substance and its mixtures in batch or continuous operations, including storage, materials transfers, mixing, large and small scale packing, maintenance and associated laboratory activities.

Cleaning and side activities such as sampling, maintenance and associated laboratory activities are covered by these spERCs (see Figure 1 below).

Dosing, mixing and filling may be a completely automated process for larger batches whereas the small batches may be processed automatically (e.g. via robot) or manually. In many cases combinations of automated and manual dosing and mixing will occur. After each batch the equipment will be cleaned with water in a closed system or by spraying, sometimes using detergents, or with steam. In some cases alcohol or other solvents are used instead of water.

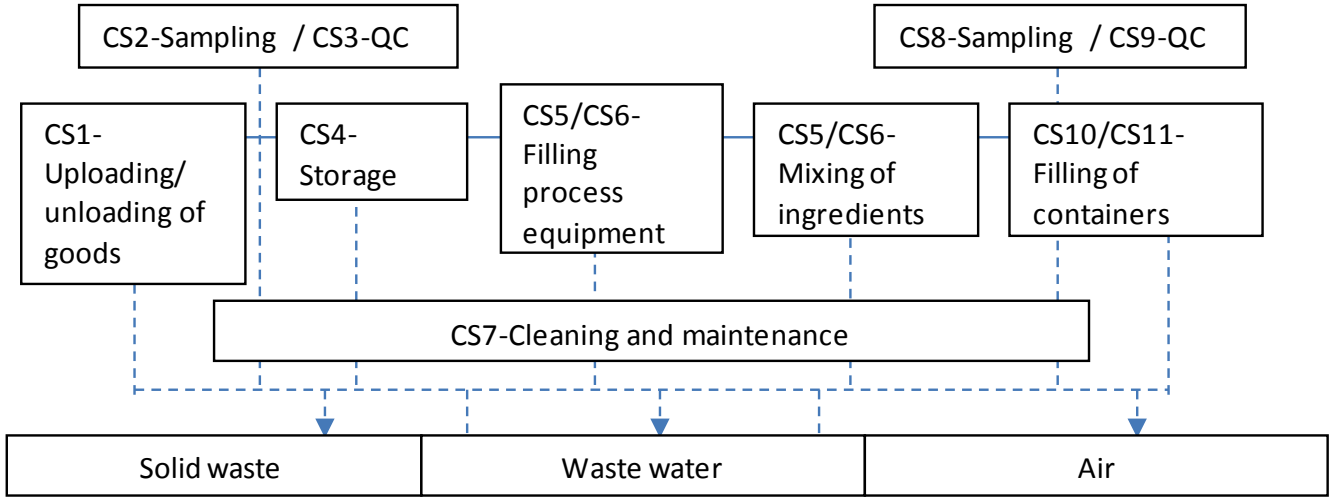

Figure 1: Operations during compounding and exposure routes (QC: Quality Control)

Waste is treated under national regulations. Spills are absorbed and collected as chemical waste. The same is true for samples, packaging materials and sludge residues from water treatment. It is disposed of to an outside contractor and may be treated, incinerated on put in a landfill, according to local regulations. The wastewater is consistently discharged to a biological treatment plant (activated sludge) which is either on the site or a municipal sewage treatment plant.

Safe Use

Communication in SDS

The REACH registrant establishes a set of standard conditions of safe use for a substance (for Compounding of fragrance compounds) by adopting the conditions specified in this spERC and recommending a Required Removal Efficiency (RRE) for adequate risk reduction.
Removal efficiency requirements, as dictated by the assumed operating conditions, are documented in the Chemical Safety Report and communicated in the Safety Data Sheet. All other parameters underlying a substance exposure scenario based on the spERC 'Formulation of fragrance compounds' are implicitly referred to via the reference to this spERC.

Scaling

Wastewater

The compounders are responsible for evaluating the compliance of their specific situations with the registrant's information. To that end, the compounders need to know their site-specific substance use rate (M_{Site}) and days emitting ($T_{Emission, Site}$), onsite and offsite emission controls and subsequent total substance emission reduction efficiency ($RE_{Total, Site} = 1 – [(1 – RE_{Onsite, Site}) \times (1 – RE_{Offsite, Site})]$), sewage treatment plant effluent flow rate ($G_{Effluent, Site}$) and receiving water dilution factor (q_{Site}).

It is simpler and thus may be preferable to some users to compare M_{Site} with M_{Safe} (*the maximum tonnage that can be safely used, within the prescribed operating conditions, OC_{spERC} and RMM, $RE_{Total, spERC}$*). Adequate control of risk exists if the following conditions are met [$RE_{Total, Site} \geq RE_{Total, SPERC}$, $G_{Effluent, Site} \geq G_{Effluent, SPERC}$, and $q_{Site} \geq q_{SPERC}$] and $M_{Safe} \geq M_{Site}$.

Local amount used, emission days per year, receiving water flow rate (or dilution factor), sewage treatment plant effluent flow rate, and risk management measure removal efficiency are the adjustable parameters for emission assessment. These parameters can be refined using site-specific information, which often is obtainable with limited effort and expertise. Adjusting the assessment by refining these parameters is referred to as scaling. Scaling is applied to evaluate compliance of a specific use with a generic Exposure Scenario. For that reason, site parameter values which deviate from the default values need to reflect the actual situation.

The release factors are an additional set of adjustable parameters; however, refining the default values requires significant justification and, thus, is beyond the boundary conditions defined in the spERC Factsheet. For that reason, release factor refinements do not constitute a spERC-based assessment and must be considered an element of downstream user chemical safety assessment.

More guidance on scaling can be found in ECHA guidance Part G – Extension of SDS as well as in Cefic guidance on spERCs (section 3).

ANNEX 5

Sensitivity Analysis of ECETOC TRA parameters influencing soil compartment

Sensitivity Analysis of ECETOC TRA parameters influencing soil compartment

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I. Background

In the previous IFRA guidance document, for compounding and formulation exposure scenarios (ESs), no specific value is recommended for the release fraction to air. Thus, the EUSES default value is recommended, which comes from EU TGD A&B Tables.

As part of the spERC development for compounding ES, the question arose whether this release fraction to air should and could be refined. On this basis, CEHTRA was to propose a short questionnaire to be sent to some compounders to describe the control of emission to air.

However, before drafting a questionnaire, CEHTRA conducted a sensitivity analysis to evaluate to what extent the air release affects soil compartment exposure concentrations.

Based on the result of this sensitivity evaluation CEHTRA proposes an adaptation of the spERC development strategy.

Parameterization of the Sensitivity analysis:

In order to provide a reasonable estimate for the fragrance industry the following physic-chemical properties were fixed:

Molecular weight			**4.00E+02**
Vapour pressure	*at (°C)*	**25**	**1.00E+00**
Water solubility	*at (°C)*	**20**	**1.00E+00**
Kow			**3.16E+04**
Biodegradability test result			**not biodegradable**
Chemical class for Koc-QSAR			**Predominantly hydrophobics**

II. Impact of air release to soil compartment exposure

In this sensitivity analysis, only the Operating Conditions (OCs) and possible Risk Management Measures (RMMs) have been considered, although intrinsic properties of substances (vapour pressure, logKow, water solubility) also have an important influence on air and soil emission.

The main routes of environmental fate of a substance further to emissions from industry are depicted in Figure 1.

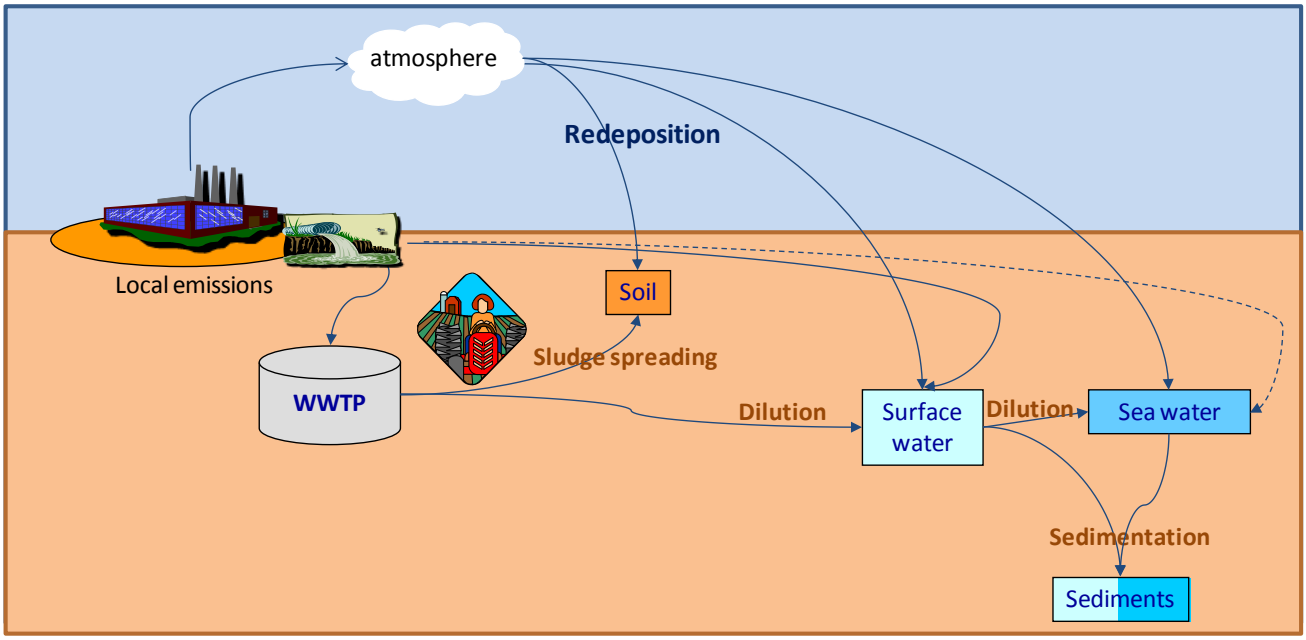

Figure 1: representation of main environmental exposition routes from air and waste water routes via industry production and use

II.1. Impact of Sludge application to agricultural soil on local soil exposure

According to the Council Directive 86/278/EEC and subsequent amendments residual sludge from municipal WWTPs can be used in agricultural soils provided the specifications laid down in the Directive are followed (although in practice this is not always the case as certain municipal WWTPs destroy the sludge). Non-municipal sludge may be used in agriculture only if it is regulated by the Member State concerned. This means that the RMM "no sludge to soil" is difficult to impose at least on small sites that do not have their own WWTP but rely on discharges to a municipal STP. When a waste water treatment plant (WWTP) is modeled in ECETOC TRA, the user can indicate whether the sludge residues are spread on agricultural soil or not. It is a "Yes or No" parameter and there is no possibility to apply various degrees of soil exposure by this route. By default in the model it is assumed that sludge is applied to soil, as a worst case.

When assuming that sludge goes to soil, the PEC in soil is almost *100 times* greater than when no sludge to soil is assumed. Therefore this parameter has a high impact on soil exposure.

II.2. Impact of release to air on local soil exposure

In the ERC 2 (corresponding to compounding and formulation ESs), it is assumed that 2.5% of used tonnage is released in the air. In A&B Tables the release fraction ranges from 0.25% to 2.5% depending on the vapour pressure (<10 or >1000 Pa) of the substance (Table A2.1, MC 3). The ERC 2 value is the highest one of A&B Tables, which is a worst case.

Therefore, soil exposure was calculated using a release fraction to air of 2.5% or 0%, with or without considering application of sludge to soil. The results are presented in Table 1.

Table 1: sensitivity of fraction release to air on local soil exposure, with or without sludge application to soil

Condition	(1)	(2)	(1)	(2)
SludgeToSoil? (yes/no)	no		yes	
Local release fraction to air	**2.50E-02**	**0.00E+00**	**2.50E-02**	**0.00E+00**
Local release fraction to sewage	5.00E-02	5.00E-02	5.00E-02	5.00E-02
Local release fraction to soil	0.00E+00	0.00E+00	0.00E+00	0.00E+00
PEC for local soil (mg.kgdwt-1)	3.07E-03	1.54E-03	4.39E+00	4.39E+00
Delta (1)/(2)	**2.0**		**1.0002**	
PEC for local freshwater sediment (mg.kg_{dwt}-1)	3.42E+00	3.42E+00	3.42E+00	3.42E+00
Relative ratio sediment / soil	**1.11E+03**	**2.22E+03**	**1.28E+00**	**1.28E+00**

When considering the condition “No sludge to soil”, a release fraction to air of 2.5% leads to a PEC in soil greater by a factor 2 than the PEC in soil resulting from a fraction to air of 0%. However, these PECs in soil are lower than the PEC in freshwater sediment by a factor of greater than 1000. Therefore, *in this case the soil is not the critical compartment*, even with the worst case release fraction to air of ERC2.

When considering the condition “Yes sludge to soil”, the impact of air release up to 2.5% becomes negligible, the difference being less than a thousandth, using a worst case logKow of 4.5 and low vapour pressure (worst case).

Overall, the emission fraction to air appears to be virtually negligible, even with the worst case value of ERC 2.

II.3. Impact of vapour pressure on local soil exposure

The influence of vapour pressure on local soil exposure was evaluated. The water solubility was set to 1 mg/L, the parameter “sludge to soil” was set to “NO”.

The local PEC in soil was calculated for various magnitude of vapour pressure (0.001; 1; 1000; 100,000; 10,000,000 Pa) (Figure 2).

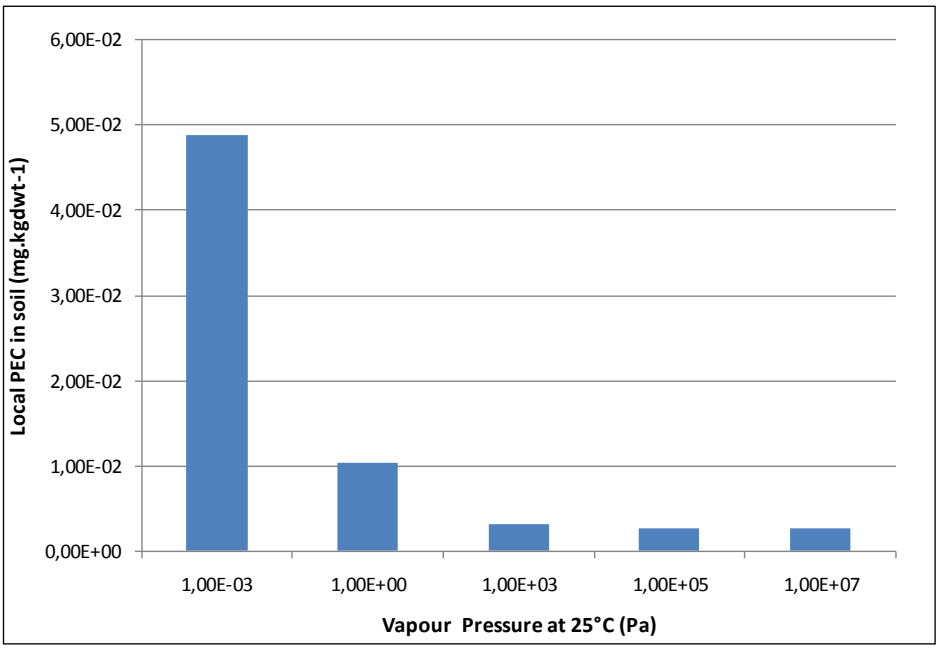

Figure 2: Sensitivity analysis of vapour pressure on local PEC in soil calculated with ECETOC TRA integrated tool v2

These results show that the exposure of local soil is higher at low vapour pressure. The main explanation is that in the model, the substance released to air is more subject to redeposition on local soil when it has a low volatility.

II.4. Impact of release to sewage on local soil exposure

When it is assumed that sludge residues from WWTP are applied to natural soils (which it is, by default and as mentioned above, is the case for many municipal WWTPs), the fraction of tonnage released to effluent is an important parameter since it will determine the concentration of substance in sludge.

The sensitivity of this parameter has been evaluated. The PEC in local soil was compared using a release fraction to sewage of 0.5 and 0.05. The results are shown in Table 2 below.

The modification factor of PEC in soil is directly proportional to the release fraction to sewage used, a factor of 10 in this case.

Table 2: sensitivity of fraction release to sewage on local soil exposure, with sludge application to soil

Condition	A	B
SludgeToSoil? (yes/no)	yes	yes
Local release fraction to air	0.00E+00	0.00E+00
Local release fraction to sewage	**5.00E-01**	**5.00E-02**
Local release fraction to soil	0.00E+00	0.00E+00
Local PEC in grass land, averaged over 180 days (mg.kgdwt-1)	4.39E+01	4.39E+00
Delta (A/B)	**10.0**	

Therefore, the release fraction to sewage appears to be an important parameter influencing soil exposure when sludge application to soil is assumed.

III. Discussion

The influence of release fraction to air on soil exposure appears to be very limited in any case, even when the worst case value of ERC 2 is used.

Considering this, it seems pointless to send a questionnaire to get specific information about on-site conditions affecting air emissions.

However, the ECETOC TRA parameter “Sludge to soil?” has a major impact on soil exposure. Soil is likely to become the critical compartment in terms of risk and exposure when application of sludge to soil is assumed, (a factor of greater than 2 times the concentration found in sediments). This issue may become even more serious in the absence of terrestrial studies where the PNEC determined from the PE method may further decrease compared to that in sediment. On the other hand, if no application of sludge to soil is assumed then the risk and exposure of soil compartment becomes insignificant. Therefore this parameter should be considered carefully.

During the review and evaluation of environmental emission scenarios for compounding and formulation stages initiated by RIFM[16], some information was collected on waste treatment. However, the questionnaire sent to compounders and formulators were not focused on the treatment of industrial sludge residues from on-site treatment.

As mentioned in the EFFA document (2009), "[Sludge residues are] disposed of to an outside contractor and may be treated, incinerated or put in a landfill, according to local regulations"[17]. Furthermore, most compounders and formulators treat their wastewater on-site and a biological treatment system is used in some cases. If no on-site treatment is provided, the effluent is discharged to a municipal WWTP.

As discussed above, municipal WWTPs may or may not apply sludge to soil, thus it is not possible to control this parameter in the generic scenario if waste water goes directly to municipal WWTP without a preliminary on-site treatment.

Nevertheless, large compounders or formulators treat their effluents on-site, and in most cases they appear to treat their discharges without use of a municipal WWTP (EFFA[1]). However, in some cases they discharge these effluents to a municipal WWTP. The efficiency of on-site treatment ranges from 70 to 90%[18]. Even if municipal WWTPs applied sludge to soil, the concentration of substance in sludge would probably be negligible. Therefore the assumption "No sludge to soil" would be realistic in this case, providing that industrial sludge residues from on-site treatment are not applied to soil.

Conclusion

The sensitivity analysis shown that emission to air has a significant but negligible contribution to soil exposure. Therefore the worst case value of ERC 2, which corresponds to compounding and formulation ES, should be used in the spERC development for compounding ES, i.e. 2.5%.

The major soil exposure route, as calculated by ECETOC TRA, comes from the application of sludge residues from WWTP to natural soils. This condition is systematically assumed by the model in tier 1 assessment as a worst case. It can be changed to the contrary (no sludge to soil) if there is enough justification or if the registrant decides to impose this as a standard RMM.

The exposure to local soil increases when vapour pressure of the substance decreases, due to higher redeposition.

[16] EFFA document 9S3975.01/R0007/Nijm, 2009
[17] EFFA document 9S3975.01/R0007/Nijm, 2009, section 3.2, page 27
[18] EFFA document 9S3975.01/R0007/Nijm, 2009, section 3.2, page 24