

Chesar 3 User manual



chesar

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1.1	November 2016	Adaptation to Chesar 3.1 new functionalities, in particular inclusion of SWEDs and more reference to use maps.
2.0	June 2017	Adaptation to Chesar 3.2 new functionalities
3.0	November 2018	Adaptation to Chesar 3.4 new functionalities, in particular related to use maps
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1. Introduction and scope of Chesar

1.1 What is Chesar and why to use it?

Chesar stands for **C**hemical safety **a**ssessment and **r**eporting tool. It has been developed by the [European Chemicals Agency \(ECHA\)](http://echa.europa.eu) with the aim to support companies in carrying out their Chemical Safety Assessments (CSAs) and in preparing their Chemical Safety Reports (CSRs). For this purpose the principles related to chemical safety assessments as described in the *Guidance on Information Requirements and Chemical Safety Assessment* (available on the ECHA website: <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>) have been converted into an IT application¹.

Chesar helps to ensure **consistency** between the IUCLID technical registration dossier, the chemical safety assessment (CSA) and the information communicated to downstream users. Furthermore, Chesar increases the **efficiency** in conducting CSAs as it provides a structured **workflow** for the assessment process and facilitates the **re-use** (or update) of assessment elements generated in the single Chesar instance or imported from external sources. The tool also enables **automated** generation of CSRs and ESs for communication from the assessment in a standardised format.

Chesar is designed to support the transfer of information on uses and conditions of use from downstream sectors to registrants in the form of **use maps** developed by sector organisations². These use maps include a package of information, i.e. the identification of the relevant uses in the downstream sector and realistic descriptions of the conditions of use, which is the key input to the exposure assessment for worker, consumer and environment (see <http://echa.europa.eu/csr-es-roadmap/use-maps>)³. To support the IT exchange of information for (re-)use of assessment elements Chesar XML exchange formats have been defined. **Sector organisations** can help registrants' CSR preparation by making their use maps available in XML format. This supports cross-industry harmonisation of description of uses and conditions of safe use.

Chesar is also compatible with the use of the phrase catalogue for safe use communication that has been developed under Cefic's **ESCom** project (see <https://cefic.org/guidance/reach-implementation/escom-package-guidance/>).

How does it work in practice? To use Chesar a registrant needs to have sufficient information available on substance properties, uses, the tonnages related to each use and the conditions under which the uses take place.

A registrant has to assess the properties of his substance for his registration and to report those properties in IUCLID. To ensure consistency between the technical dossier submitted for registration and the CSA, Chesar imports all the needed substance properties from IUCLID.

In exposure assessment, exposure estimates have to be compared to the predicted no-effect levels, when available. The purpose of this comparison is to determine whether safe use of a substance can be concluded. In Chesar, exposure estimates can be obtained using three plugged in tools: the *ECETOC TRA worker* and the *ECETOC TRA*

¹ In particular, the part D on a workflow for exposure assessment, R14 for workers exposure assessment, R15 for consumer exposure assessment and R16 for environment exposure assessment are of high relevance for Chesar users.

² A short manual for sector organisations developing use maps, SPERCs, SCEDs, SWEDs is available in <https://chesar.echa.europa.eu/support/manuals-tutorials>.

³ Standard formats for such descriptions are available, also known under their acronyms: Specific Environmental Release Categories (SPERCs), Specific Consumer Exposure Determinants (SCEDs), Sector-specific Worker Exposure Descriptions (SWEDs).

consumer tool (available on <http://www.ecetoc.org/tra>) as well as EUSES 2.1.2 fate model for the environmental exposure estimates. Chesar also supports the assessments based on other exposure estimation tools or measured data. However no automated calculation of exposure estimates can be performed for other tools.

If the substance is hazardous but predicted no-effect-levels are not available, Chesar supports exposure scenario building with qualitative risk characterisation.

With Chesar it is possible to generate a full CSR combining the information on substance properties in the IUCLID technical dossier with the exposure assessment carried out by Chesar. Furthermore, the use description and an extract of the exposure assessment can be exported from Chesar to the registrant's IUCLID substance dataset.

Finally, with Chesar it is possible to generate exposure scenarios for communication to be annexed to the Safety Data Sheets (extended SDS).

Figure 1 illustrates how the data are expected to be exchanged between the different systems. All the data exchanges are supported by IT exchange formats.

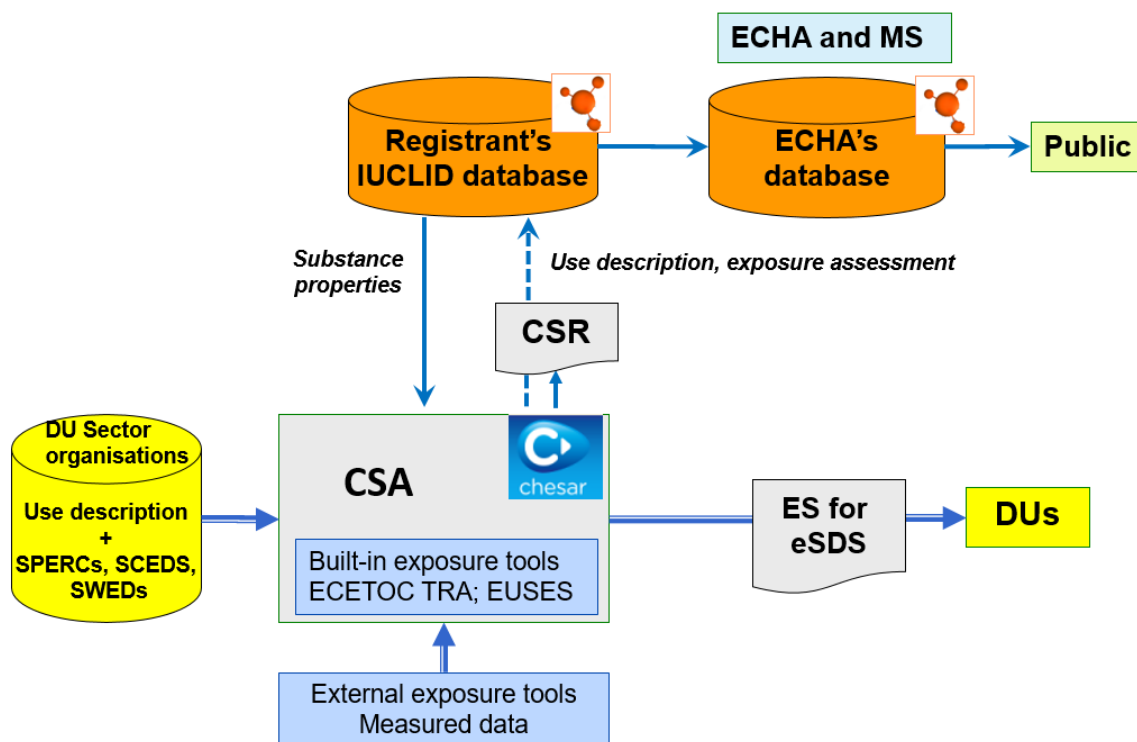


Figure 1: IT support to data flow

1.2 How has Chesar been developed?

A consultation group composed of industry representatives and a few Member States has followed the development of the tool, supporting ECHA in setting the specifications and testing the tool during its development. Developments in industry, such as Generic Exposure Scenarios (GES), use maps, Specific Environmental Release Categories (SPERCs), Sector-specific Worker Exposure Descriptions (SWEDs), Specific Consumer Exposure Determinants (SCEDs) and ESCom package (exposure scenario for communication phrase catalogue and XML) have been taken into account for Chesar.

Chesar 1.0 was released in May 2010 and was a IUCLID plug-in. After version 2.0,

Chesar became a web application. Chesar 2.3 was released in May 2014. Chesar 3.0 was released in June 2016. Assessments carried out with Chesar 2.3 can be migrated to Chesar 3 (see frequently asked questions on the Chesar website for more information).

To be involved in the future development of the tool you may indicate your interest by signing in to the Chesar website (<https://chesar.echa.europa.eu>).

Acknowledgements

ECHA thanks the members of the Chesar consultation group for their input during the Chesar development process and its testing. ECHA also thanks the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC) for having made the code of the ECETOC TRA worker tool available free of charge and for having supported the ECHA team in the implementation of the tool.

1.3 Before starting using Chesar

Before downloading and installing Chesar please **read carefully** the relevant information available on the Chesar website (<http://chesar.echa.europa.eu/>) and in particular:

- The installation manuals
- The release note which
 - lists the key new features
 - describes identified “known issues”

Chesar 3 has an **on-line help system**. Pressing the  icon available in most of the screens opens a short targeted help.

In case you face any issue or have any suggestion please provide them via the ECHA regulatory advice and support form (<http://echa.europa.eu/contact>).








2. Assessment workflow supported by Chesar

REACH requires exposure assessment and risk characterisation only for substances meeting the criteria for being classified as hazardous, or which are assessed to be a PBT/vPvB, or where certain information requirements have been adapted based on exposure considerations. If none of these three conditions applies, no exposure assessment is needed. Otherwise an exposure assessment has to be carried out addressing all hazards identified.

Chesar is divided in seven major groups of functionalities listed below. They are called **Boxes**. Boxes 1 to 5 support various steps in the assessment workflow. Box 6 supports the process via a library of CSA elements. Box 7 is about user management.

An icon is associated with each Box. All the icons form the main toolbar:



	Box 1	Substances
	Box 2	Uses
	Box 3	Exposure assessment
	Box 4	CSR
	Box 5	ES for extended SDS
	Box 6	Library
	Box 7	Users

The connections between the different Boxes and the resulting workflow is visualised in the figure below and briefly explained in the following section. More details are provided in the next chapters, as well as in the on-line help.

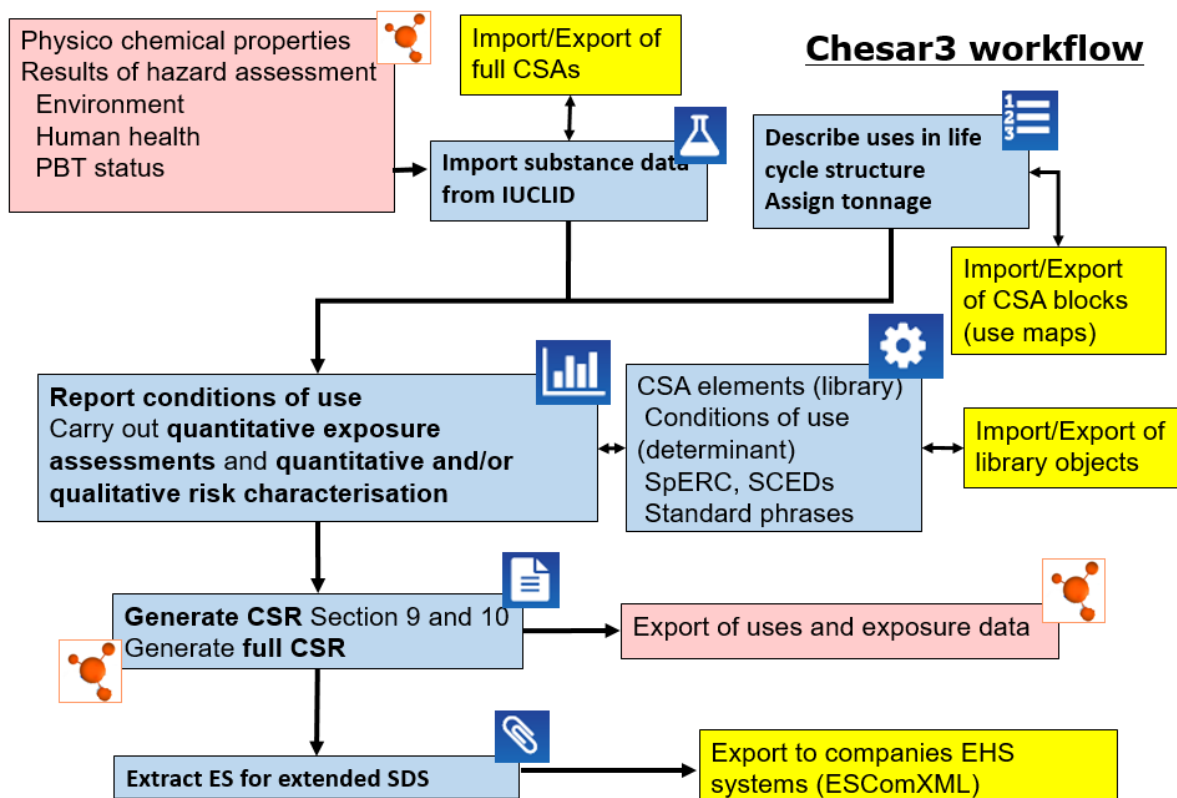


Figure 2: Chesar Assessment Workflow



Box 1 Substances

To start the assessment process for a certain substance with Chesar, the hazard assessment according to Annex I of REACH must be available. Thus, all the information related to the substance's intrinsic properties needed for exposure assessment and risk characterisation is available in the IUCLID endpoint summaries. The Chesar user - the assessor – needs to import this information into Chesar with the Box 1 functionalities. This includes the conclusions from the hazard assessment, directly determining the required scope of exposure assessment and the type of required risk characterisation (qualitative or quantitative).

From Box 1 it is also possible to import and export full CSAs, e.g. for exchange with other assessors or for other substances.



Box 2 Uses

In Box 2, the assessor describes the uses of the substance in a structured way to ensure consistency between the use description and the exposure assessments. The assessor has to report the relevant uses of the substance following the Chesar life cycle tree structure, considering human health and environmental aspects as well as the tonnage break-down to the different uses. For each use, contributing activities for the environment and for human health can be created.

It is also possible to import or export life cycle trees or the so called CSA blocks (parts of life cycle tree with corresponding exposure assessment) to be used as starting point for the assessment of a substance.

Assessors can also upload sector use maps having been made available by sector organisations as Chesar importable files (see section [4.3 Import of use map](#)).



Box 3 Exposure assessment

In Box 3, the assessor has to identify and report the conditions for safe use for each contributing scenario.

The scope of exposure assessment (route/types of effects for humans, and environmental compartments to be covered) has been determined when importing the hazard conclusions from IUCLID (see Box 1). Depending on the substance properties and the uses, it may be sufficient to apply only the plugged in exposure estimation tools to demonstrate that the expected exposure is lower than the DNELs and PNECs. However, exposure datasets obtained by other methods may be needed in the following situations:

- The processes or activities relevant for a use cannot be assessed with the plugged-in tools (e.g. production of metal powders in hot or wet processes cannot be assessed with the ECETOC TRA for workers).
- The substance properties and/or the conditions of use are outside the boundaries of applicability of the tool (e.g. assessment of exposure to fumes from hot processes is not possible with ECETOC TRA for workers).
- After exhausting all available refinement options, the plugged-in tool still predicts an exposure exceeding the derived no-effect levels.

In such situations other exposure assessment methods need to be applied (including measured data). Chesar supports the systematic and transparent manual reporting of such assessments.

For hazards without DNELs or PNECs, conditions of use suitable to sufficiently control exposure for the specific hazard should be identified and reported.

Finally the assessor completes the risk characterisation, quantitatively and/or qualitatively as appropriate.



Box 4 CSR

In Box 4 the assessor can review the CSR which will be generated and report additional explanations for the CSR on the overall assessment approach applied or specific explanations at the level of single exposure scenarios.

In this Box it is also possible to generate sections 9 and 10 of the CSR as well as a full CSR (part A and B) integrating the information from IUCLID.

The use description as well as an extract of the exposure assessment can be exported to IUCLID section 3.5.



Box 5 ES for communication

Box 5 supports the assessor in generating the exposure scenarios for communication (named SDS ES in Chesar). They are to be annexed to the extended Safety Data Sheet (eSDS) being sent down the supply chain. The exposure scenarios for communication are based on the exposure scenarios for the CSR. In Box 5 the assessor can automatically generate default SDS ES for the full life cycle or for selected uses, including the standard phrases associated with the conditions of use selected in Box 3. The assessor may decide to add/remove standard phrases to each single condition of use in the SDS ES. Chesar supports the export of the SDS ES in ECom XML format so that the information can be further processed in the recipient IT systems. Chesar also supports the generation of the SDS ES in an rtf format, possibly in any EU language if ECom standard phrases have been used systematically and if a translation of the ECom phrase catalogue is uploaded in the library.



Box 6 Library

Box 6 contains all functionalities of the Chesar library. The library enables creation, storage, import and export of objects that the assessor may need in his CSA work process. In Chesar 3 the following library objects can be managed: Condition of use templates, Specific Environmental Release Categories (SPERCs), Specific Consumer Exposure Determinants (SCEDs), Sector-specific Worker Exposure Description (SWEDs) and standard phrases.

Some conditions of use are already built-in Chesar and are always available in the library. They mainly correspond to input to built-in release/exposure estimation tools but also to some agreed standardised conditions.

SPERCs, SCEDs and SWEDs correspond to sets of information describing specific conditions of use (and the corresponding release estimates to water, air, soil and waste for SPERCs) developed by industry sectors as part of their use maps.

The information in the exposure scenarios attached to the extended safety data sheets (eSDS) should be conveyed in the form of standard phrases. Chesar enables the import of standard phrases from phrase catalogues that have been developed respecting the Chesar format. A catalogue already available is the one developed by Cefic's ECom project.

All these library objects are meant to be used across various assessments and, by this, to contribute to the harmonisation and efficiency of the assessments.

Please be aware that sectors may update the different elements of the published use maps, and also the ECom catalogue is foreseen to be regularly updated. Consequently you also need to regularly update your library.



Box 7 Users

Box 7 relates to the user and role management and is particularly relevant for the use of the Server version of Chesar. In addition, for users intending to create objects in the library, the assignment of a legal entity⁴ will enable identification of the author of the object.

⁴ A IUCLID 6 legal entity can be exported directly from your IUCLID instance.

3. Box 1: Manage substances and CSAs

3.1 Purpose of information requirements under REACH

To enable exposure assessment and risk characterisation, the intrinsic properties of a substance need to be systematically characterised. This includes the properties that:

- drive releases from processes and products;
- determine the fate and distribution in the environment;
- lead to adverse effects on human health and/or in the environment;
- lead to explosion, flammability or oxidising hazards.

In order to facilitate the identification of appropriate risk management measures and to enable risk characterisation, the available knowledge on the substance properties is converted into a hazard characterisation:

- Conclusions on PBT and vPvB properties potentially triggering measures to minimise releases;
- Classification and labelling triggering certain risk management strategies;
- Derivation of no-effect levels below which no adverse effects are to be expected (DNELs and PNECs), providing the threshold for limiting exposure.

The IUCLID dossier contains a full documentation of the available information. Selected parts of this documentation are to be reported in chapter 1 to 8 of the Chemical Safety Report (CSR).

Chesar imports the information needed for carrying out the exposure assessment and risk characterisation from IUCLID.

3.2 From IUCLID to Chesar


Information on the substance's intrinsic properties necessary for the chemical safety assessment must be entered into the correct sections and fields of IUCLID, so that it can then be imported into Chesar and correctly used for the assessment.

For each individual endpoint⁵ several records (endpoint study records) can be created in IUCLID for reporting the results of one or several studies carried out on the substance. In case several studies are available for one endpoint, one single value (e.g. a vapour pressure or DNEL) has to be selected or derived to enable the exposure estimation and risk characterisation. To do so, specific IUCLID sections (so-called **endpoint summaries**) exist for reporting the outcome of the assessment of the given endpoint. Such information, when relevant for the chemical safety assessment process, is imported and used in Chesar. This mainly concerns:

- Physico-chemical properties (section 4 of IUCLID)
- Environmental fate properties (section 5 of IUCLID)
- Environmental hazard conclusion (section 6 IUCLID summary), including PBT status (section 2.3 IUCLID summary)
- Human health hazard conclusion (section 7 IUCLID summary)

Based on the information on hazard conclusions uploaded from IUCLID, Chesar describes the type of risk characterisation required.

⁵ physico-chemical or fate property but also ecotoxicological or toxicological endpoints

 In Chesar 3 a set of new functionalities has been implemented to enable the assessment of substances where more than one set of properties is needed. For that so called **assessment entities** have to be defined in IUCLID. See section 9 for more information.

1.1.1 Import of data from IUCLID to Chesar

There is a web service connection between IUCLID 6 and Chesar 3. When both IUCLID 6 and Chesar 3 are running you can search in IUCLID database directly from Chesar and import the dataset by a simple click.

Similarly in Box 4 it is possible to export data to IUCLID by a simple click.

1.1.2 Modification of data

It is possible in Chesar to modify the values of all physico-chemical and fate parameters as well as the hazard conclusions, without changing the values in IUCLID. Nevertheless it is very important that before finalising the CSR the data are synchronised between IUCLID and Chesar.

1.1.3 Synchronisation of data

If substance property data are updated in IUCLID 6 for a substance that has already been assessed in Chesar, the assessor needs to re-import the data from IUCLID 6 into Chesar to initiate the update of the CSA.

The Chesar synchronisation workflow is twofold:

- It displays the changes that have been made in the IUCLID 6 substance dataset and, once the substance is updated in the Chesar database,
- It adapts, where possible (including recalculation of some exposure estimates and RCR when relevant) the existing assessments on the basis of the property changes.

The adaptation of the assessment depends on the nature of the property changed:

- If one or more physico-chemical properties used by the exposure estimation tools built-in Chesar (ECETOC TRA workers and consumers as well as EUSES) are modified, the exposure estimates are recalculated as well as the RCRs.
- If the value of any DN(M)EL or PNEC is modified then the RCR values are recalculated;
- If the type of hazard conclusion is changed (e.g. qualitative to quantitative, higher qualitative hazard to lower qualitative hazard or vice versa), Chesar automatically indicates some of these modifications, but mostly the assessor needs to complement the change with additional information.

3.3 Creation of a Chesar substance

Information on the substance's intrinsic properties necessary for the chemical safety assessment can also be entered directly in Chesar. Once the information is available, Chesar can use it for performing the assessment. However, it is not possible to define substances for which more than one set of properties is needed (i.e. no assessment entities can be defined directly in Chesar). In case substances are created directly in Chesar, it is important to note that there will be no possibility to export the information to IUCLID nor to generate a full CSR for these substances.

3.4 CSA management

Each assessed substance in Chesar should have at least one CSA (Chemical Safety Assessment). Therefore, when starting an assessment, a CSA is automatically created by Chesar. In a standard assessment situation, this will be sufficient. There are no uses associated to a CSA when starting the assessment.

An assessor can also re-use an existing CSA for a substance as the starting point for the CSA for another substance. Import, export and storage of CSA file can be managed from **CSA management** in Box 1.

It is also possible to create several CSAs in Chesar, for example when a lead registrant wants to carry out a joint CSA and his own complementary CSA.

When creating a *Joint CSA* this will trigger

- That all uses transferred from Chesar to IUCLID section 3.5 are marked as "use assessed in a joint CSR"
- The generation of a "joint" full CSR (as explained in section 6.2).

4. Box 2: reporting uses

4.1 Purpose of use reporting under REACH

In a Chemical Safety Report (CSR) all identified uses of a substance are to be addressed, and the whole life cycle of the substance related to these uses is to be covered. Registrants are expected to provide:

- A systematic overview of uses including intuitive use names and an indication of what the substance technically does in these uses;
- For each use an overview on the contributing processes or activities, i.e. an intuitive use name for each contributing activity and a corresponding use descriptor category;
- A further description of the processes covered under each use.

Reporting of uses needs to be done in a systematic and structured way to enable an efficient, complete and transparent assessment. Structured reporting of uses also facilitates communication with the different groups of downstream users.

Chapter R.12 of ECHA's Guidance on Information Requirements and Chemical Safety Assessment (http://guidance.echa.europa.eu/guidance_en.htm) provides detailed guidance on use description.

Assessors are expected to base their description of uses on information from downstream users, in order to obtain a realistic and relevant starting point for their assessment. Various downstream user sector organisations are publishing **use maps** in order to provide this information to registrations in a consistent and ready to use way. ECHA provides a single point of access for existing use map information.

4.2 Life cycle tree elements

A life cycle tree in Chesar can have a maximum of 8 life cycle stages (= use types). They are:

- Manufacture
- Formulation or repacking
- Use (of substances as such or in mixture) at industrial sites
- Widespread use (of substance as such or in mixture) by professional workers
- Consumer use (of substance as such or in mixture)
- Service life (consumer)
- Service life (industrial sites)
- Service life (professional workers)

At each life cycle stage one or more uses can be created, depending on differences in the conditions of use and potentially resulting in differences in the emission factors. For each use created in Box 2, an exposure scenario (with the same name) is created in Box 3.

In addition to the 8 life cycle stages, two further elements are part of the default life cycle tree:

- **Manufacture/Import:** The life cycle tree is created from this node. This element

at the top of the life cycle cannot be removed. It serves as the basis for calculation of the balance of tonnage to be assessed in the CSA. Also, there is a text field available where the assessor can insert a narrative that provides a concise overview on all the uses for the CSR Chapter 9.0.1.

- **Market sectors:** This element can be used in a flexible manner to build groups of uses according to formulating sectors, end-use sectors, particular customer groups or different functions the substance may deliver. Use maps (see section 4.3) are also a type of market sector.

Each **use** can be defined by an intuitive name, by an overall description of the technical processes carried out, and by a set of use descriptors. Then various information can be reported for the use, some needed for the CSA/CSR and for the ES for communication, and some only meant to populate the related fields in IUCLID.

For each use, two or more **contributing activities** can be defined. As a minimum, there needs to be one for human health and one for the environment. A contributing activity is described by its name and the assigned use description category.

The names of the uses and the contributing activities can be reported in the form of free text or in the form of standard phrases for communication in the supply chain (see section 7).

The uses in Chesar can be represented in a hierarchical way, helping to get a good overview of the use pattern of a substance in a mass flow perspective. It may also help to connect market information with information requirements for the assessment, and to establish communication links with downstream organisations. At each level the tree can be branched out or not, depending on whether the conditions of use are different or similar across products and/or sectors.

There are several ways to build the life cycle tree. Life cycle tree elements can be added manually, or a complete life cycle tree, use maps or CSA blocks can be imported. The following table shows which elements are imported in each of these cases.

	Life cycle tree	Use map	CSA block
Use description (Box 2)	List of uses incl. contributing activities (CA). Replaces any previous uses	(One or) more uses incl. CAs added to already available uses.	One or more uses incl. CAs added to already available uses
Conditions of use	Not included	Included	Included
Exposure assessment and risk characterisation	Not included	Not included	Exposure assessment and quantitative risk characterisation included. Qualitative risk characterisation not included
Information for ES for communication	Not included	Included	Included

4.3 Import of use map

Registrants can find and download Chesar files with use maps from <http://echa.europa.eu/csr-es-roadmap/use-maps> if made available by sectors.


The relevant use map can be imported in Box 2. Assessors are then expected to delete, if necessary, the uses or the contributing activities which are not relevant for their assessed substance and adapt the tonnage information to the substance tonnage. Additional information with regard to the use description can also be provided by registrants, such as, as a minimum, the technical function of the substance in the use. In case service life is part of the use map, the link between the uses leading to service life and the service life may have to be adapted by the assessor depending on the technical function of the registered substance.

When an updated use map is published by a sector, the new version can also be imported. The differences compared to the version already available in the life cycle tree will be shown, and a choice can be made whether the previously deleted uses and contributing activities should be included in the import.

Note: If downstream organisations have published/updated their use maps without making them available also as Chesar import files, seek for confirmation with the sector when Chesar files will become available. It is not advisable to manually transfer whole use maps into your assessment.

4.4 Exchange of a Chesar life cycle tree

All uses reported in a life cycle tree format can be exported and imported. This may be useful, for example, if the derived life cycle tree is applicable as a starting point for various substances manufactured by a company or in a sector.

 A life cycle tree in Chesar will only contain information on the use description. No information on the conditions of use are exported.

4.5 Exchange of Chesar CSA blocks

A CSA block consists of a use or a market sector (including all related uses and contributing scenarios) with all the related exposure estimates, exposure scenarios and risk characterisation. Also a stand-alone contributing scenario can be exported as a CSA block. Exporting of CSA building blocks may be useful if such blocks are planned to be re-used for a substance with similar uses. A CSA block can be imported and integrated into a life cycle tree.

If the imported CSA block contains exposure datasets generated with one of the exposure estimation methods plugged into Chesar, the exposure assessment is automatically recalculated for the properties of the substance under assessment. Also the risk characterisation is adapted. Note that if exposure datasets have been reported manually (being either carried out by an external tool or corresponding to measured data), the exposure estimates may not be appropriate for other substances.

4.6 Link to exposure assessment (Box 3)

For each use, an exposure scenario is created in Box 3. The title section of the exposure scenario consists of the corresponding information on uses and contributing activities entered in Box 2. This one-to-one relationship is meant to support consistency between use description and exposure scenario building.

In addition to their descriptor-functions, some of the descriptor-lists also support identification of the suitable exposure estimation entry in one of the **Tier 1 exposure estimation tools** plugged into Chesar. Assignment of:

- An environmental release category (ERC) and a tonnage for each use

- A process category (PROC) for a workers' contributing scenario
- A product category (PC) or article category (AC) for consumers' contributing scenario

enables the derivation of default conservative exposure/release estimates with the plugged-in exposure estimation tools, the ECETOC TRA and EUSES with the ERC-release factors. These estimates are driven by the operational conditions reflected in the use category and by the intrinsic properties of the substance.

4.7 Link to exposure scenario for communication (Box 5)

For each use, an exposure scenario for communication is created in Box 5, based on the exposure scenario for the CSR created in Box 3. As for the CSR, the title section of the exposure scenario consists of the information on uses and contributing activities entered in Box 2.

This information can be standard phrases (for example developed at sector level and made available via the ESCom Catalogue, see section 8.2.5) or free text information created by the single assessor. The use of standard phrases in the exposure scenario for communication facilitates easy recognition of exposure scenarios by downstream users, and the translation of exposure scenarios into the various languages.

Therefore it is advised to import a standard phrase catalogue and to make use of standard phrases as far as possible. When a relevant standard phrase is not available, proposals for new phrases can be submitted to ESCom (see <https://cefic.org/guidance/reach-implementation/escom-package-guidance/>). Preferably such proposals should be made by industry sectors rather than by individual registrants. Note: Free-text information created by the single assessor cannot be included into the ESCom XML export file transferring the exposure scenario for communication down the supply chain.

5. Box 3: Exposure assessment

5.1 Purpose of exposure assessment under REACH

Exposure assessment under REACH includes two elements: i) characterising the operational conditions and risk management measures ensuring control of risk (and hence safe use) and ii) predicting the exposure to humans and to the environment occurring under these conditions. If the predicted exposure is lower than the derived/predicted no-effect-levels (DNEL/PNEC), when available, control of risk is demonstrated. In the absence of a no-effect-level the exposure estimates cannot be compared with a threshold, and thus no risk characterisation ratio (RCR) can be calculated. In such case appropriate risk management measures should be identified and justified based on qualitative risk characterisation. Quantitative exposure assessments can be used as supportive information in a qualitative risk characterisation. For example, data-sets corresponding to uses taking place under contained conditions could be used to demonstrate minimisation of exposure.

In the risk characterisation the assessor is expected to systematically demonstrate that i) exposure assessment has been carried out for all hazards and all uses identified, and ii) that the expected exposure resulting from the use conditions (described in the exposure scenario) does not lead to adverse effects.

5.2 Description of the conditions of use

The generated exposure estimates must be referenced to the conditions under which such exposure occurs. Such conditions of use may correspond to:

- The input parameters of a plugged-in or external exposure estimation tool
- The conditions under which releases or exposure have been measured
- Risk management measures with a certain effectiveness that can be applied to reduce an estimated release or exposure
- Measures minimising exposure in the context of qualitative risk characterisation

The conditions of use (see section 8.2.1) are stored in the internal library of the tool and can be used for any assessment, when relevant. Standard phrases can be associated to them for facilitating the generation of the ES for communication.

There are various ways on how conditions of use get into the library:

- Some are available by default in Chesar 3 library (called built-in conditions of use).
- An assessor may import them as such or as part of SPERCs, SWEDs or SCEDs when created by e.g. sector associations, or as part of assessments created by other Chesar users (importing a *Chesar substance*, a *Chesar CSA*, a *Chesar use map* or a *Chesar CSA block*).
- They can also be created by the assessor himself.

5.3 Environmental assessment

The environmental protection targets to be taken into account are: water and sediment organisms (freshwater and marine), predators in the aquatic food chain (freshwater and marine), sewage treatment plant organisms, agricultural soil organisms, predators in the terrestrial food chain, and air.

In addition exposure estimates are to be generated for intakes by humans via the environment. This includes concentration of substance in air, drinking water and different food items (e.g. root crops, dairy products, meat and fish).

In the use description (Box 2), uses at industrial sites and widespread uses (by professional workers and consumers) are systematically differentiated. The exposure assessment for these two types of uses differs from each other:

- Uses at **industrial sites** are assessed for one generic, representative site per use. It is assumed that a certain tonnage is used at this one single generic site, and that a certain fraction of the use tonnage at this site is released (depending on the conditions of use). The release factor depends on the operational conditions and risk management assumed for the generic site. As there may be very large and very small industrial sites for one use, two contributing scenarios (or even the definition of two different uses) may be needed to reflect the difference in conditions and tonnage. By default it is assumed that the discharge from the site is treated in a standard (municipal) biological sewage treatment plant (STP), releasing to a standard environment, and that the STP sludge is applied to agricultural soil. However the assessor can change these assumptions.
- For **widespread uses** by consumers or professional workers (e.g. consumer activities, professional cleaning or other maintenance services, office work, "use" of houses and roads) it is assumed that the market tonnage is evenly distributed in space and time. The assessment is carried out for a standard town with 10,000 inhabitants and a corresponding use tonnage (fraction of the market tonnage). Depending on the conditions of use a certain fraction of this tonnage is assumed to be released to the sewage system, and treated in a standard (municipal) biological sewage treatment plant. Usually the assessor will not overwrite these default assumptions on the local conditions for a substance marketed across Europe. The releases from all uses into the municipal sewage system are aggregated to derive an aggregated exposure estimate for widespread uses.

Exposure concentrations in the different environmental compartments can be estimated by the EUSES 2.1.2 fate model, based on the release rates to water, air and soil. EUSES 2.1.2 is built-in Chesar. The Chesar release module supports several methods for estimating the release rates: release factor based on the ERC, estimated release factor based on Specific Environmental Release Categories (SPERCs, see section 8.2.2) or on another source of information, or measured release. In addition releases to external waste treatment can be reported. Releases to waste may be generated from the process itself (including the fraction left in a packaging when relevant) and by transfer of substance to waste by the on-site risk management measures (applied to waste water or exhaust air). Detailed explanations of environmental exposure assessment are available in the Guidance on Information Requirements and Chemical Safety Assessment Chapter R16: Environmental exposure assessment.

The Predicted Environmental Concentrations (PECs) for the generic site or generic town are estimated taking into account the so-called "local concentrations" (Clocal) and "regional concentrations". The regional concentration results from all the uses of a substance and is calculated by EUSES in the background. The regional concentration is added to the local concentration for deriving the local PEC, in order to take into account that a single site or a single town does not discharge into a virgin environment, but just adds to emissions released by other sites or towns.

The following scheme summarises the main steps of exposure assessment for the environment. A default assessment can be carried out, if an Environmental Release Category (ERC) and a tonnage has been assigned to the use in Box 2.

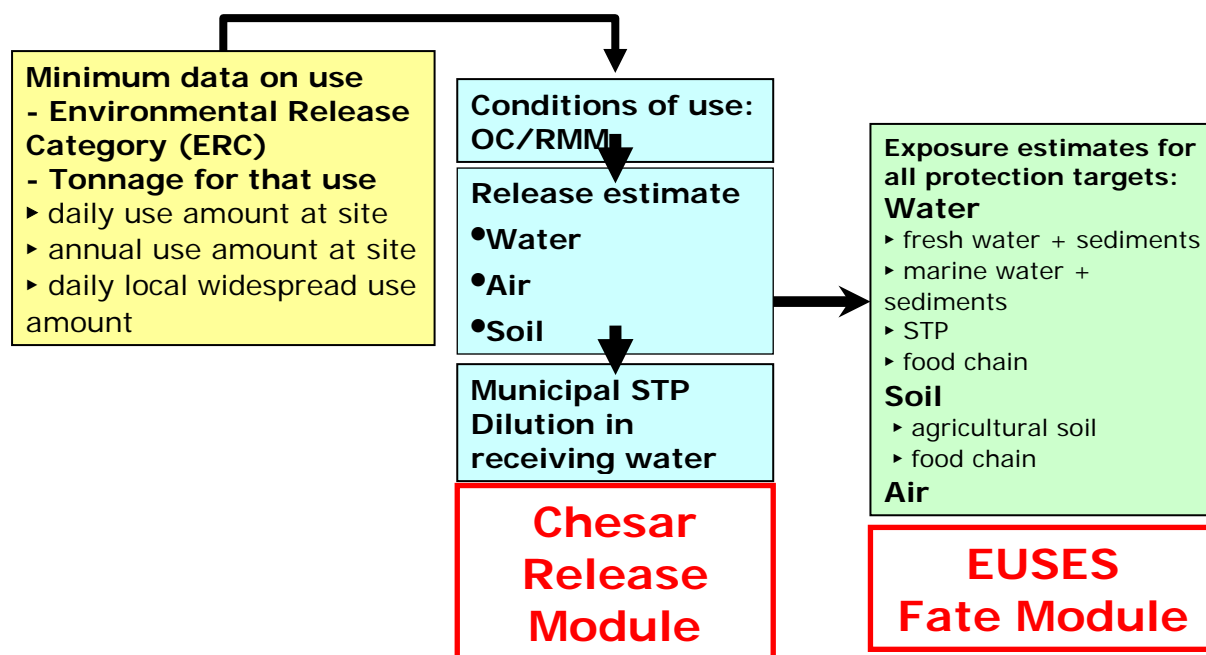


Figure 3: Environment assessment workflow

For substances considered as being PBT or vPvB, releases have to be minimised, and therefore appropriate conditions of use have to be reported to ensure this. The release estimation is done as for non PBT-substances. Exposure however cannot be estimated with sufficient reliability in a **regional** environment. This is due to the large uncertainties in predicting the fate, distribution and long-term effects of such substances in the environment, in particular regarding accumulation in the food chain. Consequently no regional concentrations are calculated. It is nevertheless possible to report measured regional concentrations if available. For the **local** environment however the concentrations (C_{local}) for water, air and agricultural soil are estimated.

5.4 Assessment for human health


The registrant under REACH is required to provide information on various toxicological endpoints in his registration. This includes local effects (irritation, corrosion) and systemic effects (mutagenicity, carcinogenicity, reproductive toxicity, or toxic effects to other organs). Such effects may occur after short single exposure or after long-term repeated exposure. The exposure triggering such effects may take place via inhalation, dermal contact or oral intake. Oral intake is only considered for consumers/general population.

Where a hazard has been identified, exposure assessment and risk characterisation is required for the corresponding route(s) of exposure, types of effect and target groups. Exposure information obtained with exposure estimation tools or measured data may be used.

The ECETOC TRA Workers exposure estimation tool (v3) is built-in to Chesar. It can provide estimates for long-term (repeated) inhalation and dermal exposure. It can also provide estimates for short-term (acute) inhalation exposure occurring during a work day. Sector-specific worker exposure descriptions (SWEDs) can be used as input in order to carry out the assessment based on realistic and representative conditions of use.

Also the ECETOC TRA Consumers exposure estimation tool (v 3.1) is built-in to Chesar. Note that there are some deviations compared to the ECETOC implementation of the TRA, as the implementation in Chesar has been aligned with the principles laid down in the update of Guidance R15. It can provide estimates for long-term (repeated) inhalation, dermal and oral exposure. Specific Consumer Exposure Determinants (SCEDs) can be used as input where no product specific inputs are available in the TRA, or where an assessor wishes to overwrite the build-in defaults (see section 8.2.3).

The ECETOC TRA tools are available on ECETOC website <http://www.ecetoc.org/tra>

 Owners of other exposure tools may decide to provide the outputs of their assessments in a Chesar compatible format, so that they can be easily uploaded and integrated into the Chesar-based CSA. For more information, contact the Chesar helpdesk at <https://echa.europa.eu/contact/reach>

6. Box 4: Generating the CSR and exporting information to IUCLID

Sections 9 and 10 of the CSR are generated from Chesar. In line with the principles laid down in the CSR format prescribed in Annex I of the REACH regulation, the Chesar generated CSR differs in two aspects from the REACH Annex I format:

- A Section 9.0 has been included for enabling the registrant to provide some systematic explanation across the whole exposure assessment; this also includes information on common (not use-specific) risk management measures that are applicable across all exposure scenarios, and where section 7 and 8 of the safety data sheet is a more suitable place for communication than repeating such measures in each exposure scenario for communication.
- The risk characterisation per use has been merged with the exposure estimation, and thus Chapter 10 only refers to risks resulting from exposure across uses (aggregated exposure from multiple sources).

The structure of section 9 and 10 of the CSR as generated by Chesar is provided in Annex 1 (see section 10).

6.1 Completing the information before generating the CSR

Before generating the CSR the assessor will be able to view and edit the full CSR in Box 4. He may in particular want to provide some general explanations to facilitate the understanding of his CSR. He can explain his approach to the assessment (for all or at least for most of his ESs) for the environment, man via environment, workers and consumers. This may include explanations on the assessment methods applied, the approach taken to identify the representative operational conditions and risk management measures for the different uses, or approaches to qualitative risk characterisation.

Also, the assessor may want to add information on common (not use-specific) risk management measures that are applicable across all exposure scenarios. Such information is reported in section 9.0 of the CSR but not transferred to the exposure scenario for communication, and may include for example information on glove material or measures related to physicochemical hazards.

6.2 Generating a full CSR with IUCLID

To generate a full CSR, the data from IUCLID to populate sections 1 to 8 are needed. The full CSR can be generated in Chesar when a connected IUCLID instance is running. For that all the uses need to be first exported to IUCLID to ensure synchronisation between section 2 of the CSR on manufacture and use (generated from the data in IUCLID) and sections 9 and 10.

When generating the full CSR the system will check that the data on the substance properties are synchronised between IUCLID and Chesar. If not, data from IUCLID will have to be re-imported in Chesar before a full CSR can be generated.

From Chesar, it is also possible to create the CSR record in IUCLID (in section 13.1). In this newly created section, together with the information related to CSR part A, the full CSR report and the export of the CSA in Chesar format can be automatically attached with the CSR is generated. At the same time, Chesar can also report directly to IUCLID the relevant exposure information.

7. Box 5: Generating exposure scenarios for communication

7.1 Purpose of exposure scenarios for communication under REACH

Chesar generates the set of exposure scenarios to be annexed to the safety data sheet of the substance. A table of contents provides an overview on all the ESs contained.

The exposure scenarios for communication are meant to transport selected parts of the information documented in the CSR to the users of the substance (downstream users). The exposure scenarios are expected to be use-specific and to describe in terms of operational conditions and risk management measures how the substance can be safely used. The title of the exposure scenario should enable downstream users of substances to identify whether the exposure scenario contains information relevant to them. They compare then the relevant exposure scenario communicated to them with their actual conditions of use on site, and the design and intended use of mixtures and articles they produce (if relevant). Based on this, downstream users should be able to establish whether or not they work within the conditions that have been demonstrated to be safe in the registrant's CSA.

The exposure scenario for communication may also include information related to exposure estimates and the method/tool applied for exposure assessment. This is to ensure transparency, to facilitate interpretation of the exposure scenario by the downstream users, and eventually to enable recalculation of exposure estimates with modified conditions of use.

7.2 Structure of the ES for communication

An exposure scenario for communication consists of four sections:

- **Section 1: Title section.** This section provides an overview on the use addressed in the exposure scenario, by reporting the main elements of the use description: name of the use, of the contributing scenarios (and their relevant use descriptor and SPERC/SWED/SCED used if applicable), as well as information on the relevant market (sector of use, product category).
- **Section 2: Conditions of use affecting exposure.** This section contains the operational conditions and the risk management measures for each of the contributing scenarios of the exposure scenario. Each contributing scenario may be structured with a number of sub-headlines labelling the different types of operational condition or risk management measures.
- **Section 3: Exposure estimation and reference to its source.** This section contains the exposure estimates and risk characterisation ratios, when available, for each contributing scenario and a corresponding reference to the exposure estimation method/tool applied.
- **Section 4: Guidance to DU to evaluate whether he works inside the boundaries set by the ES.** This section can be used to provide advice to downstream users on how the exposure estimates may be re-calculated based on modified input parameters on the condition of use.

Chesar generates the exposure scenario for communication

- In printable format (rtf): various options are offered to the user for some customisation of this print out, for example the possibility to:

- Include or exclude the ES sub-headings in section 2
- Prevent repetition of conditions of use which are the same for all the contributing scenarios within one use
- Include or exclude section 3⁶
- Select an EU language. Note that the content of the ES will only be translated if ECom standard phrases have been used and if translations of those phrases have been uploaded in Chesar.
- In ECom XML format to facilitate the automated transfer of the information into the receiving safety data sheet systems along the supply chain.


⁶ Section 3 cannot be added in case of substances assessed via assessment entity groups.

8. Box 6: Library

8.1 Purpose of the library in Chesar

Chesar contains an internal library of objects that are used within the chemical safety assessment. Such library aims to enable:

- The creation of assessment elements that are necessary for the assessment of substances in a Chesar format;
- The use of standard assessment elements in a consistent way across different assessments;
- The harmonisation in the description of the conditions of use;
- The exchange (import and export) of such objects among assessors.

 When installing Chesar, the library only contains built-in conditions of use, mainly needed for the plugged-in exposure tools. It is up to the assessor to populate and manage the content of his own library.

The objective of having a centralised library for the distributed version of Chesar is to facilitate harmonisation of assessments carried out within a given company. Also the exchange of library elements among users across companies should facilitate the harmonisation and efficiency of assessments.

Harmonisation will in particular be supported if industry associations “create” assessment elements in a Chesar format and make such elements (for example use maps) available to all registrants. This way the single registrants would not need to create all parts of their individual CSAs but will mainly work with imported elements.

8.2 Overview on the objects in the library

So far five objects can be managed in the library: conditions of use, SPERCs, SWEDs, SCEDs and standard phrases.

When creating objects in the library, metadata have to be defined. Such metadata are meant to facilitate the management of the library objects. For example, metadata is needed to facilitate the selection (including automatic pre-selection) of relevant objects for a given assessment case.

8.2.1 Conditions of use

In the context of Chesar, a **condition of use** is a condition or a measure driving the exposure of a substance to man or environment, e.g. the amount of substance used per day at a site, or local exhaust ventilation (LEV) installed at a work place. Conditions of use can have different characteristics, for example, they can be quantitative or qualitative by nature, or they can have an impact on one or more routes of release/exposure. Some conditions of use can take different values (e.g. the concentration of substance in a mixture, the level of room ventilation or the type of onsite waste water treatment). The conditions of use relevant for a given exposure estimation tool may be pre-defined by the tool, and thus the assessor only needs to select the appropriate values for his assessment case. In other cases, the assessor himself may need to select appropriate conditions of use from his library, or even create new conditions of use before he carries out his assessment.

A **condition of use template** is a set of information systematically characterising a

condition of use and defining the values it could take. Once created and ready for use, a condition of use template cannot be modified. If changes are needed, a new template needs to be created. One can start by making a copy of the previous template.

The Chesar library contains by default a set of built-in conditions of use template that

- are used in the exposure estimation tools plugged into Chesar: ECETOC TRA workers v3, ECETOC TRA consumers 3.1 and EUSES.
- are required by some of the most commonly used exposure estimation tools for workers: ART, MEASE, Stoffenmanager, EMKG tool.

8.2.2 Specific environmental release categories (SPERCs)

SPERCs are used for environmental assessment. A SPERC corresponds to a set of information describing specific conditions of use and the associated release estimates. The SPERC also contains information specifying which processes/activities it covers.

SPERCs are typically worked out by downstream user organisations in order to describe the typical conditions of use in their sector. This supports the registrants to make realistic assumptions on the conditions of use for their assessment. With Chesar, sectors can generate SPERCs in a Chesar importable format and integrate them into their use maps.

8.2.3 Sector-specific workers exposure descriptions (SWEDs)

SWEDs are used for workers assessment. A SWED is a set of conditions of use (operational conditions and risk management measures) for activities carried out by workers. Those conditions are reported in a way which facilitates their use for exposure estimation by exposure tools such as ECETOC TRA.

SWEDs are typically worked out by downstream user organisations in order to describe the typical conditions of use in their sector. This supports the registrants to make realistic assumptions on the conditions of use for their assessment. With Chesar, sectors can generate SWEDs in a Chesar importable format and integrate them into use maps.

8.2.4 Specific consumer exposure determinants (SCEDs)

SCEDs are used for consumer assessment. A SCED is a set of information predefining consumer exposure determinants. A SCED also contains information specifying the product it covers.

SCEDs are typically worked out by downstream user organisations; more specifically by those, whose members formulate mixtures which are used as finished products by consumers. They describe the typical conditions of use related to a certain product type (habits and practices). This supports the registrants to make realistic assumptions on the conditions of use for their assessment. With Chesar, sectors can generate SCEDs in a Chesar importable format and integrate them into their use maps.

8.2.5 Standard phrases

The information to be communicated via the exposure scenario in the extended safety data sheets (extended SDS) should be communicated in the form of standard phrases to enable translation into national languages.

In addition, there is an IT standard to convey the ES information between IT systems within the supply chain. This standard, called ESComXML, is only able to convey information reported in the form of ESCom standard phrases.

Consequently it is highly recommended to select standard phrases for exposure scenario or contributing scenario names as well as for conditions of use. For that, the assessor should import a library of standard phrases into his Chesar. ESCom phrase catalogue is updated every 6 months by ESCom and available in a Chesar compatible format at <https://cefic.org/guidance/reach-implementation/escom-package-guidance/>.

It is also possible to import translations of the ESCom phrase catalogue.

8.3 Managing library objects

In order to best support harmonisation on the description of the conditions of use across registrants, it is preferable that the SPERCs, SCEDs and SWEDs are developed in a Chesar format by the sector associations themselves. A short manual for sector organisations developing use maps, SPERCs, SCEDS and SWEDs is available in <https://chesar.echa.europa.eu/support/manuals-tutorials>.

As those may be updated regularly, it will be to each user of Chesar to manage its library, importing the new versions.

Functionalities exist in Chesar to support manual update (i.e. triggered by assessor action) of existing assessments on the basis of updated elements.

9. Specific case when assessment entities exist

In a standard safety assessment, the fate and effect properties of a substance are characterised by **one** set of values carried forward to the exposure assessment. However, there are cases where **more than one** set of values for the fate and effect properties may be needed. This may be the case for example for multi constituent substances (covering also the case of UVCBs or mono constituent substances containing impurity(ies) with different fate/hazard profile). Also, once placed on the market and used, the substance may undergo transformation processes, for example:

- A substance may undergo unintended transformation (e.g. chemical reaction)
 - Under the conditions of use, e.g. due to energy applied in the use process;
 - Subsequent to the use of the substance, in waste (water) treatment or in the environment.
- The substance is meant to react for delivering its technical function (including reaction when incorporated into an article);
- A downstream user changes, on purpose, the form or composition of the substance in order to modify (for technical reasons) its physical or chemical properties and places the new form/composition on the market, e.g. grinding bulk material into particulate, purification of the substance;

Such transformations on use may lead to exposure to a substance with different intrinsic properties. In particular, new hazards for human health and/or the environment may occur or the hazard may disappear, and/or environmental fate properties may change. More guidance is provided in the guidance on chemical safety assessment part D: Framework for exposure assessment (see <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>).

9.1 Assessment entities in IUCLID

When preparing a registration (and potentially building up the testing strategy) an assessor should ensure consistency between the composition/form of the substance placed on the market, the conditions under which the substance will be used and the information to determine the properties of this composition/form.

When more than one fate/hazard profile is relevant for a substance, **assessment entities** should be defined in IUCLID. Assessment entities aim to support a transparent organisation of assessment data in IUCLID for substances with a more complex chemistry. The assessment entity is a wrapper [container] for a set of substance property data used for assessment purpose across all endpoints. It enables the assessor to define consistent datasets of properties that are relevant for specific compositions/forms (placed on the market or generated upon use). These datasets are then used to assess the substance over its life cycle, considering its chemical behaviour in the different foreseen uses. More information is provided in the manual *How to prepare registration and PPORD dossiers* (<http://echa.europa.eu/manuals>).

9.2 Approach in Chesar when assessment entities are defined in IUCLID

When assessment entities have been defined in IUCLID, the set of substance property data relevant for each of them is imported into Chesar.

In Chesar, the assessor needs to define for each contributing activity which assessment entities he wants to use to carry out the assessment. For this he needs to define assessment entity groups, i.e. assessment entities that go together per assessment. Such assessment entity groups may include one assessment entity or multiple entities.

An assessor may decide to only take into account one assessment entity per assessment for example:

- Assessment entities have been defined corresponding to various compositions of the substance having different hazard profiles, and these compositions are specific for certain type of uses: In such case the assessor would select one composition (and the related hazard characteristic) for assessing the contributing activities in the corresponding use.
- Two different assessment entities have been defined corresponding to the lead constituents in a UVCB driving the risk related to human health and the risk related to environment: In such case the assessor would select one assessment entity for all the contributing activities related to workers and the other one for all the contributing activities related to the environment.

An assessor may also decide to perform parallel assessments for several assessment entities. This means estimating exposure for several assessment entities under the conditions of use described in the contributing scenario. Such approach may be taken when, for example,

- Various (groups of) constituents, behave very differently leading to potentially very different levels of exposure in the various environmental compartments
- The substance transforms on use or in the environment and exposure occurs to both the parent and the transformation product(s).

The risk then has to be characterised on the basis of exposure estimates for several assessment entities. When a quantitative risk characterisation is to be carried out (because PNECs/DNELs have been derived for the various assessment entities), then the assessor may decide to sum up the risk characterisation ratios (RCRs) across all the assessment entities. Clear and transparent documentation of the approach taken is to be provided.

In order to support such assessment approach (workflow) in Chesar, the following functionalities are provided:

- In Box 1: creation of assessment entity groups (AEG). An AEG may be composed of one or more assessment entities. As many AEG as needed can be defined (for various uses, for various target groups, etc.)
- In Box 2: assignment of AEG to contributing activities. This step identifies which assessment entities have to be taken into account in the exposure assessment of each contributing activity.
- In Box 3: exposure estimation and risk characterisation for all assessment entities part of the AEG assigned to each contributing activity.
- In Box 4: all the information is transparently reported in the CSR

The functionality has not been yet implemented with regard to the communication down in the supply chain. This means that in such cases, the ES for communication will only be composed of section 1 (Title) and 2 (conditions for safe use).

10. Annex 1: Structure of section 9 and 10 of the CSR

The structure of the section 9 and 10 of the generated CSR is described below.

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0. Introduction

9.0.1. Overview on uses

9.0.2. Assessment entity groups

9.0.3. Introduction to the assessment for the environment

9.0.3.1. Tonnage

9.0.3.2. Scope and type of assessment for the environment

9.0.3.3. Fate and distribution parameters

9.0.3.4. Comments on assessment approach for the environment

9.0.3.5. Scope and type of assessment for man via environment

9.0.3.6. Comments on assessment approach for man via the environment

9.0.4. Introduction to the assessment for workers

9.0.4.1. Scope and type of assessment for workers

9.0.4.2. Comments on assessment approach for workers

9.0.5. Introduction to the assessment for consumers

9.0.5.1. Scope and type of assessment for consumers

9.0.5.2. Comments on assessment approach for consumers

9.1. Exposure scenario #: <Use.Type> - <Use.Name>

9.1.1. (9.x.i) Env CS i: <Contributing scenario label> (<ERC.code>)

9.1.1.1. Conditions of use

9.1.1.2. Releases

9.1.1.3. Exposure and risks for the environment and man via the environment

9.1.2. (9.x.j.) Worker CS j: <Contributing scenario. Name> (<PROC.code>)

9.1.2.1. Conditions of use

9.1.2.2. Exposure and risks for workers

9.1.3. (9.x.j.) Consumer CS j: <Contributing scenario. Name> (<PC.code> or <AC code>)

9.1.3.1. Conditions of use

9.1.3.2. Exposure and risks for consumers

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Human health

10.1.1. Workers

10.1.2. Consumers

10.2. Environment (combined for all emission sources)

10.2.1. All uses (regional scale)

10.2.1.1. Total releases

10.2.1. Regional assessment

10.2.3. Local exposure due to all widespread uses

10.2.4. Local exposure due to combined uses at a site

11. Annex 2: Glossary

Acronyms used in Chesar

AC	Article Category
C&L	Classification and Labelling
CSA/CSR	Chemical Safety Assessment / Chemical Safety Report
DNEL	Derived No Effect Level
DMEL	Derived Minimum Effect Level
ES	Exposure Scenario
ERC	Environmental Release Category
PBT	Persistent, Bioaccumulative, Toxic substance
PC	Product Category
PNEC	Predicted No Effect Concentration
PROC	Process Category
RCR	Risk characterisation ratio
SCED	Specific Consumer Exposure Determinant
SPERC	Specific Environmental Release Category
SDS	Safety Data Sheet
SWED	Sector-specific Workers Exposure Description
SU	Sector of Use
TRA	Targeted Risk Assessment
vPvB	very Persistent and very Bioaccumulative substance

Terms with a specific meaning in the context of Chesar

Article Category (AC): Characterises into which types of articles the substance is processed.

Chesar CSA: A CSA (chemical safety assessment) in Chesar consists of use description, exposure assessments and risk characterisations:

- A life cycle tree (description of uses) including all the contributing scenarios for the different uses to be assessed;
- For each contributing scenario: exposure estimates when relevant and risk characterisations per route of exposure and type of human health effect, and per environmental compartment respectively. These risk characterisations correspond to the conditions of use specified in each of the contributing scenario.

Chemical Product Category (PC): Characterises in which types of mixtures (including products with only one component) the substance is finally used, e.g. paints, lubricants, cleaners, adhesives.

Chesar substance: Chemical substance assessed with Chesar. The data elements associated with a Chesar substance are:

- A subset of substance intrinsic properties, imported from IUCLID and needed for the assessment;
- One or several Chesar CSAs.

Condition of use: a condition of use is a condition or measure driving the exposure of a substance to man or environment, e.g. the amount of substance used per day at a site, or local exhaust ventilation (LEV) installed at a work place.

Condition of use template: a condition of use template is a set of information systematically characterising a condition of use (including meta-data) and defining the values it could take.

CSA block: A CSA block is a use (or market sector) of a substance⁷ with all its contributing scenarios (or uses and contributing scenarios) and the related exposure estimates, exposure scenarios and risk characterisations. A CSA block can also consist of a single contributing scenario with its related exposure estimates, exposure scenarios and risk characterisation.

Environmental Release Category (ERC): Characterises the use from the environmental perspective.

Exposure estimation method: Exposure can be estimated by different exposure estimation tools (plugged in Chesar or not) or based on measured exposure data.

Exposure scenario (ES): An exposure scenario (ES) describes the conditions of use (operational conditions and risk management measures) suitable to control the risk (ensure safe use) for a certain use. One or more processes/activities may contribute to a use, and these processes are to be characterised in terms of human exposure and environmental exposure. The characterisations at process/activity level are called **contributing scenarios (CS)**. Each ES contains one or more CS related to environment and one or more CS related to human health (worker or consumer). Each CS contains a set of conditions of use for the environment or for human health. If such an activity can be carried out under different conditions within the use, two or more contributing scenarios will be built for the same process or activity.

IUCLID substance: Substance for which a IUCLID substance dataset has been created. Part of the information contained in a IUCLID substance dataset can be imported into Chesar and used as a starting point for the assessment.

Life cycle tree: All the uses are described in Chesar in the form of a so called life cycle tree. A life cycle tree can be exported and reused for describing the uses of other substances.

Life cycle stage: There are four basic steps in the life cycle of a substance: manufacture, formulation, end-use and (article) service life. It is assumed that manufacture and formulation always take place at industrial sites (few or many in a region). End-uses and (article) service life may take place in industrial sites (few or many in a region) and/or by professional workers (widespread, outside industrial sites) and/or consumers. Consequently, eight different types of uses are pre-defined in Chesar. These types of uses are called "life cycle stages". The consequences of this differentiation in terms of assessment are explained in more detail in section 5.3 of this

⁷ This may be the property profile of a virtual substance, for which Chesar then recalculates the assessment with the actual substance data, assumed the imported CSA building block has been generated with one of the exposure estimation tools plugged in to Chesar.

manual. Note: For further explanation on how to differentiate between uses at industrial sites and widespread uses by professional workers, see IR&CSA Guidance R.12, Appendix 12.3.

Main exposure dataset: Exposure dataset used for the risk characterisation.

PROcess Category (PROC): Characterises in which application techniques or process types the substance is applied (workers exposure perspective).

Quantitative condition of use: Enables the reporting of a condition of use in the form of a numerical value.

Qualitative condition of use: Enables the reporting of conditions of use in a qualitative way (text description). A qualitative condition of use template can define a single value or a group of potential values for the condition of use.

Release estimation method: The release to the environment can be estimated by different release estimation models (SPERCs, ERC based release factors or other release factors) or based on measured releases.

Release factor: The release factor is expressed in % and represents the fraction of substance released to a given release route.

- **Before on-site RMM:** This is the release factor usually provided by the release estimation model, not taking into account the effectiveness of additional risk management measures (RMM).
- **After on-site RMM:** This is the release factor once all on-site risk management measures have been applied (this excludes the effectiveness of the standard (municipal) biological STP calculated by EUSES). It corresponds to the overall release factor from the site.

Release rate:

- **Local:** The release rate is expressed in kg/day and corresponds to the amount of substance released over a day from a site or a standard municipality. When a release factor is provided, the release rate is equal to the release factor multiplied by the daily tonnage.
- **Regional:** The regional release rate corresponds to the overall release amount from the use to the region.

Risk characterisation for physicochemical hazards: If hazards to human health resulting from the physicochemical properties of the substance (flammability, explosiveness, oxidising potential) have been identified, the risk characterisation should justify that the severity and likelihood of adverse events is negligible. Such risk characterisation will make reference to the measures required to ensure the control of risk (reported in the exposure scenario or in section 9.0.4.2 of the CSR under “General information on risk management related to physicochemical hazards”).

Risk characterisation ratio (RCR): An RCR value can be calculated for each compartment (of the environment) or route/type of effect (for human health). It corresponds to the ratio between the estimated exposure value for the given compartment or route/type of effect and the corresponding hazard threshold (PNEC or DNEL) value.

RMM with effectiveness: Enables the reporting of risk management measures (text description) with a numerical effectiveness value. An RMM with effectiveness condition of use template can define a single value or a group of potential values for the RMM.

SCEDs: Specific Consumer Exposure Determinants are used for consumer assessments. They inform on conditions of use for consumer products, i.e. habits and practices of how consumers actually use the products as well as assumptions on the product design that can influence the assessment, using primarily Tier 1 exposure models such as the ECETOC TRA. A SCED contains information for one type of product or article.

SDS ES (safety data sheet exposure scenario): Annex to the extended safety data sheet that is used to communicate the conditions of safe use of substances. There is an SDS ES item for each use of the substance life cycle. An SDS ES has four sections (as described in section 7.2 of this document). The information contained in the SDS ES may be expressed in standard phrases. The use of standard phrases will facilitate the exchange and processing of the information.

Scope of assessment: Covers both the scope of exposure assessment (i.e. whether exposure assessment is expected for a route of exposure, type of human health effect and/or environmental compartment) and the type of risk characterisation required:

- **Quantitative** risk characterisation: is performed when a DNEL or PNEC is available and a risk characterisation ratio (RCR) can be derived i.e. the ratio between predicted exposure and a predicted effect threshold.
- **Qualitative** risk characterisation: is performed when hazards have been identified, but no DNEL/PNEC is available. It consists of a qualitative argumentation that the likelihood and extent of exposure is negligible compared to the level of hazard identified. For PBT substances (or substances assessed as if they were a PBT) a specific qualitative assessment is also performed for the environment.
- **Semi-quantitative** risk characterisation: is performed when hazards have been identified but no DNEL/PNEC is available. It consists of a qualitative argumentation which is however supported by a comparison of predicted exposure against a threshold different than a DNEL.

Sector of Use (SU): Characterises in which sector of the economy the substance is used, e.g. manufacture of rubber products or building and construction works.

SPERCs: Specific Environmental Release Categories are used for environmental assessments. They describe specific conditions of use and the corresponding release estimates (to water, air, soil, and waste). They are typically developed to refine the emission estimates obtained by using the Environmental Release Categories (ERC) release factors.

Supportive exposure dataset: Exposure dataset which is reported in the exposure estimation used as supportive information in the risk characterisation. The assessor must make sure that the conditions of use under which this dataset was obtained corresponds to the exposure scenario and the related main exposure dataset. These conditions are not reported in exposure scenario.

SWEDs: Sector-specific Workers Exposure Descriptions inform on conditions of use (operational conditions and risk management measures) for activities carried out by workers. They can be used as input to exposure estimation tools.

Technical Function: Characterises what the substance technically does in a mixture or an article, e.g. flame retardant, antioxidant.

Type of effect: In the context of hazard assessment for human health the term refers to both duration of exposure (acute/short term and long-term) and local or systemic effects. The hazard has to be assessed for all exposure routes and types of effects, and if some hazard is identified an exposure assessment and risk characterisation are to be

carried out.

Use: One or more uses can take place per life cycle stage. A use is defined by the similarity of activities or processes carried out by a defined group of actors in the market. A use consists of one or more **contributing activities (CA)** related to the environment and one or more contributing activities related to workers or consumers.

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