THE INTERNATIONAL
FRAGRANCE ASSOCIATION

REACH Exposure Scenarios For Fragrance Substances

Version 3
January 2023

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 (A.I.S.E., 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.

Update Version 2.1 December 2012:

After publication of version 2 of this guidance document in April 2012 several important documents/tools were updated by their respective owners, most importantly the A.I.S.E. use mapping tables for industrial and institutional end-uses, the A.I.S.E. and Cosmetics Europe SPERC overview tables and factsheets and the introduction of ECETOC TRA v3. After review of the updated information, it was found that the changes were significant enough to warrant an update of the guidance. This version remains available on IFRA website.

Update Version 3 December 2022:

IFRA created a subgroup from the REACH TF, dedicated to the exposure scenario for mixtures. In 2019, prior to starting the assessment of the IFRA GMES (Generic Mixture Exposure Scenario), the working group agreed on the need to update this Guidance document. Subsequent to the “Use Map Package” developed under the ECHA CSR/ES Roadmap, A.I.S.E. and Cosmetics Europe amended their use maps using harmonized formats (ESCom standard phrases, SWEDs, SCEDs and SPERCs). The changes are reflected in this document.
Another main change is the deletion of the former GES3 “Industrial end-use of washing and cleaning products”, which was considered as non-applicable to the fragrance Industry. The institutional use of fragranced end-products at industrial site has been included in the new GES3 “Professional end-use of washing, cleaning and disinfecting products (including use at industrial sites)” (former GES4). Furthermore, the working examples as presented in former Chapter 4 have been removed.

Document History

Version	Comment	Date
Version 1	First edition	February 2010
Version 2	Second edition	April 2012
Version 2.1	Revision of version 2	December 2012
Version 3	Deletion of the GES “Industrial end-use of washing and cleaning products” and inclusion of the institutional use of fragranced end-products at industrial sites in the GES “Professional end-use of washing, cleaning and disinfecting products (including use at industrial sites)”. Update of the Life Cycle Stages of a substance. Update of the Use Mapping process and selection of use descriptors based on the ECHA CSR ES Roadmap. Update and adjustment of the A.I.S.E. and Cosmetics Europe Use Maps to reflect the activities/processes applicable to fragranced end-products. Grouping of PROCs in the use mapping tables (Tables 4-10). Removal of the use descriptors “Sectors of use”. Introduction and definition of the ESCom phrases, SWEDs & SCEDs and inclusion in the Identified Uses tables. Creation of IFRA SWEDs for GES1 and FFEP (Formulation of Fragranced End-Products) SWEDs for GES2. Mention on the use of CHESAR for exposure estimations and use mappings; mention of the DNEL generator from IUCLID. Additional guidance on the management of ES received by DU. Addition of default operating temperature (25°C) as a worker exposure modifier tier 1 parameter within ECETOC TRA V3.1. Environmental emission to soil removed from Figure 4 (GES 3 to 9). Update of outdated weblinks, hazard statements, regulations. Deletion of outdated comments on ECETOC version update, projects (EDANA use mapping tables). Update of Annexes 1 and 3 Insertion of Annex 6 (IFRA SWEDs)	December 2022

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 nine 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 SWEDs and 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 A.I.S.E. 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.

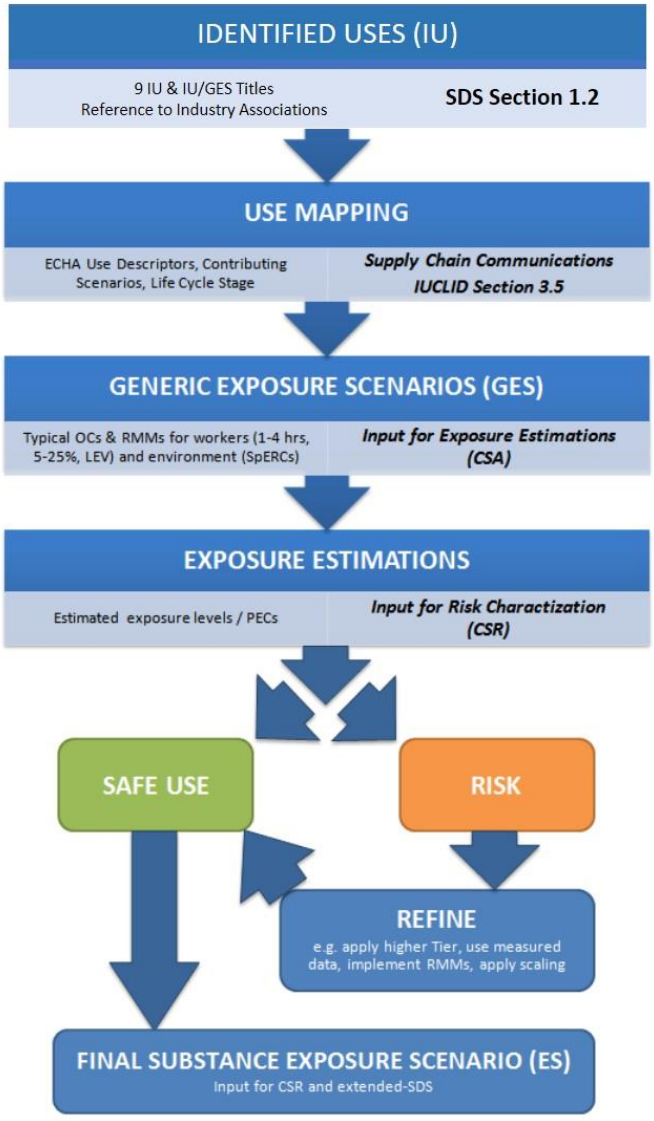


Figure 1: Stepwise Process to prepare Exposure Scenarios for a fragrance substance

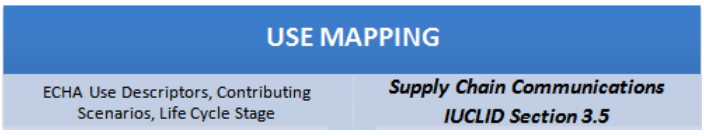
As a **first step**, uses of the substance are identified at a high level, following its entire life cycle: manufacturing, formulation, professional end-use and consumer end-use. As a result of this, **nine main Identified Uses** (IUs) can be identified for fragrance substances, covering all common uses 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

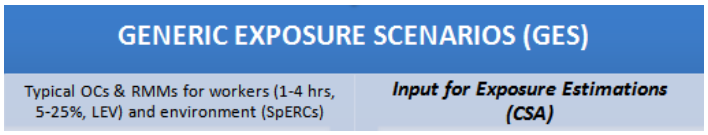
IU n°	IU Title	Reference
IU 0	Manufacturing of fragrance substances *	**Site specific**
IU 1	GES1 - Formulation of fragrance compounds (mixing of fragrance substances into fragrance compounds)	**IFRA**
IU 2	GES2 - Formulation of fragranced end-products (mixing of fragrance compounds into fragranced end-products)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

** No GES for manufacturing (site specific)*

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



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 (PROC, PC, ERC, etc.) and the life cycle stage is indicated. Use Mapping tables developed by A.I.S.E. 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.



As a **third step**, **Generic Exposure Scenarios (GES)** are provided for all Identified Uses. 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, EUSES). 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 "Sector-specific Worker Exposure Descriptions" (SWEDs). For consumer exposure, use determinants (e.g., concentration in product, frequency of use) are described and expressed as "Specific Consumer Exposure Determinants" (SCEDs). 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" (SPERCs).

As part of this document, IFRA has established a GES for formulation of fragrance compounds for workers and the environment. As part of this GES, two IFRA SPERCs for large/medium sites and for small sites as well as seven SWEDs have been developed. For the other Identified Uses the latest updated GESs (including SPERCs, SWEDs and SCEDs) from A.I.S.E. 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.

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 (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.

CONTENTS

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
ext-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/m^3	:	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
PEL	:	Predicted exposure level
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
SCED	:	Specific Consumer Exposure Determinant
SPERC	:	Specific environmental release category
STP	:	Sewage Treatment Plant
SU / SoU	:	Sector of use
SWED	:	Sector-specific Worker Exposure Description
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 containing a fragrance compound with, i.e., denatured alcohol, surfactant 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)	SPERCs inform on operational conditions and risk management measures and the corresponding release factors to water, air, soil and waste. Registrants can use the information as an input to their environmental exposure assessments. SPERCs include suitable standard phrases that help the registrant communicate effectively with the downstream user.
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* the substance is finally contained when it is supplied to end-uses (by industrial, professional or consumer users)
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)
Sector-specific Worker Exposure Description (SWED):	SWEDs inform on operational conditions and risk management measures for activities by workers. Registrants can use the information as an input to their exposure assessments. SWEDs include suitable standard phrases that help registrants effectively communicate the exposure scenarios attached to the safety data sheet to the downstream user.
Specific Consumer Exposure Determinant (SCED):	SCEDs inform on conditions of use for substances in consumer products. This includes information on the design of a consumer product type (e.g., package size and design) and information on the habits and practices of how consumers actually use the products. Registrants can use the information as an input to their exposure assessments. SCEDs include suitable standard phrases that help the registrant to communicate effectively with the downstream user.

*The term chemical product covers both substances as such or in a preparation (mixture)

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 guidance document 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 that 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 on a substance-by-substance basis.

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, A.I.S.E., 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 first published 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 the first version of the guidance, which took place during October 2011 – March 2012, with the support of service provider CEHTRA. Around 2016-2017 new use mappings from A.I.S.E. and Cosmetics Europe became available. Because in these use maps the contributing scenarios were further condensed and SWEDS and SCEDs were introduced the IFRA REACH TF decided to revise their guidance once more. This was done during the period 2019-2020, again with the support of CEHTRA.

This further 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 entire REACH submission process of the Work Group and its contracted consultant, CEHTRA. It is meant to serve, as did the previous versions 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 nine main Identified uses (IUs) specifically for the fragrance industry. As has been discussed above manufacturing is not in scope. Information from A.I.S.E. and Cosmetics 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, SWEDs and SCEDs for many uses.

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 or 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.

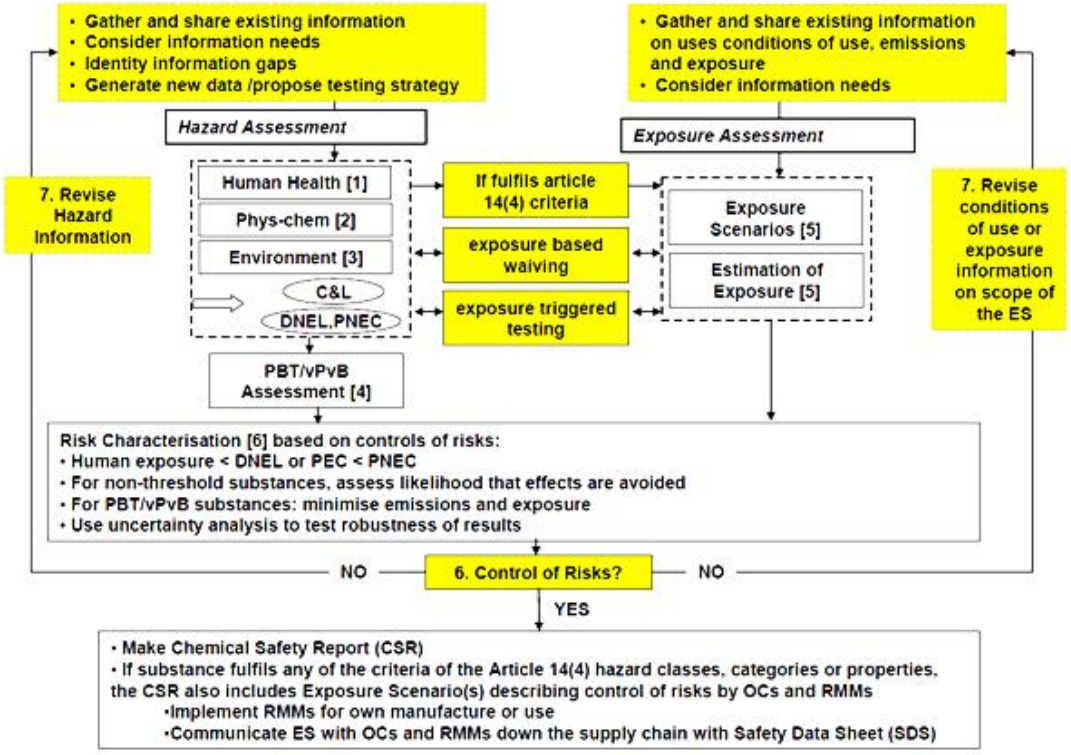


Figure 2: Chemical Safety Assessment Framework[2]

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

[2] "ECHA Guidance on information requirements and chemical safety assessment Part A", V 1.1

As a first step in the CSA, also referred to as a Tier 0 assessment, the hazards of the substance ≥ 10 tons/year are rated based on the hazard classification according to the current CLP (Regulation (EC) 1272/2008). This assessment can result in one of the following conclusions:

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: Framework for exposure assessment" (https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment). The relevant life cycle stages for the fragrance industry can be found in Figure 3.

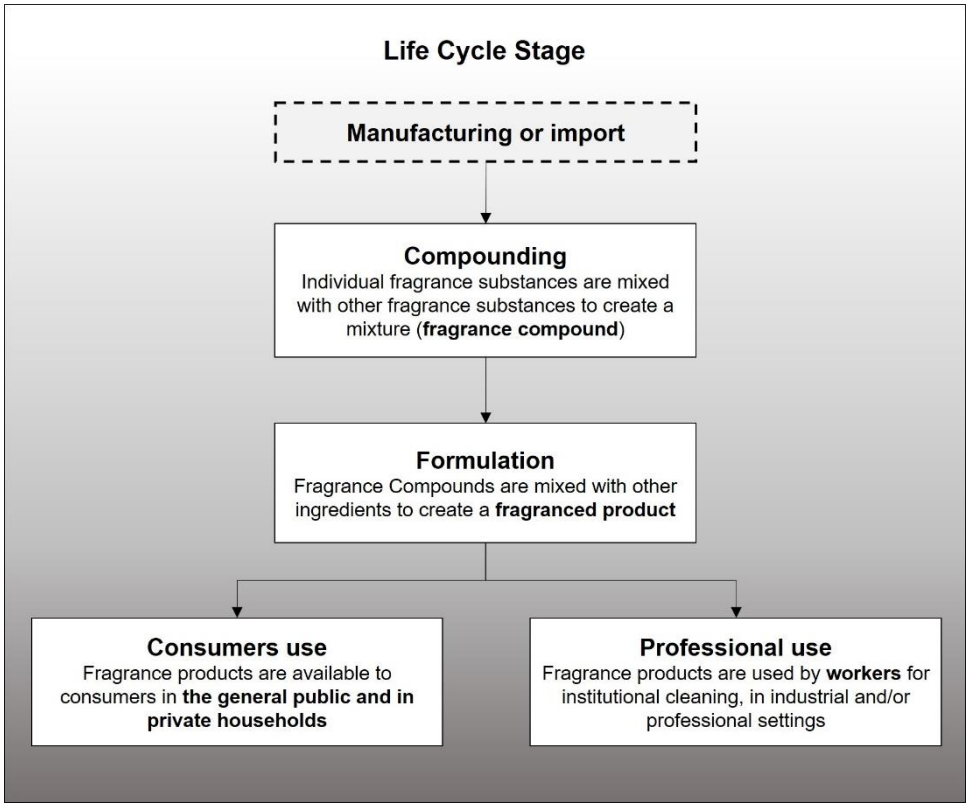


Figure 3: Relevant life-cycle stages for the fragrance industry

2.1.1 The CSA framework

In this guidance document the steps as presented in Figure 2 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 2.3.1.2)
   - Exposure Scenarios (see 2.3.2)
     - Workers (see 2.3.2.1)
     - Consumers (see 2.3.2.2)
     - Environment (see 2.3.2.3)
   - Exposure Estimates (see 2.3.3)
     - 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. 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. In the ECHA Use maps library you can find the IFRA SPERC factsheet. Alternatively, the CSR can be reported in a Word document (.rtf file) and the template can be found at https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats .

The format is available on ECHA website 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 – Part D: Framework for exposure assessment, section D6 (Building the Chemical Safety Report)”, (https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

In the Annex to the SDS (extended-SDS) 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 and RMMs described in an exposure scenario that they have received are different from their own specific situation. The CHESAR tool offers the possibility to automatically generate SDS annexes from Exposure Scenarios.

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” (https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment). Since 2018 IUCLID also incorporates a DNEL generator which offers the possibility to calculate and report derived non-effect levels according to the ECHA guidance. ECETOC developed a more refined approach for derivation of the DNEL (Technical report 136, 2021 – Assessment Factors to Derive DNELs – Critical Evaluation of the Status Quo freely available from the ECETOC website https://www.ecetoc.org/publications/technical-reports/). It is advised to compare both methods when setting the final DNEL. The choice for using the ECETOC 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” (https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

As with the derivation of the DNEL, assessment factors are also applied to the ecotoxicological endpoints (L(E)C50/EC10/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 micro-organisms in 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, https://echa.europa.eu/csr-es-roadmap/use-maps/templates-and-submission, 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 A.I.S.E. and Cosmetics Europe.

For environment, worker and consumer exposure assessment, a harmonised description of conditions of use can be used for the CSA and as input for most common exposure estimation tools when documented in a specific factsheet:

- for environment: Specific Environmental Release Categories (SPERC) - SPERCs are used for environmental assessment. SPERCs inform on operational conditions and risk management measures and the corresponding release factors to water, air, soil and waste. Registrants can use the information as an input to their environmental exposure assessments. SPERCs include suitable standard phrases that help the registrant communicate effectively with the downstream user.

- for workers: Sector-specific Workers Exposure Description (SWED) – SWEDs are used for workers assessment. SWEDs inform on operational conditions and risk management measures for activities by workers. Registrants can use the information as an input to their exposure assessments. SWEDs include suitable standard phrases that help registrants effectively communicate the exposure scenarios attached to the safety data sheet to the downstream user.
- for consumers: Specific Consumer Exposure Determinant (SCED) - SCEDs are used for consumer assessment. SCEDs inform on conditions of use for substances in consumer products. This includes information on the design of a consumer product type (e.g., package size and design) and information on the habits and practices of how consumers actually use the products. Registrants can use the information as an input to their exposure assessments. SCEDs include suitable standard phrases that help the registrant to communicate effectively with the downstream user.

In this IFRA guidance document only 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).

2.3.1.1 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” (https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment). The following use descriptors are included:

- **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 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	PROC	PC	AC	ERC
Manufacturing	+	NA	NA	+
Formulation of fragrance compounds	+	NA	NA	+
Formulation of fragranced end-products	+	NA	NA	+
Professional end-use	+	+	NA	+
Consumer end-use	NA	+	+	+

NA = not applicable

2.3.1.2 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.

- A.I.S.E. 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. Since its first version in 2009, the A.I.S.E. use mapping table has been updated several times (see details in A.I.S.E. link: https://www.A.I.S.E..eu/our-activities/regulatory-context/reach/description-of-uses.aspx).
  The IFRA guidance takes into consideration those A.I.S.E. updates until 2020.
- the Cosmetics Europe list reports uses in the cosmetics industry. The uses are reported according to the Use Map 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: https://cosmeticseurope.eu/cosmetics-industry/cosmetics-industry-and-reach/ Updates until 2020 are included in this document.

2.3.2 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.”

2.3.2.1 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 doses or concentrations for worker inhalation and dermal exposure. Those conditions of use (operational conditions and risk management measures) can be put in a sector specific set for activities carried out by workers in a way which facilitates their use for exposure estimation by exposure tools and

applications (such as ECETOC TRA and ART). Those worker sets are named SWEDs (sector-specific workers exposure descriptions).

2.3.2.2 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). Those conditions of use (operational conditions and risk management measures) can be put in a sector specific set for activities carried out by consumers in a way which facilitates their use for exposure estimation by exposure tools and applications (such as ECETOC TRA, REACT and ConsExpo). Those consumer sets are named SCEDs (specific consumers exposure determinants).

2.3.2.3 *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 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).

2.3.3 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: https://www.ecetoc.org/tools/tra-main/ (select download integrated tool). Prior to the ECETOC TRA model, the Joint Research Centre of the European Commission had developed EUSES for environmental exposure assessment. 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. The EUSES and ECETOC TRA model is implemented in the CHESAR application developed by ECHA to help companies with their chemical safety assessment for REACH. When using CHESAR, PROCs, SWEDs, SCEDs, ERCs and SPERCs can be selected directly for calculations.

By running the models in the ECETOC TRA or CHESAR application, 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, e.g. PNEC or DNEL).

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 ESCom (exposure scenario communication) standard for the exchange of exposure scenario (ES) data, between IT systems, was developed to allow consistent and harmonised transfer of ES information through the supply chain, using standardised phrases and information.
The catalogue is developed and maintained by the ESCom standard phrases working group. This works with the European phrase catalogue group (EuPhraC), overseen by Business Europe, to develop and maintain a shared library of unique ES phrases. EuPhraC focuses on standard phrases for the main body of the safety data sheet (SDS), while ESCom focuses on those for the ES, annexed to the SDS.
You can find the most recent version of the ESCom phrase catalogue here: https://cefic.org/guidance/reach-implementation/escom-package-guidance/.
The ESCom catalogue is as well available in a format that can be imported into ECHA's CHESAR tool.

The ECHA guidance document: "Guidance on the compilation of safety data sheets (https://echa.europa.eu/-/guidance-on-the-compilation-of-safety-data-sheets)", contains more information concerning the ext-SDS. Appendix 1 of the guidance document referred to above indicates where the information of the CSA should be placed in the chapters of the ext-SDS.
Further information can be found in the ECHA "Guide on safety data sheets and exposure scenarios".

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 within twelve months of receipt of the safety data sheet (exempted for substances used less than 1 tonne per year), and ECHA reporting
- Scaling: recalculate exposure & risk using modelling tools using the on-site conditions

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.

The ECHA Guidance for Downstream Users (https://echa.europa.eu/regulations/reach/downstream-users) aims at assisting companies in checking compliance with exposure scenarios (including scaling), with further examples given in the Practical Guide 13 “How downstream users can handle exposure scenarios” (https://www.echa.europa.eu/web/guest/practical-guides).

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). If not imported into the EU, 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 by professionals and/or consumers. They can be used for institutional cleaning in both industry and professional settings 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.

To which extent the waste life cycle stage of a substance is relevant depends on several considerations. In this context, R.18.2.3.1 (Guidance on information requirements and chemical safety assessment, Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage (ECHA 2012; version 2.1), gives guidance on the assessment of the relevance of the waste life cycle stage. Based on the assessment IFRA concluded that an exposure assessment of the waste stage for substances manufactured and used as fragrance materials, does not need to be performed because the following criteria according to R.18.2.3.1 apply:

- only small fractions of the mass flow of the substance end up in the waste stage.
- the conditions in the waste stage are already covered in the EA for other life cycle stages, and it can be concluded that the expected releases to the environment from the waste stage are significantly lower than those from the previous life cycle stages
- the expected concentration of the substance at waste stage falls below the cut-off concentrations laid down in article 14(2) of REACH, and the overall amount of substance in waste is sufficiently low so that no relevant release rates to the environment could occur.

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 chapter 3.

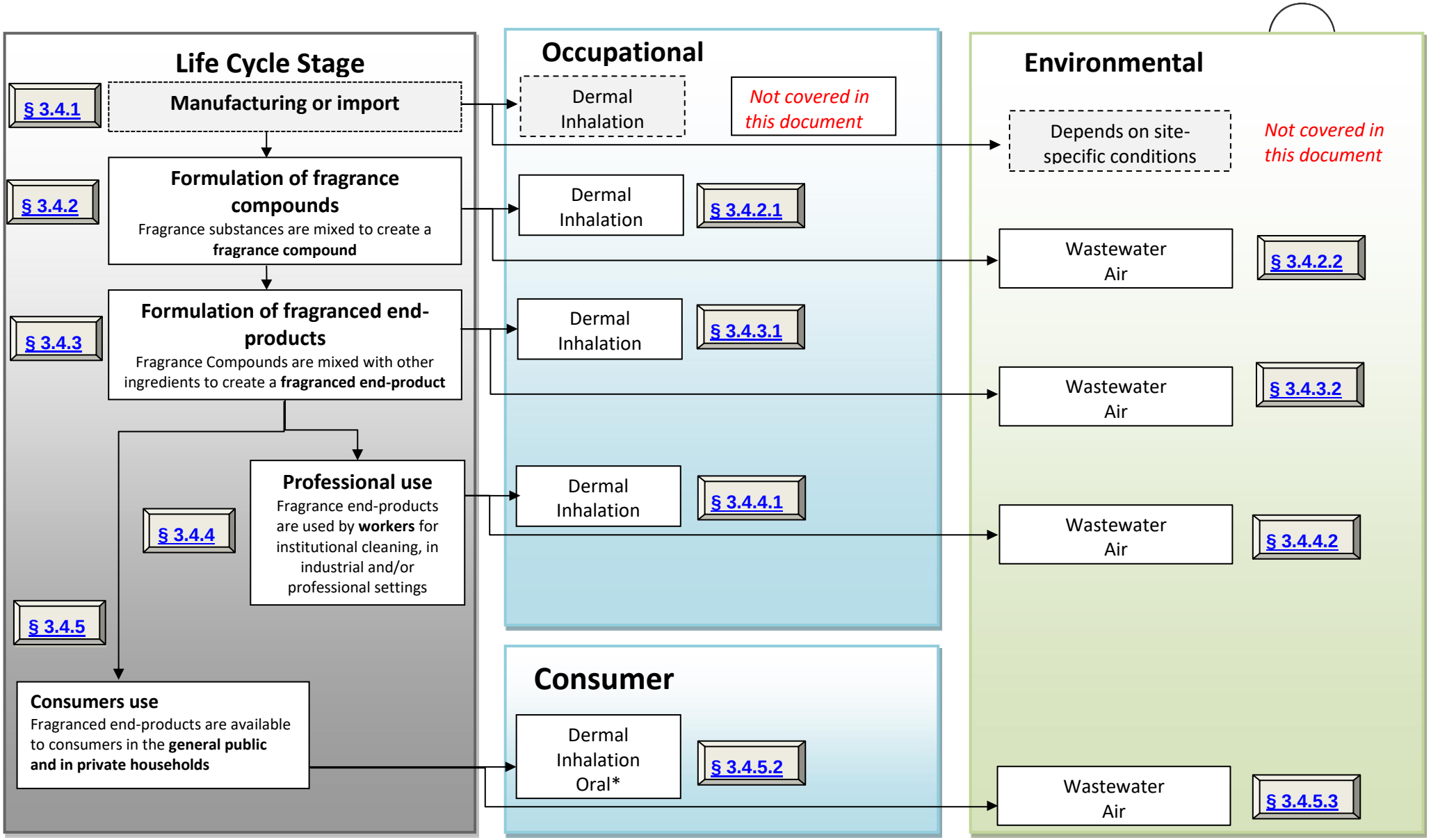


Figure 4; "Different life-cycle stages of fragrance substances in a Generic Exposure assessment for human and environmental.
**Only in Tier 1.5 consumer exposure assessment (considering indirect contact by oral)*

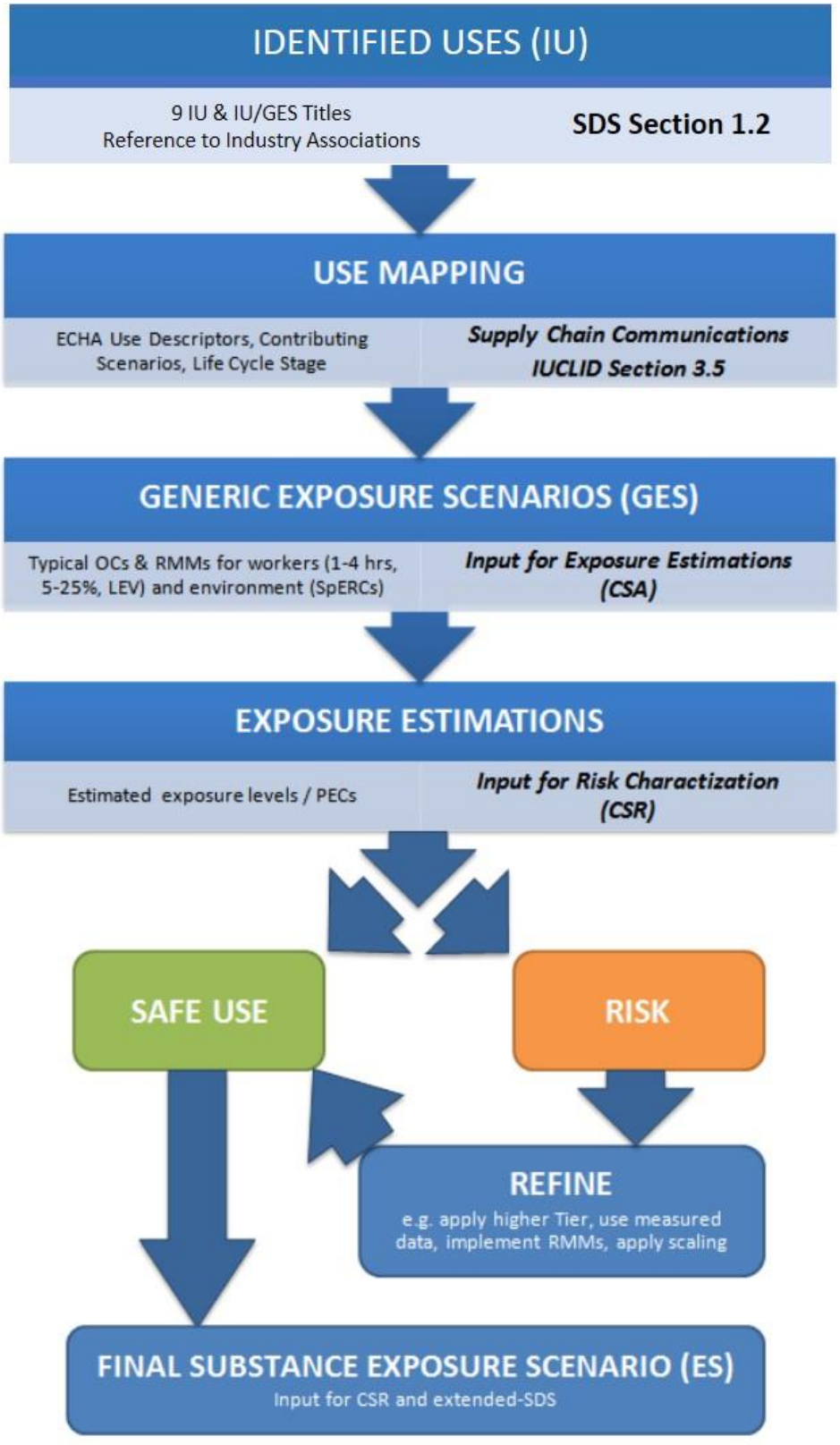


Figure 5: Stepwise process to prepare Exposure Scenarios for a fragrance substance

3.2 Identified uses

Nine 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 (A.I.S.E., Cosmetics Europe). For IU 9 the end-use of cosmetics by consumers has been expanded with the end-use by professionals. For use in cosmetics, only the environmental risk needs to be considered according to REACH Article 14.5(b). The environmental emissions resulting from consumer and professional use are both considered wide dispersive emissions and fall under the same ERC (ERC8a) and can therefore be grouped under the same Identified Use. 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. The same is true for scented articles, such as clothes, erasers, toys and CDs. 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 (see chapter 3.4). 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.

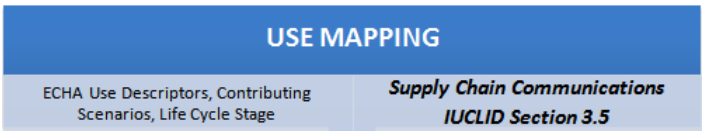
Table 3: Identified Uses (IU) and Generic Exposure Scenarios (GES) for fragrance substances

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)	**A.I.S.E. / CosEU**
IU 3	GES3 - Professional end-use of washing, cleaning and disinfecting products (including use at industrial sites)	**A.I.S.E.**
IU 4	GES4 - Professional end-use of polishes and wax blends	**A.I.S.E.**
IU 5	GES5 - Consumer end-use of washing and cleaning products	**A.I.S.E.**
IU 6	GES6 - Consumer end-use of air care products	**A.I.S.E.**
IU 7	GES7 - Consumer end-use of biocides	**A.I.S.E.**
IU 8	GES8 - Consumer end-use of polishes and wax blends	**A.I.S.E.**
IU 9	GES9 – Consumer (and Professional) end-use of cosmetics **	**CosEU**

** No GES for manufacturing (site specific)*

*** Only includes environmental exposure, assessment of human exposure is exempt from REACH. Emissions to the environment resulting from consumer and professional use are comparable and can therefore be grouped under the same Identified Use.*

3.3 Use Mapping



The Use Mapping for IU 1-9 is provided below in Tables 4 to 9. The Use Mapping for manufacturing of fragrance substances is not included because this information needs to be generated by the manufacturers themselves.

The use map for formulation of fragranced end-products is following the Use code “A.I.S.E._F_001_v1” from the A.I.S.E. Use Map and the Use code “sector_F_001_v1” from the Cosmetics Europe Use Map, but has been adjusted in such a way that it provides the most realistic description of this life cycle stage for mixtures with fragrances. In principle, this use considers the same activities to be applicable as have been described for the formulation of fragrance compounds use (IU 1), with one addition i.e., the process to make e.g., granular detergents which is best described by PROC14. Compared to the A.I.S.E. and CE Use Maps the following changes were made: PROC2 and 4 were not considered as relevant for the work with fragranced mixtures and are therefore not included. PROC 15 (Quality control) was considered as relevant and added to the use mapping.

For the Professional end-use of washing and cleaning products (including use at industrial sites) and the Professional end-use of polishes and wax blends (IU 3-4) the A.I.S.E. Use Mapping was used. For the Use Mapping the A.I.S.E. activities/SWEDs were grouped by PROCs as in this chapter only the Use descriptors should be defined (PROCs & ERCs) and not the exposure scenarios with operational conditions (OC). For the generic exposure scenarios (GES) (see chapter 3.4) the different A.I.S.E. activities/SWEDs were assessed on their own.

Regarding the use of fragranced end-products by consumers (IU 5-9), the A.I.S.E. and Cosmetics Europe information was taken over without any 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

9), so therefore only the environmental risk needs to be considered (Article 14.5(b) of the REACH Regulation).

For each activity of industrial and professional IU (1 to 4), the ESCom code associated to PROC number is indicated in the tables 4 to 7 below to facilitate harmonised transfer of ES information through the supply chain. Several codes are currently available for a same PROC due to different versions of the ECHA Use Description publications in the EuPhraC library version 5.4.

The information from the Use Mapping tables can be used to complete Chapter 3.5 of IUCLID. If the registrant uses CHESAR the IUCLID chapter 3.5 can be automatically filled by CHESAR and no manual work in IUCLID is necessary for completion.

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

Manufacture	Formulation	End Use: Industrial	End Use: Professional	End Use: Consumer	Service Life	IU description	Process category (PROC)	ESCom code (Unique Phrase Code)	Product category (PC)	Environmental release category (ERC)
IU 1 – Formulation of fragrance compounds[Ŧ]										
	X					Material transfers from/to vessel/container at dedicated facility	PROC8b	16009150800 10088224500	--	ERC2 11133170171 10060200730
						Storage	PROC1	16009145100 10060200554		
						Mixing operations (closed systems) in batch process including filling of equipment and sample collection	PROC3	16009145800 10060200556		
						Mixing operations (open systems) in batch process including filling of equipment and sample collection	PROC5	10060200558 16009150100		
						QC laboratory	PROC15	10060200574		
						Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC9	11133170153 10060200562		
						Equipment cleaning and maintenance	PROC8a	16009150600 10060200561		

[Ŧ]ESCOM phrase will be included here when published in the update of eSDSphraC library 5.4

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

Manufacture	Formulation	End Use			Service Life	IU description	Process category (PROC)	ESCom code (Unique Phrase Code)	Product category (PC)	Environmental release category (ERC)
		Industrial	Professional	Consumer						
IU 2 – Formulation of fragranced end-products[Ŧ]										
	X					Material transfers from/to vessel/container at dedicated facility	PROC8b	16009150800 10088224500	--	ERC2 11133170171 10060200730
						QC laboratory*	PROC15	10060200574		
						Storage	PROC1	16009145100 10060200554		
						Mixing operations (closed systems) in batch process including filling of equipment and sample collection	PROC3	16009145800 10060200556		
						Mixing operations (open systems) in batch process including filling of equipment and sample collection	PROC5	10060200558 16009150100		
						Equipment cleaning and maintenance*	PROC8a	16009150600 10060200561		
						Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC9	11133170153 10060200562		
						Production of preparations or articles by tabletting, compression, extrusion, pelletisation	PROC14	16009151600 10060200566		

**not included in the A.I.S.E. Use Map but added as considered as relevant for industry*

[Ŧ]ESCOM phrase will be included here when published in the update of eSDSphraC library 5.4

Table 6: Use mapping for Professional end-use of washing, cleaning and disinfecting products (including use at industrial sites) (IU 3)

Manufacture	Formulation	End Use			Service Life	IU description	Process category (PROC)	ESCom code (Unique Phrase Code)	Product category (PC)	Environmental release category (ERC)
		Industrial	Professional	Consumer						
IU 3 – Professional end-use of washing, cleaning and disinfecting products (including use at industrial sites) 11133165906 (Professional use); 11133165946 (Washing and cleaning products)										
			X			Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions	PROC1	16009145100 10060200554	PC35 PC8	ERC8a 10060200739 16009171900
						Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition	PROC3	16009145800 10060200556		
						Chemical production where opportunity for exposure arises	PROC4	16009150000 10060200557		
						Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	PROC8a	16009150600 10060200561		
						Transfer of substance or mixture (charging and discharging) at dedicated facilities	PROC8b	16009150800 10088224500		
						Roller application or brushing	PROC10	10060200563		
						Non industrial spraying	PROC11	10088224800		
						Treatment of articles by dipping and pouring	PROC13	10060200565		
						Manual activities involving hand contact	PROC19	16009152500 10060200575		

Table 7: Use mapping for Professional use of polishes and wax blends (IU 4)

Manufacture	Formulation	End Use			Service Life	IU description	Process category (PROC)	ESCom code (Unique Phrase Code)	Product category (PC)	Environmental release category (ERC)
		Industrial	Professional	Consumer						
IU 4 – Professional use of polishes and wax blends 11133165906 (Professional use); 11133165942 (Polishes and wax blends)										
			X			Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions	PROC1	16009145100 10060200554	PC31	ERC8a 10060200739 16009171900
						Chemical production where opportunity for exposure arises	PROC4	16009150000 10060200557		
						Transfer of substance or mixture (charging and discharging) at non-dedicated facilities	PROC8a	16009150600 10060200561		
						Roller application or brushing	PROC10	10060200563		
						Treatment of articles by dipping and pouring	PROC13	10060200565		
						Manual activities involving hand contact	PROC19	16009152500 10060200575		

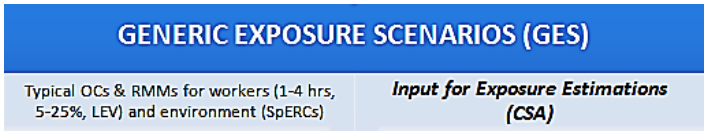
Table 8: Use mapping for Consumer end-use of washing and cleaning products (IU 5)

Manufacture	Formulation	End Use			Service Life	IU description	Product category (PC)	Article category (AC)	Environmental release category (ERC)
		Industrial	Professional	Consumer					
IU 5 – Consumer end-use of washing and cleaning products 11133170849 (Consumer use of washing and cleaning products)									
				X		Laundry products	PC35	--	ERC8a
						Fabric conditioners			
						Surface cleaners; non-spray application			
						Liquid surface cleaner; Spray application			
						Machine dishwashing products			
						Hand dishwashing products			

Table 9: Use mapping for Consumer end-use of air care products (IU 6), biocides (IU 7), polishes and wax blends (IU8) and cosmetics (IU9)

Manufacture	Formulation	End Use			Service Life	IU description	Product category (PC)	Article category (AC)	
		Industrial	Professional	Consumer					
IU 6 – Consumer end-use of air care products 11133165905 (Consumer uses; 11133165913 (Air care products)									
				X		Air care products; non-aerosol Air care products; aerosol	PC3	--	ERC8a
IU 7 – Consumer end-use of biocides 11133165905 (Consumer uses); 11133165918 (Biocide)									
				X		Insecticides: liquid electric, spray neat Repellents	PC8	--	ERC8a
IU 8 -Consumer end-use of polishes and wax blends 11133165905 (Consumer uses); 11133165942 (Polishes and wax blends)									
				X		Polishes and wax blends; non-Spray application Polishes and wax blends; Spray application	PC31	--	ERC8a
IU 9 – Consumer (and Professional) end-use of cosmetics 11133165905 (11133165906) (Consumer uses (Professional uses)); 11133165919 (Cosmetics, personal care products)									
				X		End-use of cosmetic products	PC39 PC28	--	ERC8a

3.4 Generic Exposure Scenarios for Fragrance Substances



The following chapters provide Generic Exposure Scenarios (GES) for each identified use which are the basis for exposure calculations and risk assessments. It should be noted that for some GES the concentration may be lower than the applicable concentration limit as listed in REACH Article 14.2, (e.g., concentration of a fragrance substance in washing, cleaning and disinfectant end-products or polishes and wax blends). The following should be taken into account:

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 cut-off value referred to in Article 11, paragraph 3 of Regulation (EC) No 1272/2008;
- (b) 0.1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to this Regulation (PBT/vPvB).

In these cases, an Exposure Scenario for the relevant GES 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 2-9, Exposure Scenarios for these end-uses should be included in the registration dossier by default.)

3.4.1 Manufacturing

Fragrance substances can either be extracted from natural sources or manufactured via chemical synthesis. For each EU 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[3]. 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.

[3] OECD, 2010. Emission Scenario Document on the blending of fragrance oils into commercial and consumer products, ENV/JM/MONO(2010)38.

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 11) 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 is derived/defined. Losses of the substance and subsequently potential release to the environment, is indicated by the blue lines of Figure 6.

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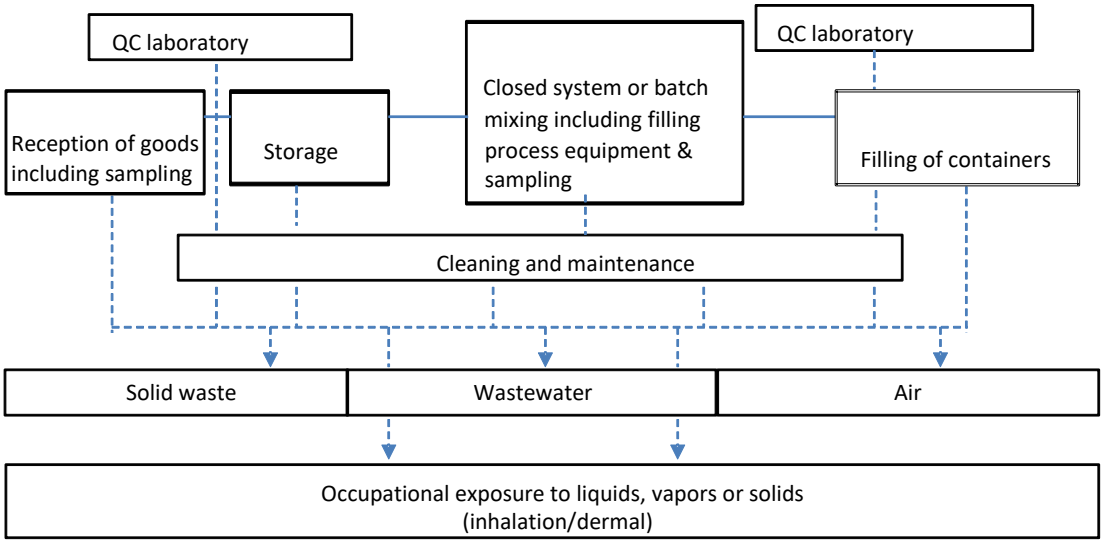

Figure 6: Operations during formulation of fragrance compounds and exposure routes (QC: Quality Control)

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 which are 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 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 (IFRA_SWED_GES1_CS1_8b and IFRA_SWED_GES1_CS6_9);
- exposure to liquids, vapours, and solids during dosing into the mixing vessels and during mixing process and during sampling (IFRA_SWED_GES1_CS3_3 and IFRA_SWED_GES1_CS4_5);
- exposure to liquids, solids and vapours during quality controls (IFRA_SWED_GES1_CS5_15);
- exposure to liquids, vapours and aerosols during container and equipment cleaning (IFRA_SWED_GES1_CS7_8a);
- exposure to liquids and vapours during the packaging of compounds and storage (IFRA_SWED_GES1_CS2_1).

For a first-tier quantitative worker exposure estimation by inhalatory and dermal routes, the ECETOC TRA model can be used which is also included in CHESAR. The handling activities during compounding are related to use descriptors.
For each IFRA GES1 Contributing Scenario (CS), an IFRA SWED has been developed with typical OCs and RMMs to refine Tier 1 TRA inputs for these activities in the fragrance industry. The relevant SWED codes are indicated in table 10 for all CS. All the detailed SWED information is reported in ANNEX 6.

The exposures during these handling activities are grasped into seven Contributing Scenarios/SWEDs 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.

It is considered that the default temperature for all activities is ambient temperature (25°C).

For each SWED the typical Ocs are presented for exposure duration and substance in preparation (Table 10). The exposure duration for each handling is estimated by experts in the fragrance compounding industry based on common industrial practices. For batch mixing (IFRA_SWED_GES1_CS4_5) 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 contributing scenario (IFRA_SWED_GES1_CS1_8b), a first step is to apply the “substance in preparation: NO” TRA input as the worker is exposed to the neat substance. Additionally, if this transfer concerns fragrance compounds TRA input “5 to 25%” can be taken instead of “substance in preparation: NO”.

For storage (IFRA_SWED_GES1_CS2_1) a TRA default value “substance in preparation: NO” is used as the worker is exposed to the neat substance.

For mixing processes (IFRA_SWED_GES1_CS3_3 & IFRA_SWED_GES1_CS4_5) and Quality Control (IFRA_SWED_GES1_CS5_15) 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 two 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 the SWEDs 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 IFRA SWEDs as listed in Table 10, 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.

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Table 10: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES 1 Formulation of fragrance compounds

Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier1 ECETOC TRA V3.1					
			temperature	duration	substance in preparation	indoor	respiratory protection	gloves
SWED code	title					without LEV basic GV		
IFRA_SWED_GES1_CS1_8b	Material transfers from/to vessel/container at dedicated facility	PROC8b	25 °C	15 min to 1 hour	no / yes at 5-25%	x	not use	not use
IFRA_SWED_GES1_CS2_1	Storage	PROC1	25 °C	15 min to 1 hour	no	x	not use	not use
IFRA_SWED_GES1_CS3_3	Mixing operations (closed systems) in batch process including filling of equipment and sample collection	PROC3	25 °C	1 to 4 hours	yes at >25%	x	not use	not use
IFRA_SWED_GES1_CS4_5	Mixing operations (open systems) in batch process including filling of equipment and sample collection	PROC5	25 °C	1 to 4 hours	yes at >25%	x	not use	not use
IFRA_SWED_GES1_CS5_15	QC laboratory	PROC15	25 °C	< 15 min	yes at >25 %	x	not use	not use
IFRA_SWED_GES1_CS6_9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC9	25 °C	15 min to 1 hour	yes at 5 – 25 %	x	not use	not use
IFRA_SWED_GES1_CS7_8a	Equipment cleaning and maintenance	PROC8a	25 °C	1 to 4 hours	yes at 5 – 25 %	x	not use	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 (https://echa.europa.eu/documents/10162/17224/information_requirements_r16_en.pdf/b9f0f406-ff5f-4315-908e-e5f83115d6af?t=1455553705739) 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 wastewater 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[4]. The SPERC factsheet is available in the ECHA Use maps library where it can be downloaded (https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library).

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 wastewater (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 not more than 0.2%. All surveyed compounding sites are operating during at least 250 days per [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 below 500 Pa (Table 11).

The default value of 2.5% release to air is being used. In a sensitivity 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 sources 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%.

[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

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 11: 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 (https://ifrafragrance.org/docs/default-source/policy-documents/ifra_sperc_factsheet_v1_en_december_2020_en.pdf?sfvrsn=91d73523_2) and in the ECHA Use maps library (https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library).

These SPERCs can be used instead of ERC2 as a refinement. The list of these SPERCs is presented in the Table 12 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 12: List of IFRA SPERCs for compounding for a Tier 1.5 assessment

SPERC Code	SPERC description	Glossary text	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to wastewater	Release fraction to soil	River flow rate for dilution (m^3/day)	Type of On-Site risk management measure implemented	MSPERC (kg/d)
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.	2	250	yes	0.025	0.002	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.	2	250	yes	0.025	0.005	0	18000	-	-

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.

A.I.S.E. and Cosmetics Europe (CE) have done a Use Mapping and established Generic Exposure Scenarios which have been used when relevant for fragrance substances. Compared to the A.I.S.E. and CE Use Maps the following changes were made: PROC2 and 4 were not considered as relevant for the work with fragranced mixtures and are therefore not included. PROC 15 (Quality control) was considered as relevant and added to the use mapping.
As A.I.S.E. did not develop SWEDs for this scenario, IFRA developed these FFEP (Formulation of Fragranced End-Products) SWEDs based on estimations by experts in the formulation of fragrance end-products industry (see Table 13). The concentration of a fragrance substance for some of the GES for formulation of fragranced end-products may be lower than the applicable concentration limit as listed in REACH Article 14.2 (see chapter 3.4). In this case an Exposure Scenario for this GES 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.

3.4.3.1 Occupational exposure during formulation of fragranced end-products

Similar to the formulation of fragranced compounds as shown in Figure 6, there are numerous points 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;
- exposure to liquids and vapours during dosing into the mixing vessels and during mixing process
- exposure to liquids and vapours during quality controls;
- exposure to liquids, vapours and aerosols during container and equipment cleaning;
- exposure to solids during tableting and compression of compact detergents;
- exposure to liquids and vapours during the packaging of fragrance end-products and storage.

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.
For each IFRA GES2 Contributing Scenario (CS), a FFEP (Formulation of Fragranced End-Products) SWED has been developed with typical Ocs and RMMs based on information from the fragrance end-product industry to refine Tier 1 TRA inputs for these activities. The relevant SWED codes are indicated in Table 13 for all CS.

The main difference between GES1 compounding and GES2 formulation of end-products is the “PROC14 – production of preparations of articles by tabletting, compression, extrusion, pelletisation”. This Contributing Scenario covers the production of compact detergents and cosmetic products (FFEP_SWED_GES2_CS8_14).

The exposures during these handling activities are grasped into eight Contributing Scenarios to which PROCs and a set of predefined Ocs and RMMs (SWEDs) 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.

It is considered that the default temperature for all activities is ambient temperature (25°C).

For each SWED the typical Ocs are presented for exposure duration and substance in preparation (Table 13). 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 (FFEP_SWED_GES2_CS5_5) 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 five contributing scenarios, 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 3 last steps of the formulation process (Table 13), 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 19).

The use of Risk Management Measures (e.g., LEV, skin and respiratory protection) are not included in the SWEDs 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 SWEDs as listed in Table 13, 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.

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Table 13: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES2 Formulation of fragranced end-products

Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier1 ECETOC TRA V3.1					
			temperature	duration	substance in preparation	indoor without LEV basic GV	respiratory protection	gloves
SWED code	title							
FFEP_SWED_GES2_CS1_8b	Material transfers from/to vessel/container at dedicated facility	PROC8b	25 °C	15 min to 1 hour	yes at 5 – 25 %	x	not use	not use
FFEP_SWED_GES2_CS2_15	QC laboratory	PROC15	25 °C	< 15 min	yes at 5 – 25 %	x	not use	not use
FFEP_SWED_GES2_CS3_1	Storage	PROC1	25 °C	15 min to 1 hour	yes at 5 – 25 %	x	not use	not use
FFEP_SWED_GES2_CS4_3	Mixing operations (closed systems) in batch process including filling of equipment and sample collection	PROC3	25 °C	1 to 4 hours	yes at 5 – 25 %	x	not use	not use
FFEP_SWED_GES2_CS5_5	Mixing operations (open systems) in batch process including filling of equipment and sample collection	PROC5	25 °C	1 to 4 hours	yes at 5 – 25 %	x	not use	not use
FFEP_SWED_GES2_CS6_8a	Equipment cleaning and maintenance	PROC8a	25 °C	1 to 4 hours	yes at < 1 %	x	not use	not use
FFEP_SWED_GES2_CS7_9	Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	PROC9	25 °C	15 min to 1 hour	yes at < 1 %	x	not use	not use
FFEP_SWED_GES2_CS8_14	Production of fragranced end-products by tableting compression, extrusion, pelletisation	PROC14	25 °C	> 4 hours	yes at < 1 %	x	not use	not use

3.4.3.2 Environmental exposure during formulation of fragranced end-products

The emission to wastewater differentiates between the various fragranced end-products. For formulation ERC2 has a default release factor of 2% to wastewater 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 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 (https://www.A.I.S.E..eu/our-activities/regulatory-context/reach/environmental-exposure-assessment.aspx) and Cosmetics Europe (CE) website (https://cosmeticseurope.eu/cosmetics-industry/cosmetics-industry-and-reach/) and in the ECHA Use maps library (https://echa.europa.eu/csr-es-roadmap/use-maps/use-maps-library). A list of these SPERCs is reproduced in the Table 14.1 below including an indication of typical volume percentage ranges of EU Tonnage of fragrance substance per SPERC, based on an internal assessment of sales data by a representative IFRA member company. Please be aware that Cosmetics Europe is currently in the process of updating their spERCs for their formulation scenarios. An update is expected in Q1 2023.

Although all the SPERCs are presented here, the registrant or downstream user should select only applicable SPERCs based on their knowledge of product type. Registrants who do not have any knowledge about what end-products their substance is used in are advised to include all SPERCs. Also, it is possible to group some of these SPERCs based on release fractions, number of emission days or specific RMM.
In order to facilitate this approach, IFRA proposes a grouping of SPERCs from A.I.S.E. and Cosmetics Europe after having discussed this with these stakeholders. These SPERCs have been grouped based on release fraction to water and site scale (large/medium or small) and are presented in Table 14.2 below. IFRA also proposes typical volume percentage ranges of EU Tonnage of fragrance substance per SPERC group. However, if a registrant has more specific data about the volume distribution of their specific substance, this of course should prevail over this generic proposal.

Note that Cosmetics Europe has included a SPERC (Cosmetics Europe SPERC 2.1.j.v2) with a release fraction to water 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 14.1: List of A.I.S.E. and Cosmetics Europe SPERCs for formulation of fragranced end-products for a Tier 1.5 assessment

SPERC Code	SPERC description	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to wastewater	Release fraction to soil	Standard municipal STP	MSPERC (kg/d)
A.I.S.E. SPERC 2.1.a.v3	A.I.S.E. – Formulation of granular Detergents/Maintenance Products: Regular & Compact (large scale >10,000 t/product a)	2	300	yes	0.001	0.0005	0	yes	*
A.I.S.E. SPERC 2.1.b.v3	A.I.S.E. – Formulation of granular Detergents/Maintenance Products: Regular & Compact (medium scale 1,000 – 10,000 t product/a)	2	300	yes	0.001	0.001	0	yes	*
A.I.S.E. SPERC 2.1.c.v3	A.I.S.E. – Formulation of granular Detergents/Maintenance Products: Regular & Compact (small scale <1,000 t product/a)	2	150	yes	0.001	0.002	0	yes	*
A.I.S.E. SPERC 2.1.g.v3	A.I.S.E. – Formulation of liquid Detergents/Maintenance Products: Low Viscosity (large scale >10,000 t/product a)	2	300	yes	0	0.0005	0	yes	*
A.I.S.E. SPERC 2.1.h.v3	A.I.S.E. – Formulation of liquid Detergents/Maintenance Products: Low Viscosity (medium scale 1,000 – 10,000 t product/a)	2	300	yes	0	0.001	0	yes	*
A.I.S.E. SPERC 2.1.i.v3	A.I.S.E. – Formulation of liquid Detergents/Maintenance Products: Low Viscosity (small scale <1,000 t product/a)	2	150	yes	0	0.002	0	yes	*
A.I.S.E. SPERC 2.1.j.v3	A.I.S.E. – Formulation of liquid Detergents/Maintenance Products: High Viscosity (large scale >10,000 t/product a)	2	300	yes	0	0.001	0	yes	*
A.I.S.E. SPERC 2.1.k.v3	A.I.S.E. – Formulation of liquid Detergents/Maintenance Products: High Low Viscosity (medium scale 1,000 – 10,000 t product/a)	2	300	yes	0	0.002	0	yes	*

SPERC Code	SPERC description	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to wastewater	Release fraction to soil	Standard municipal STP	MSPERC (kg/d)
A.I.S.E. SPERC 2.1.l.v3	A.I.S.E. – Formulation of liquid Detergents/Maintenance Products: High Viscosity (small scale <1,000 t product/a)	2	150	yes	0	0.004	0	yes	*
Cosmetics Europe SPERC 2.1.a.v2	Cosmetics Europe – Formulation of low viscosity liquids (large scale)	2	250	yes	0	0.001	0	yes	*
Cosmetics Europe SPERC 2.1.b.v2	Cosmetics Europe – Formulation of low viscosity liquids (medium scale)	2	250	yes	0	0.002	0	yes	*
Cosmetics Europe SPERC 2.1.c.v2	Cosmetics Europe – Formulation of low viscosity liquids (small scale)	2	250	yes	0	0.004	0	yes	*
Cosmetics Europe SPERC 2.1.d.v2	Cosmetics Europe – Formulation of Fine Fragrances – Cleaning with Water	2	250	yes	0	0.015	0	yes	*
Cosmetics Europe SPERC 2.1.f.v2	Cosmetics Europe – Formulation of High Viscosity Body Care Products (medium scale)	2	250	yes	0	0.01	0	yes	*
Cosmetics Europe SPERC 2.1.g.v2	Cosmetics Europe – Formulation of High Viscosity Body Care Products (small scale)	2	250	yes	0	0.02	0	yes	*
Cosmetics Europe SPERC 2.1.h.v2	Cosmetics Europe – Formulation of Non-liquid Creams (large scale)	2	250	yes	0	0.01	0	yes	*
Cosmetics Europe SPERC 2.1.i.v2	Cosmetics Europe – Formulation of Non-liquid Creams (medium scale)	2	250	yes	0	0.02	0	yes	*

SPERC Code	SPERC description	Specifies ERC	Release times per year (d/year)	With STP:	Release fraction to air	Release fraction to wastewater	Release fraction to soil	Standard municipal STP	MSPERC (kg/d)
Cosmetics Europe SPERC 2.1.j.v2	Cosmetics Europe – Formulation of Non-liquid Creams (small scale)	2	250	yes	0	0.04	0	yes	*
Cosmetics Europe SPERC 2.2.a&b&cv2	Formulation of cosmetic products involving cleaning with organic solvents (varnish, removers, decorative cosmetics, spray, lacquer, fine fragrance, solar oil, solid products) (all scales)	2	250	yes	0	0	0	yes	*
Cosm. Eur. / A.I.S.E. SPERC 2.3.a.v3	Cosmetics Europe / A.I.S.E. – Formulation of solid cosmetic and home care products (large scale >10,000 t/product a)	2	300	yes	0.00006	0.0005	0	yes	*
Cosm. Eur. / A.I.S.E. SPERC 2.3.b.v3	Cosmetics Europe / A.I.S.E. – Formulation of solid cosmetic and home care products (medium scale 1,000 – 10,000 t product/a)	2	300	yes	0.00006	0.001	0	yes	*
Cosm. Eur. / A.I.S.E. SPERC 2.3.c.v3	Cosmetics Europe / A.I.S.E. – Formulation of solid cosmetic and home care products (small scale <1,000 t product/a)	2	150	yes	0.00006	0.002	0	yes	*

*for AISE and Cosmetics Europe M_{SPERCs} please refer to the AISE/Cosmetics Europe Background Documents for formulation (ERC 2)

Table 14.2: IFRA proposal for grouping of A.I.S.E. and Cosmetics Europe SPERCs based on release rates to water*

IFRA SPERC Group Title	A.I.S.E./Cosmetics Europe SPERC Codes	Release times per year (d/year)	Release fraction to air	Release fraction to wastewater	Release fraction to soil	Size of site	%-range of EU Tonnage	IFRA SPERC Group (SG) Code
A.I.S.E. Granular & Low Viscosity Liquids + CE/A.I.S.E. solid cosmetic & home care products – large scale	A.I.S.E. 2.1.a, g CE/A.I.S.E. 2.3.a	300	0.001	0.0005	0	large	30-45%	IFRA SG-1
A.I.S.E. Granular & Low Viscosity Liquids + CE/A.I.S.E. solid cosmetic & home care products – medium scale	A.I.S.E. 2.1.b, h CE/A.I.S.E. 2.3.b	300	0.001	0.001	0	medium	10-18%	IFRA SG-2
A.I.S.E. Granular & Low Viscosity Liquids+ CE/A.I.S.E. solid cosmetic & home care products – small scale	A.I.S.E. 2.1.c, i CE/A.I.S.E. 2.3.c	150	0.001	0.002	0	small	9-14%	IFRA SG-3
A.I.S.E. High Viscosity Liquids + CE Low Viscosity Liquids – large scale	A.I.S.E. 2.1.j CE 2.1.a	300**	0	0.001	0	large	8-13%	IFRA SG-4
A.I.S.E. High Viscosity Liquids + CE Low Viscosity Liquids – medium scale	A.I.S.E. 2.1.k CE 2.1.b	300**	0	0.002	0	medium	2-7%	IFRA SG-5
A.I.S.E. High Viscosity Liquids + CE Low Viscosity Liquids – small scale	A.I.S.E. 2.1.l CE 2.1.c	150**	0	0.004	0	small	2-7%	IFRA SG-6
CE Fine Fragrances (cleaning with solvent) – all scales	CE 2.2.a-c (v2)	250	0	0	0	small, medium and large	12-20%	IFRA SG-7
ERC 2 default – all scales	CE 2.1.d-j (v2)	250	0	0.02	0	small, medium and large	1-2%	IFRA SG-8

*Release rates to air differ within these groups. The worst-case release rate is covered in this grouping. If this does not result in safe use conditions each SPERC has to be calculated individually.

** In version 2 of their SPERCs CE is taking into account 250 release days.

3.4.4 Professional end-use of fragranced end-products (including uses at industrial sites): GES 3-4

This chapter introduces the following two GESs, based on information provided by A.I.S.E.:

- GES 3 Professional end-use of washing and cleaning and disinfecting products (including use at industrial site) (Table 15)
- GES 4 Professional end-use of polishes and wax blends (Table 16)

In March 2022 A.I.S.E. has done their last update on the improved Use Maps and their SWEDs. Two new SWEDs have been added: the AISE_SWED_PW_8b_1 and AISE_SWED_PW_8b_2 – for Transfer of products via a dedicated system (bottle/bucket/machine). The Tables 15 and 16 are taking into account these modifications.

In previous versions of the IFRA Guidance REACH ES for Fragrance Substances industrial end-use of fragranced end-products was included as a separate use. For this version the uses were re-evaluated and specifically the use of fragranced end-products for cleaning industrial equipment was discussed. The IFRA Working Group decided that these products are used for institutional cleaning and thus this use should be regarded rather a professional use than an industrial use. ECHA guidance R12 (page 59 and further) uses the following distinction in description for ERC4 (use of nonreactive processing aids at industrial sites, previously assigned to the industrial use scenario) and ERC8a (wide dispersive use of non-reactive processing aids for the professional use scenario):

- ERC4: Production activities where the substance is used as a cleaning agent (solvent or surfactant)
- ERC8a: Down the drain product like e.g., Use of detergents in fabric washing, use of machine wash liquids and lavatory cleaners, use of automotive and bicycle care products (polishes, lubricants, de-icers)

The IFRA Working Group considers indeed fragrances to be included in those products described by ERC8a but not those covered under ERC4. The latter being more cleaning of distillation equipment where normally no fragrance containing products are involved.

With respect to an environmental exposure assessment the professional use of cleaning products including uses at industrial sites is similar to the end-use of cleaning products by private households and can be considered a wide-dispersive use. 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 where. If such an approach is followed in the CSA it should be thoroughly explained. This approach can be justified since the total volume of fragrance substances that is applied for professional use is a fraction of the volumes going to consumer uses. The approach can therefore be considered as a realistic approach as all these products go down the drain and only the municipal treatment plant is considered for wide-dispersive use.

The new Professional use from Cosmetics Europe “Hairdressing services” is covered by cosmetic regulation for human health. The environment for this use is covered by GES9 “Consumer (and Professional) end-use of cosmetics” as the same ERCs/SPERCs are relevant (see chapter 3.4.5.3). Therefore, no additional GES for “Hairdressing services” is necessary.

In a professional setting the washing and cleaning products or polishes and wax blends 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 (see chapter 3.4). 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.

3.4.4.1 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 V3 can be used as a Tier 1 model. A.I.S.E. provided information on the use descriptors and refined Tier 1 TRA inputs for the two GESs (3 and 4) in terms of SWEDs.

The contributing scenarios and refined Tier 1 TRA inputs for GES3 and GES4 are given in the following Tables 15 and 16. The A.I.S.E. SWEDs have been grouped based on their similarity in activity. The similarity is shown by the activity description, same PROC code and same Operational Conditions (temperature, duration, percentage in the mixture). If A.I.S.E. SWEDs differ only in the advised PPE (e.g., gloves) the SWED with the less stringent conditions (e.g., without gloves) should be used for risk assessment. Only if safe use can't be demonstrated under these conditions, the more stringent conditions should be considered. The SWEDs with the more stringent conditions are the ones put in brackets in Table 15 and 16. As the SWEDs for PROC8a and PROC8b cover the same operational conditions and PPE, the SWEDs for PROC8a (non-dedicated facilities) cover the SWEDs for PROC8b (dedicated facilities) as well. Only if the mentioned operational conditions are not save for PROC8a, PROC8b has to be assessed.

The default temperature for A.I.S.E. SWEDs is ambient temperature (25°C).
All A.I.S.E. SWEDs are available in the chr3 format for use in CHESAR. If those are used the percentage of substance in the mixture has to be adjusted from 100% (A.I.S.E. default) to < 1% as relevant for fragrance substances. If the typical Ocs and RMMs as defined in the SWEDs do not result in safe use, the activities have to be assessed individually.

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Table 15: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES3 Professional end-use of washing and cleaning products (including use at industrial sites)

GES3 – Professional end-use of washing, cleaning and disinfecting products (including use at industrial sites)											
A.I.S.E. SWED n°	Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier1 ECETOC TRA V3							
				operating temp.°C	duration	%	outdoor	indoor		respiratory protection	gloves and other dermal protection
	Name	Description						with LEV	without LEV		
AISE_SWED_PW_1_1	Professional use; Use in closed process	Application of the product is highly automated. Cleaning in place within highly enclosed production equipment.	PROC1	25°C	> 4 hours	< 1 %			x		
AISE_SWED_PW_3_1	Professional uses; Use in closed process	Automated or semi-automated application of products in a closed process with occasional exposure.	PROC3	25°C	> 4 hours	< 1 %			x		
AISE_SWED_PW_4_1	Professional uses; Semi-closed system	Automated or semi-automated application of products in a semi-closed process.	PROC4	25°C	> 4 hours	< 1 %			x		
(AISE_SWED_PW_8a_1_L) (AISE_SWED_PW_8a_1_S) AISE_SWED_PW_8a_2_L AISE_SWED_PW_8a_2_S	Transfer of product to a container (bottle/ bucket/ machine)	Liquid. Transfer of liquid from large container into a bottle, bucket or machine, without dedicated equipment and containment techniques in place.	PROC8a	25°C	15 min to 1 hour	< 1 %			x		(x)*
AISE_SWED_PW_8b_1 (AISE_SWED_PW_8b_2)	Transfer of a product via a dedicated system (bottle/bucket/machine)	Transfer from large container into a bottle, bucket or machine with dedicated equipment and containment techniques in place.	PROC8b	25°C	15 min to 1 hour	< 1 %			x		(x)*

**dermal protection to be considered only for A.I.S.E. SWED in brackets (X)*

GES3 – Professional end-use of washing, cleaning and disinfecting products (including use at industrial sites)											
A.I.S.E. SWED n°	Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier1 ECETOC TRA V3							
				operating temp.°C	duration	%	outdoor	indoor		respiratory protection	gloves and other dermal protection
	Name	Description						with LEV	without LEV		
AISE_SWED_PW_10_1 (AISE_SWED_PW_10_2)	Professional uses; Brushing after trigger spraying or brushing with tools	Brushing after trigger spraying or brushing with tools	PROC10	25°C	> 4 hours	< 1 %			x		(x)*
AISE_SWED_PW_11_1 (AISE_SWED_PW_11_2)	Professional uses; Trigger spraying and spraying	Spraying application of product.	PROC11	25°C	15 min to 1 hour	< 1 %			x		(x) *
(AISE_SWED_PW_11_3) AISE_SWED_PW_11_4	Professional uses; Trigger spraying and spraying	Spraying application of product.	PROC11	25°C	> 4 hours	< 1 %			x		(x)*
(AISE_SWED_PW_13_1) AISE_SWED_PW_13_2	Professional uses; Treatment of articles by dipping, soaking or pouring;	Treatment of articles by dipping or pouring.	PROC13	25°C	15 min to 1 hour	< 1 %			x		(x) *
AISE_SWED_PW_13_3	Professional uses; Treatment of articles by dipping, soaking or pouring; short-term	Treatment of articles by dipping or pouring.	PROC13	25°C	<15 min	< 1 %			x		x
AISE_SWED_PW_19_1 (AISE_SWED_PW_19_2)	Professional uses; Manual application	Manual application of product.	PROC19	25°C	> 4 hours	< 1 %			x		(x) *

**dermal protection to be considered only for A.I.S.E. SWED in brackets (X)*

Table 16: Overview of typical refined Tier 1 inputs for all contributing scenarios of GES4 Professional end-use of polishes and wax blends

GES4 - Professional end-use of polishes and wax blends											
A.I.S.E. SWED n°	Contributing Scenario		Process category (PROC)	Worker Exposure Modifier Tier1 ECETOC TRA V3							
				operating temp.°C	duration	%	outdoor	indoor		respiratory protection	gloves and other dermal protection
	Name	Description						with LEV	without LEV		
AISE_SWED_PW_1_1	Professional uses; Fully closed equipment	not specified	PROC1	25°C	> 4 hours	< 1 %			x		
AISE_SWED_PW_4_1	Professional uses; Semi-closed system	not specified	PROC4	25°C	> 4 hours	< 1 %			x		
(AISE_SWED_PW_8a_1_S) AISE_SWED_PW_8a_2_S	Transfer of professional product via a dedicated system (bottle/machine); medium RMM	not specified	PROC8a	25°C	15 min to 1 hour	< 1 %			x		(x)*
AISE_SWED_PW_10_1 (AISE_SWED_PW_10_2)	Professional uses; Brushing	not specified	PROC10	25°C	> 4 hours	< 1 %			x		(x)*
(AISE_SWED_PW_13_1) AISE_SWED_PW_13_2	Professional uses; Treatment of articles by dipping, soaking or pouring; including short-term	not specified	PROC13	25°C	15 min to 1 hour	< 1 %			x		(x)*
AISE_SWED_PW_13_3	Professional uses; Treatment of articles by dipping, soaking or pouring; including short-term	not specified	PROC13	25°C	< 15 min	< 1 %			x		x
AISE_SWED_PW_19_1 (AISE_SWED_PW_19_2)	Professional uses; Manual application; medium RMM	not specified	PROC19	25°C	> 4 hours	< 1 %			x		(x)*

**dermal protection to be considered only for A.I.S.E. SWED in brackets (X)*

3.4.4.2 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 ERC for professional use is ERC8a (indoor use).

SPERCs developed by A.I.S.E. and Cosmetics Europe 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 A.I.S.E. and Cosmetics Europe are presented in Table 17 below[6].

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[6] See A.I.S.E. website https://www.aise.eu/our-activities/regulatory-context/reach/description-of-uses.aspx and Cosmetics Europe website https://cosmeticseurope.eu/cosmetics-industry/cosmetics-industry-and-reach/

Table 17: A.I.S.E. and Cosmetics Europe SPERCs for Professional and Consumer end-use of fragranced end-products for Tier 1.5 assessment

SPERC Code	SPERC description	Specifics ERC	Fraction used at main source	Fraction of EU tonnage used in region	Release times per year (d/year)	Release fraction to air	Release fraction to wastewater	Release fraction to soil	Standard municipal STP
A.I.S.E. SPERC 8a.1.a.v3	A.I.S.E. - Wide Spread Use in 'Down the Drain' laundry detergents, cleaning and maintenance products (Consumers and Professionals)	8a	0.00075	0.04	365	0	1	0	yes
A.I.S.E. SPERC 8a.1.b.v3	A.I.S.E.- Wide Spread Use in Aerosol products for cleaning and maintenance products (non-volatile)	8a	0.00075	0.04	365	0	1	0	yes
A.I.S.E. SPERC 8a.1.c.v3	A.I.S.E.- Wide Spread Use in Aerosol products for cleaning and maintenance products (volatile, incl. propellants)	8a	0.00075	0.04	365	1	0	0	yes
Cosmetics Europe 8a.1.a.v2	Wide Dispersive Use in 'Down the Drain' products - hair and skin care products (Consumers and Professionals)	8a	0.00075	0.053	365	0	1	0	yes
Cosmetics Europe 8a.1.b.v2	Wide Dispersive Use in Aerosol products for hair and skin care (Propellants)	8a	0.00075	0.053	365	1	0	0	yes
Cosmetics Europe 8a.1.c.v2	Wide Dispersive Use of Aerosol products for hair and skin care (non-Propellants)	8a	0.00075	0.053	365	0	1	0	yes

3.4.5 Consumer use of fragranced end-products: GES 5, 6, 7, 8 and 9

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

The human health aspects of cosmetics have already been assessed under the Cosmetic Products Regulation (CPR) ((EC) No 1223/2009) 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 CPR.

Furthermore, for assessment of consumer exposure reference to Article 14.2 should be made as the concentration in these products may be lower than the applicable concentration limit as listed in REACH Article 14.2 (see chapter 3.4). 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 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 as described in Table 3 (chapter 3.2).

- GES 5 - Consumer end-use of washing and cleaning products (PC 35)
- GES 6 - Consumer end-use of air care products (PC 3)
- GES 7 - Consumer end-use of biocides (PC 8)
- GES 8 - Consumer end-use of polishes and wax blends (PC 31)
- GES 9 - Consumer (and Professional) end-use of cosmetics (PC 28 & PC 39)

3.4.5.2 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 PC35, PC31 and PC8.

A.I.S.E. has specified the potential consumer exposure to their products on (https://www.AISE.eu/our-activities/regulatory-context/reach/consumer-safety-exposure-assessment.aspx) including the routes of exposure as described below (Table 18).

Table 18: A.I.S.E. potential consumer exposure

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 A.I.S.E. general Figure 7 as following:

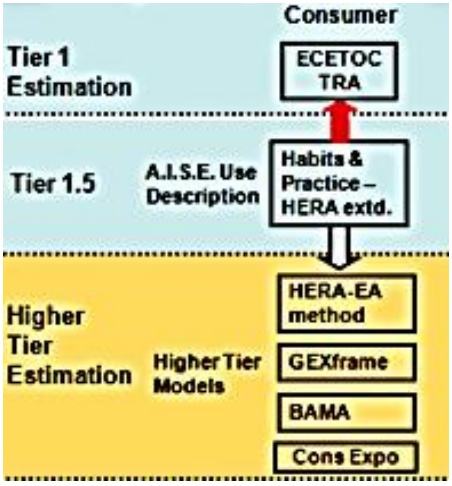

Figure 7: General picture of tiered Exposure Assessment according to A.I.S.E.

Tier 1 assessment: Tier 1 assessment generates exaggerated exposure estimates that may exceed plausible levels. For several uses, basic use information (named use descriptions) is 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 8 and Table 9 (chapter 3.3). 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 19. 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., A.I.S.E. A.I.S.E. 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 and incorporated those in their SCEDs. This information has been collected among others as a part of the HERA project of A.I.S.E.[7](See Annex 2)**.**

All A.I.S.E. SCEDs are available in the chr3 format for use in CHESAR. If those are used the concentration of substance in mixture has to be adjusted to the fragrance specific concentrations mentioned in Table 19.

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

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

- 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 a 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 8 and Table 9). 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 19: Overview of typical Tier 1.5 inputs for contributing scenarios of GES 5, 6, 7 and 8

GES no. and title / Product Category (PC)	Contributing Scenarios			Fragrance compound in fragranced end-products (%)*	Fragrance substance in fragranced end-products (%)**
	A.I.S.E. SCED n°	name	description		
GES5 - Consumer end-use of washing and cleaning products / PC35	A.I.S.E._SCED_PC35_1_a_1	**Laundry products**	**regular, compact, hand wash and automatic wash laundry products**	**1**	**0.05**
		a) laundry regular (powder, liquid)		*1*	*0.05*
		b) laundry compact (powder, liquid/gel, tablet)		*1*	*0.05*
		c) laundry additives (powder bleach, liquid bleach, tablet)		*1*	*0.05*
		d) laundry aids (ironing aids-starch spray, ironing aids-other)		*0.5*	*0.025*
	A.I.S.E._SCED_PC35_2_a_1	**Fabric conditioners**	**regular and compact fabric conditioners products**	**2**	**0.10**
	A.I.S.E._SCED_PC35_3_a_1	**Surface cleaners; Non-spray application**	**non- spray surface cleaning products such as liquid all-purpose cleaners, toilet cleaners, floor cleaners**	**6**	**0.30**
		a) Surface cleaners (liquid, powder, gel neat)		*2*	*0.10*
		b) Toilet cleaners (powder, liquid, gel, tablet)		*6*	*0.30*
		c) Carpet cleaners (liquid)		*2*	*0.10*
		d) Wipes (bathroom, kitchen, floor)		*2*	*0.10*
		e) High pressure washers/cleaners (liquid)		*2*	*0.10*
		f) Automotive care (liquid)		*5*	*0.25*
	A.I.S.E._SCED_PC35_3_b_1	**Liquid surface cleaner; Spray application**	**trigger sprays used as general hard surface cleaners**	**5**	**0.25**
		a) Surface cleaners (spray neat)		*2*	*0.10*
		b) Oven cleaners (trigger spray)		*2*	*0.10*
		c) Carpet cleaners (spray)		*2*	*0.10*
		d) Automotive care (spray)		*5*	*0.25*

	A.I.S.E._SCED_PC35_4_a_1	**Machine dishwashing products**	**automatic dishwashing products**	**1**	**0.05**
	A.I.S.E._SCED_PC35_5_a_1	**Hand dishwashing products**	**hand dishwashing products**	**1**	**0.05**
GES6 - Consumer end-use of air care products / PC 3	**A.I.S.E._SCED_PC3_7_a_1**	**Air care products; non-aerosol**	**non-aerosol air fresheners such as plug-ins, perfume in/on solid substrates (e.g. gels), candles, and diffusers (e.g. heated)**	**100**	**5**
		a) perfume in/on solid substrate (gel), diffusers (heated)		*100*	*5*
		b) candles		*10*	*0.5*
	A.I.S.E._SCED_PC3_7_b_1	**Air care products; aerosol**	**air freshener aerosols such as aqueous, non-aqueous, and concentrated mini-aerosols**	**5**	**0.25**
GES7 - Consumer end-use of biocides / PC 8	**none**	**Insecticides: liquid electric, spray neat (AISE_C_04_v1)**		**20**	**1.00**
	none	**Repellents (AISE_C_004_v1)**			
GES8 - Consumer end-use of polishes and wax blends / PC 31	**A.I.S.E._SCED_PC31_6_a_1**	**Polishes and wax blends; Non Spray application**	**non- spray polishes, cream and wax products for items such as furniture, floors, and shoes**	**2**	**0.10**
	A.I.S.E._SCED_PC31_6_b_1	**Polishes and wax blends; Spray application**	**spray polishes and waxes for items such as furniture, floors, and shoes**		

*Industrial Common Practices: upper limit percentages of fragrance compounds in fragranced end-products.
**Industrial Common Practices: calculated using a realistic percentage of 5% fragrance substance in fragrance compound

3.4.5.3 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 ERC for consumer end use is ERC8a.

SPERCs developed by A.I.S.E. and Cosmetics Europe 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 A.I.S.E. and Cosmetics Europe are presented in Table 17 above[8].

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[8] See A.I.S.E. website https://www.aise.eu/our-activities/regulatory-context/reach/description-of-uses.aspx and Cosmetics Europe website https://cosmeticseurope.eu/cosmetics-industry/cosmetics-industry-and-reach/

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							
5	GES5 - Consumer end-use of washing and cleaning products / **PC 35**	A.I.S.E. SCED PC35_1_a_1 Laundry products (regular, compact, hand wash and automatic wash laundry products)	0.3	A	-	-	-	1	857.5 Hands	-			
		A.I.S.E. SCED PC35_2_a_1 Fabric conditioners (regular and compact fabric conditioner products)	0.15	A	-	-	-	1	857.5 Hands	-			
		A.I.S.E._SCED_PC35_3_a_1 Surface Cleaners; Non-spray application (non-spray surface cleaning products such as liquid all-purpose cleaners, toilet cleaners, floor cleaners)	0.1	A	-	A	-	1	857.5 Hands	-	110	20	0.3
		A.I.S.E._SCED_PC35_3_b_1 Surface Cleaners; Spray application (trigger sprays used as general hard surface cleaners)	0.1	A	-	A	S	1	857.5 Hands	-	30	20	0.2
		A.I.S.E._SCED_PC35_4_a_1 Machine dishwashing products (automatic dishwashing products)	0.6	A	-	-	-	1	428.8 Inside hands/one hand/palm of hands	-	-	-	-
		A.I.S.E._SCED_PC35_5_a_1 Hand dishwashing products	0.3	A	-	-	-	2	857.5 Hands	.	.	.	.
6	GES6 - Consumer end-use of air care products / **PC 3**	A.I.S.E._SCED_PC3_7_a_1 Air care products; non-aerosols	0.1	A	-	A		1	35.7 fingertips	-	2.5	20	8
		A.I.S.E. SCED_PC3_7_b_1 Air care products; aerosols	0.5		-	A	S-	2		-	10	20	0.25

7	GES7 - Consumer end-use of biocides / **PC 8**	No A.I.S.E. SCED available: A.I.S.E. C19 - Air fresheners aerosol for Insecticides spray neat	0.01*****	-	-	A	S	4	-	-	10	20	0.25
		No A.I.S.E. SCED available: A.I.S.E. C19 - Air fresheners non-aerosol for Insecticides electric liquid	0.01*****	A	-	A	-	1	35.7 fingertips	-	50	20	8
8	GES8 - Consumer end-use of polishes and wax blends / **PC 31**	A.I.S.E._SCED_PC3_6_a_1 Polishes and wax blends; non-Spray applications (non-spray polishes, cream and wax products for items such as furniture, floors and shoes)	0.5	A	-	A	-	1	428.8 Inside hands/one hand/palm of hands	-	550	20	4
		A.I.S.E. SCED PC3_6_b_1 Polishes and wax blends; Spray application (spray polishes and waxes for items such as furniture, floors and shoes)	0.5	A	-	A	S	1	428.8 Inside hands/one hand/palm of hands	-	135	20	1

***** Insecticides: fraction of fragrance substance in fragranced end-product indicated in Table 19 (see §3.4.5.2)

ANNEX 2

Table of habits and practices for consumer products in Western Europe developed by A.I.S.E. (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,
Liquid	78	230	150	1.8	10	4	Hand wash (b) : 10 min			50-60% paste (powder); neat liquid
LAUNDRY COMPACT										
Powder	20	200	75	1	21	5	Machine wash: < 1 min			Laundry pretreatment: 10 min. / task,
Liquid/gel	40	140	90	2.8	10	4	Hand wash (b) : 10 min			50-60% paste (powder); neat liquid
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	--							

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.	
SURFACE CLEANERS										
Liquid (a)	30	110	60							
Powder (a)	20	40	--	1	7	2	10	20	--	Not applicable
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.

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.	
WIPES										
Bathroom			1g			7	1	10	5	based on a total weight of 7g
Kitchen			1g			3.5	2	10	5	based on total weight of 7g
Floor			26g			2	2	10	5	Wet weight not determined
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
Exposure scenario title	Manufacturing of fragrance (**site-specific**)	Formulation of fragrance compounds	Formulation of fragranced end-products	- Professional end-use of washing and cleaning and disinfecting products (including use at industrial site) - Professional use of polishes and wax blends - Consumer end-use of washing and cleaning products - Consumer end-use of air care products - Consumer end-use of biocides - Consumer end-use of polishes and wax blends - Consumer (and Professional) end-use of cosmetics
Life cycle stage	Manufacturing	Formulation	Formulation	Professional/consumer end-use
ERC	ERC1	ERC2	ERC2	ERC8a
List of possible SPERCs	-	IFRA 2.1a. v1 IFRA 2.1b.v1	A.I.S.E. SPERC 2. 1.a.v2 A.I.S.E. SPERC 2.1.b.v2 A.I.S.E. SPERC 2.1.c.v2 A.I.S.E. SPERC 2.1.g.v2 A.I.S.E. SPERC 2.1.h.v2 A.I.S.E. SPERC 2.1.i.v2 A.I.S.E. SPERC 2.1.j.v2 A.I.S.E. SPERC 2.1.k.v2 A.I.S.E. SPERC 2.1.l.v2 Cosmetics Europe SPERC 2. 1.a.v2 Cosmetics Europe SPERC 2.1.b.v2 Cosmetics Europe SPERC 2.1.c.v2 Cosmetics Europe SPERC 2.1.d.v2 Cosmetics Europe SPERC 2.1.f.v2 Cosmetics Europe SPERC 2.1.g.v2 Cosmetics Europe SPERC 2.1.h.v2 Cosmetics Europe SPERC 2.1.i.v2 Cosmetics Europe SPERC 2.1.j.v2 Cosmetics Europe SPERC 2. 2.a.v2 Cosmetics Europe SPERC 2.2.b.v2 Cosmetics Europe SPERC 2.2.c.v2 Cosmetics Europe/A.I.S.E. SPERC 2. 3.a.v2 Cosmetics Europe/A.I.S.E. SPERC 2.3.b.v2 Cosmetics Europe/A.I.S.E. SPERC 2.3.c.v2	A.I.S.E. SPERC 8a.1.a.v2 A.I.S.E. SPERC 8a.1.b.v2 A.I.S.E. SPERC 8a.1.c.v2 Cosmetics Europe 8a. 1.a.v2 Cosmetics Europe 8a.1.b. v2 Cosmetics Europe 8a.1.c.v2

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 wastewater	Release fraction to soil	River flow rate for dilution applied for PEC derivation (m^3/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 A.I.S.E. and Cosmetics Europe SPERCs Factsheets (https://www.aise.eu/our-activities/regulatory-context/reach/environmental-exposure-assessment.aspx and https://cosmeticseurope.eu/cosmetics-industry/cosmetics-industry-and-reach/). *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><td></td><td>
<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.</td></tr>
<tr><td>Related use descriptors</td><td><u>Process Categories</u>:
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
PROC9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC15: Use as laboratory reagent</td></tr>
</table>

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; - 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%;	A survey was conducted in 2008 to obtain information on the emission to water during the compounding process[9]. 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.

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

		- 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[10]	Equivalent to number of working days, based on 2002/2003 data and 2008 inquiry to compounders.[11]
	IFRA 2.1b.v1	250 days/year[12]	
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 m^3/d	Default values from REACH Guidance
	IFRA 2.1b.v1		

[10] This assumes that the release is continuous during all days of the year. If the specific fragrance ingredient 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.

[11] Ibid

[12] ibid

<table>
<tr><th colspan="4">Characteristics of Specific ERC</th><th>Justification</th></tr>
<tr><td rowspan="2">Emission Fractions (from the process)</td><td rowspan="2">To air</td><td>IFRA 2.1a.v1</td><td>0.025</td><td rowspan="2">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).

Table 4: analysis of vapour pressure of 998 chemicals used in fragrance products
<table>
<tr><td>n =</td><td>998</td><td>chemicals</td></tr>
<tr><td>>1000 Pa</td><td>25</td><td>chemicals</td></tr>
<tr><td><1000 Pa</td><td>973</td><td>chemicals</td></tr>
<tr><td>min =</td><td>8.20E-05</td><td>Pa</td></tr>
<tr><td>max =</td><td>9.999E+04</td><td>Pa</td></tr>
<tr><td>median =</td><td>2.8</td><td>Pa</td></tr>
<tr><td>99-percentile =</td><td>3258</td><td>Pa</td></tr>
<tr><td>97.5-percentile =</td><td>999</td><td>Pa</td></tr>
<tr><td>95-percentile =</td><td>453</td><td>Pa</td></tr>
<tr><td>90-percentile =</td><td>156</td><td>Pa</td></tr>
</table></td></tr>
<tr><td>IFRA 2.1b.v1</td><td>0.025</td></tr>
</table>

	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. Spilled fragrances may be collected and recycled in the process[14].
		IFRA 2.1b.v1	0	

[13] ibid.

[14] ibid.

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 wastewater 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[16]. 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.

[15] ibid.

[16] 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, material 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.

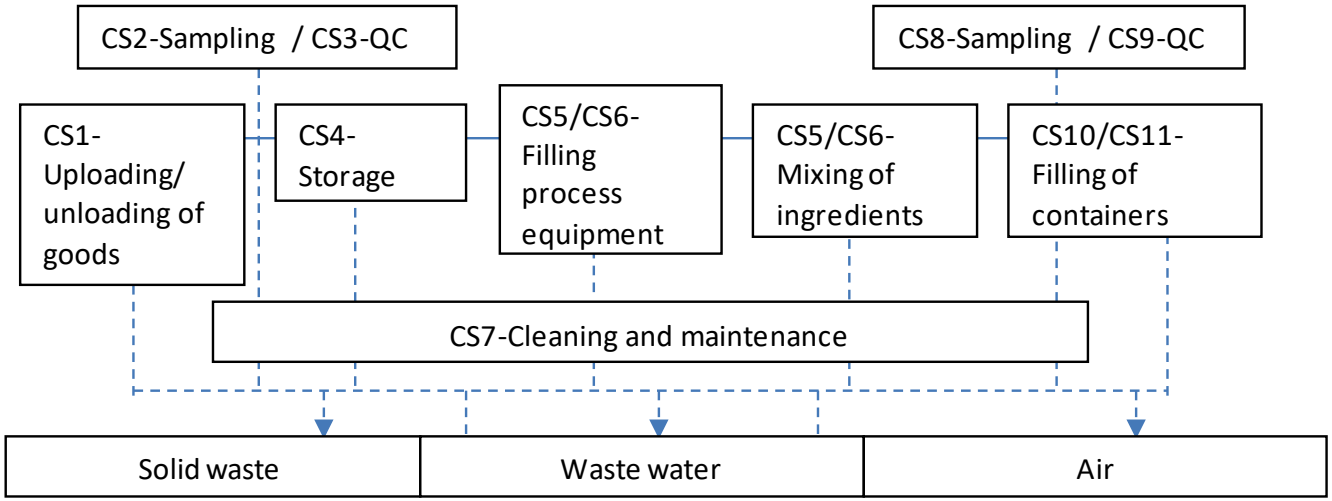

Figure 1: Operations during compounding and exposure routes (QC: Quality Control)

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 the Guidance for Downstream Users 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

Background

In the previous IFRA guidance document, v2.1, 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 proposed not to ask compounders for specific information about on-site conditions affecting air emissions but use the worst-case emission factor to air of 2.5% (ERC 2).

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 [g/mol]		**4.00E+02**
Vapour pressure [Pa] *at (°C)*	**25**	**1.00E+00**
Water solubility [mg/l] *at (°C)*	**20**	**1.00E+00**
Kow		**3.16E+04**
Biodegradability test result		**not biodegradable**
Chemical class for Koc-QSAR		**Predominantly hydrophobics**

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.

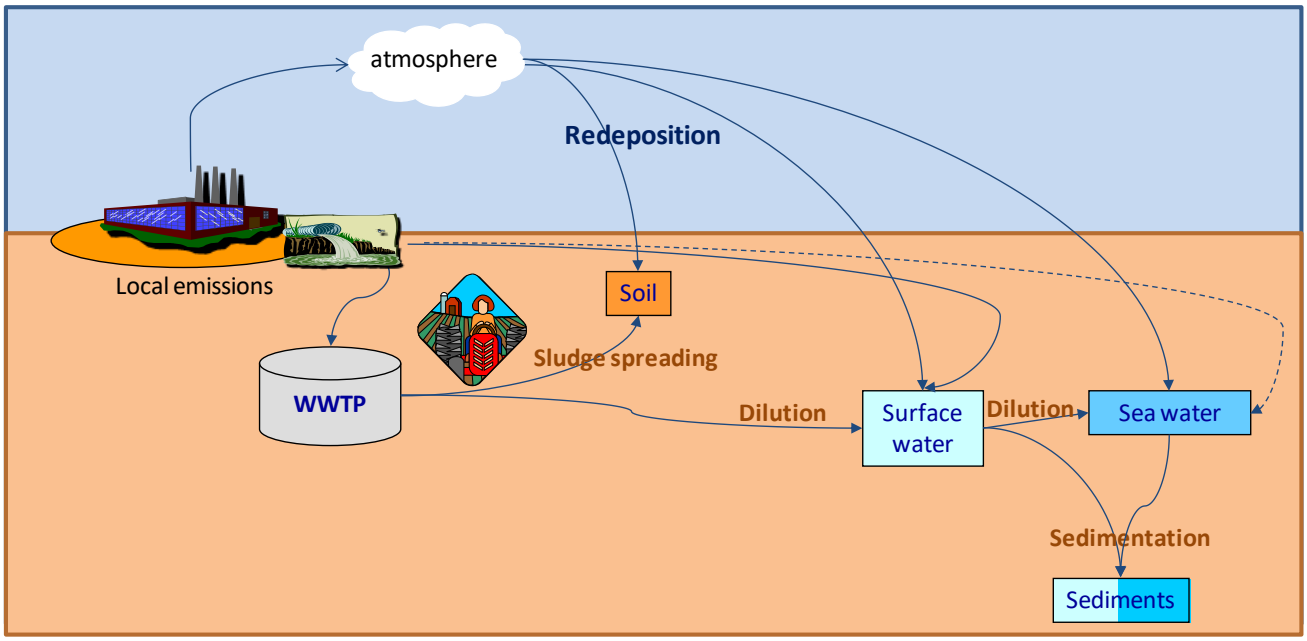

Figure 1: representation of main environmental exposition routes from air and wastewater routes via industry production and use

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 wastewater treatment plant (WWTP) is modelled 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.

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 ($_{mg.\ kgdwt}$-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.

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).

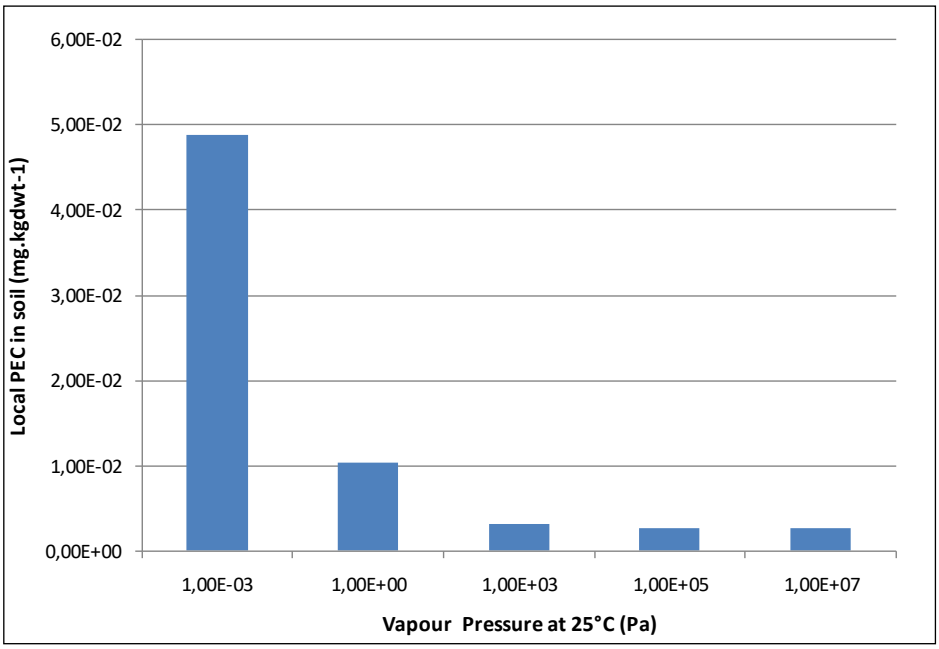

Figure 2: Sensitivity analysis of vapour pressure on local PEC in soil calculated with ECETOC TRA integrated tool v2

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.

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.

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 “SludgeToSoil?” 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[17], 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.

[17] EFFA document 9S3975.01/R0007/Nijm, 2009

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"[18]. 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 wastewater 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[19]). However, in some cases they discharge these effluents to a municipal WWTP. The efficiency of on-site treatment ranges from 70 to 90%[20]. 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.

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

[19] EFFA document 9S3975.01/R0007/Nijm, 2009

[20] EFFA document 9S3975.01/R0007/Nijm, 2009, section 3.2, page 24

ANNEX 6

SWEDs

SWED_GES1_IFRA%20V1.xlsx

Please click here below

SWED_GES2_IFRA%20V1.xlsx

Please click here below