

## Release notes Chesar 3.5

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## 1. What is new in Chesar 3.5

Chesar 3.5 implements a number of new features, as well as changes and improvements to existing features, described below. Chesar 3.5 is compatible both with IUCLID 6.3 and IUCLID 6.4. However, the new functionality described below related to the pre-filling of section 13 will not work with IUCLID 6.3 and therefore the full compatibility is only ensured with IUCLID 6.4.

### 1.1. Alignment with IUCLID

The following format change in IUCLID 6.4, affecting Chesar, has been incorporated in Chesar 3.5:

- In the endpoint summary 5.2.1 "Biodegradation in water: screening tests" the picklist entry for the field "Biodegradation in water" was changed from "under test conditions no biodegradation observed" to "not biodegradable".

In addition, the following improvements in the communication with IUCLID 6.4 have been implemented in Chesar 3.5:

- Section 13 of IUCLID can now be pre-filled by Chesar 3.5 as an optional step when generating the full CSR from Chesar (see [section 1.6](#) for more details).
- The generation of the full CSR takes into account all the improvements implemented in IUCLID 6.4 (part B sections 1-8).

### 1.2. Substance management

Substantial changes have been implemented in Chesar 3.5 in relation to the management of substances in box 1:

- Creation of a substance in Chesar. For all substances created in Chesar, as no corresponding IUCLID substance dataset is available, there is no possibility to export uses to IUCLID or generate a full CSR. There is no possibility to create a link between a substance created in Chesar and an existing IUCLID substance dataset.
- The editability has been extended to cover all substance properties as well as the hazard conclusions in box 1 for all substances available in Chesar (both created and imported from IUCLID)

Note that for REACH registrations, importing substances from IUCLID and maintaining their substance properties there, is always the preferred option and the only way to generate a complete CSR.

In the overview of hazard conclusions and scope of assessment, a protection target has been added for man via environment - inhalation local long term. An assessment for this is only needed if a corresponding DNEL has been identified.

### 1.3. Use description

Some small changes have been made to the messages displayed when clicking on the "Information on life cycle tree" button:

- A new message has been added to warn you when for a use the tonnage field is left empty.
- The calculation of the sum of the tonnages of all end uses (which is compared to the tonnage identified to be assessed) has been corrected. Contrary to the previous version, Chesar 3.5 now correctly accounts also for the end uses included under a use map and/or market sector.

## 1.4. Exposure assessment

Chesar 3.5 allows the user to define the status of a dataset (i.e. main, supportive, not used) within an assessment at the moment of the dataset creation. This possibility is offered when creating any consumers/workers/environment exposure dataset.

### 1.4.1. Environment

For non-widespread uses, a new picklist has been introduced in the environmental contributing scenarios to determine and provide insight on the basis for the daily use amount at site. Chesar 3.5 allows the calculation of the daily use amount at site not only based on the default (based on the tonnage identified in box 2 or in an associated SPERC) or manually entered information, which were already available, but also offers the possibility to calculate MSafe, as explained in the embedded help text.

The **MSafe** is the maximum daily amount that can be used safely at a site, leading to an RCR of 1 for the critical compartment (i.e. the compartment with the highest RCR).

The possibility to calculate an MSafe value is available for environmental contributing scenarios which take place at a site for substances containing no assessment entities. The MSafe is calculated per environmental contributing scenario, based on the *daily use amount at site* and the highest RCR (i.e. the RCR for the critical compartment) in that scenario before the MSafe calculation is initiated.

MSafe is calculated only if:

- all compartments have EUSES as main dataset at both local and regional scale **and**
- the critical compartment is any of the following:
  - fresh water
  - fresh water sediment
  - marine water
  - marine water sediment
  - soil

For the remaining protection targets (i.e. secondary poisoning, air, man via environment) the PEC and therefore the RCR depends on the annual use amount and the calculation of MSafe has not been implemented.

In some cases the MSafe calculation may not be accurate. These are the cases in which the release to air is driving the exposure (which is related to the annual use amount and not the daily use amount) and can occur for example when there is release to air and no release to waste water.

Regardless of the selected option for calculating the daily use amount at a site (and consequently of the annual amount at a site), note that in case the calculations (or the previously manually entered values in Chesar 3.4) lead to a daily and/or annual use amount at site which is higher than the total tonnage for the use (as included in Box 2) multiplied by the percentage of EU tonnage used at regional scale, the respective amount(s) will be set equal to the Box 2 tonnage multiplied by the percentage of EU tonnage used at regional scale.

In Chesar 3.5, it is also possible to assess the newly added protection target for man via environment: the inhalation local long term protection target.

### 1.4.2. Workers

Chesar 3.5 introduces a change in the logic of calculating the workers exposure concentration when assessment entities exist.

This change has been introduced after analysing feedback received from Chesar users indicating that, for substances assessed via the assessment entity approach, the calculation of the workers exposure concentrations in previous versions of Chesar (until Chesar 3.4) was not in line with the principles of ECETOC TRA, leading to an underestimation of the exposure. After

a careful investigation, we decided to implement the change in the ECETOC TRA worker module of Chesar 3.5. Chesar 3.5 is now aligned with the exposure modifier approach for concentration as applied in ECETOC TRA. The change applied is described in detail in the FAQ "What is the difference between the calculations of workers exposure when assessment entity exists (parallel assessment) between Chesar 3.5 and previous versions of Chesar?" (<https://chesar.echa.europa.eu/support/frequently-asked-questions>).

As a consequence of this change, the TRA worker exposure estimates for complex substances done with previous versions of Chesar will change when upgrading to Chesar 3.5. The change may impact on the risk characterisation conclusions. Depending on the extent to which the risk characterisation has changed, you may need to update the operational conditions / risk management measures to demonstrate control of risk.

Chesar 3.5 is also extending the list of external workers exposure estimation tools to cover also ECPA OWB. In relation to that, a new built-in condition of use called "Daily application rate" has been added in the Chesar library.

### **1.5. Generation of ES for communication**

The new version of the ECom XML, version 2.1, has been incorporated in Chesar.

### **1.6. Generation of CSR**

When the generation of the full CSR is launched in Chesar, the user has the possibility to create a new record in IUCLID section 13.1 of the substance from which the synchronisation happens. In this new record Chesar attaches a PDF version (or .rtf version if this option has been selected) of the full CSR (under "Chemical safety report (CSR)") and pre-fills the relevant fields (Type of CSR, CSR contains and Chemical safety assessment/report tool used).

Moreover, Chesar 3.5 can also attach the export file of your assessed substance in Chesar format (.chr3) in the "Export file (safety assessment/exposure estimation tool)" field in IUCLID.

Both the creation of section 13.1 with the CSR attached as well as the transfer of the assessed substance file to IUCLID are not mandatory. You can also proceed with the generation of the full CSR in PDF or rtf format as usual without the creation of a new record in IUCLID section 13.1, by not selecting the options mentioned above.

Note that the new functionality to create a new record in IUCLID section 13.1 does not work when Chesar 3.5 is used in combination with IUCLID 6.3. Therefore, in this case, when the generation of the full CSR is launched in Chesar 3.5, the action will be performed only when the checkboxes for creating a new record in IUCLID section 13.1 and for attaching the Chesar file are not selected.

### **1.7. User management**

Chesar 3.5 allows the creation of a Legal entity. Please note that by creating a Legal entity and associating it to a username it will allow the user (using this username) to create elements in the Chesar library having that specific legal entity as the author.

### **1.8. General**

The help text has been updated to incorporate the new features and to explain the new functionalities.

Several small modifications to streamline and improve the meaning of the messages in box 1, 3, 4 and 6 have been applied.

The supporting software for both the desktop and server version of Chesar have been updated. More information can be found in the installation manuals.

## 2. Known issues

In the new picklist "Basis for daily use amount at site", if you switch from (the pre-selected) MSPERC to any other picklist value, the explanation (if present) associated to the daily use amount condition of use coming from the SPERC, is kept. As this explanation might not be accurate for the new selection, we recommend that you remove it. To do so, you will need to switch first to "Manually entered" and remove the explanation. Once removed, you can choose your preferred option.

When generating the full CSR and selecting the option "Create a new record in IUCLID section 13.1, prefill it with the relevant information and attach the CSR", the part A of your CSR will be missing from the generated full CSR if this information was not available in IUCLID before generating the CSR. To include the part A information in the full CSR generated by Chesar, it is recommended to first generate a record in section 13.1 containing this information before proceeding with the generation of the full CSR from Chesar.

In addition, the sections 9 and 10 of the PDF version of the CSR generated by Chesar may have some small formatting issues, overall when a long text is entered in the tables.

While being in the bulk edit mode and bulk adding an RMM by changing from the default value to the non-default value then the explanation for the CSR and SDS ES will be updated accordingly but the explanation(s) of the effectiveness (if available) will not be updated.

When adding a CoU to the ES subheading "Additional good practice advice. Obligations according to article 37(4) of REACH do not apply", if another value than the default value is selected, the information for the SDS ES will not be updated accordingly. This means that the information related to the default value will be displayed in Box 5 and included in the generated SDS ES.

### 2.1. Suggestions to best use Chesar 3.5

- Do not set your browser option so that it remembers your password. If you do so, in some cases, you may not be able to connect again as the encrypted password is then saved to your database.
- With some browsers you may be confronted to a slightly different user interface with no effect on the data. If an incorrect user interface is displayed, delete the browser history to get it back to normal.
- Our recommendation is to run Chesar 3.5 with IUCLID 6.4. If instead you decide to run Chesar 3.5 with IUCLID 6.3, be aware that the new functionality for generating the section 13.1 and attaching the CSR will not be available. For more details on the compatibility between different versions of IUCLID and Chesar, please refer to the FAQ "How can I check if Chesar is compatible with IUCLID?" available at <https://chesar.echa.europa.eu/support/frequently-asked-questions>