# DU ES Conformity Concept and Tool

## - An Approach for Scaling and a Simplified DU CSA -


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ENES 5, Brussels, 21 Nov 2013

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# Purpose of Concept and Tool

- Check of DU site conditions against (quantitative, TRA based) ES information received if not all OCs and RMMs of section 2 are implemented

  => facilitates adjustment calculations for DU own uses without requiring in-depth risk assessment expertise

- Can be extended to support systematic (quantitative, TRA based) consolidation of lead / risk driving substances‘ ES information into safe use information for mixture

  => can facilitate adjustment calculations for DU’s mixtures’ safe use information for communication

- Worker part technically identical with TRA version 2 and 3
- Supportive qualitative elements for workers can be included (ECHA Guidance Part E)
- ENV part still under development and represents a simplification of the complex multimedia models with pragmatic solutions

# Concept of the “DU ES Conformity Tool“

**Standardized Input Information**

- directly generated from ECETOC TRA =>consistent with assessment for CSR
- all relevant quantitative and scalable determinants in TRA standard format
- supplier RCRs ($RCR_{supp}$)
- maximum RCR not to be exceeded in scaling
- access via information in section 4 of eSDS (e.g. link to website)

ENV input data generated automatically as of TRAv3
Worker scaling data easy to extract from TRA

NOTE: EH&S systems not prepared for communicating such information

**Tool**

- Builds on **TRA based calculations and rules to define the boundaries of scaling**
- DU enters input information (ideally by copy/paste)
- Modifies determinants included in the tool to reflect his scanario
- Tool calculates the RCRs for DU modified scenario ($RCR_{DU}$)
- Tool compares $RCR_{DU}$ with boundaries for scaling

**Two possible Outcomes**

$RCR_{DU}$ within boundaries of scaling ?

Yes

No

**Print scaling documentation**
of ES compliance via scaling

**Print Simplified DU CSR** for DU records
**+ List of Scenarios to be notified to ECHA**

Simple or automated process to link to ECHA IT systems desirable

# Key Features of Concept and Tool

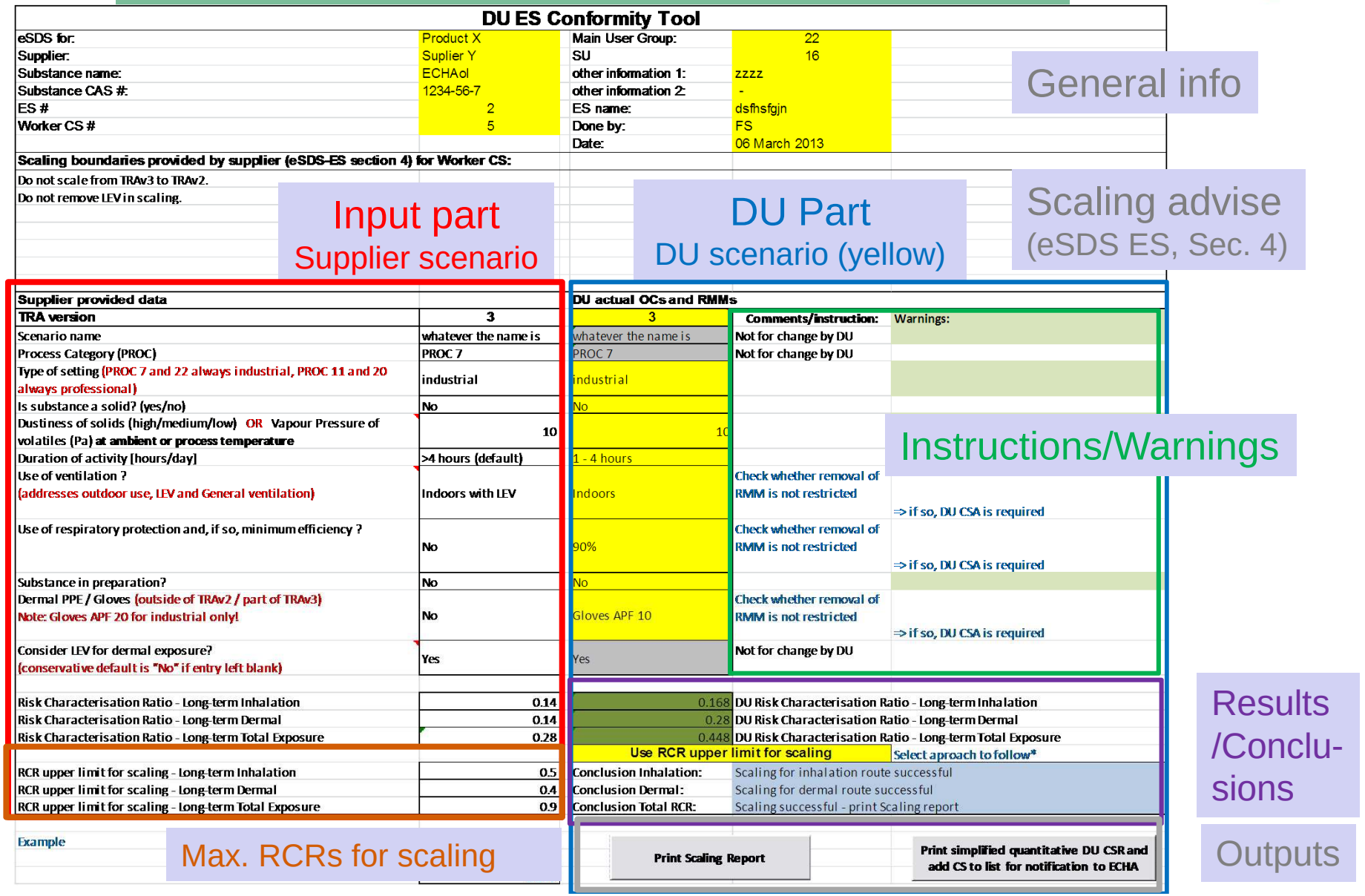
- Standardised data set of input parameters can be easily retrieved from Ecetoc TRA and ensures proper staring point for tool
- Working prototype for worker part available with one contributing scenario (CS) at a time – ENV under development
- ONE tool and same input for scaling and simplified DU CSA
  => easy to use one-page user interface
- Calculation based on the TRA algorithms and are used for scaling and simplified DU CSA
- Covers TRA versions 2 and 3 in one tool including “bridging” from v2 to v3
- Generally also applicable for CHESAR and EasyTRA
- All parameters are available for calculations incl. physical form, vapour pressure @ operating temperature
- Details of rules can still be modified for final version

# Principles Followed

- **Calculations are specific to the assessment tool / concept used for the exposure/risk assessment in the CSA/R**
  (e.g. same scaling rules for TRA, EasyTRA, Chesar)
- **Only the tool parameters (or a sub-set thereof) can be used**
  - Consistency ensured via standardised input parameters
- **For the environment, tool can only be used for point sources**
- **Quantitative adjustments are possible for all determinants:**
  - in the ES, either directly stated in eSDS-ES sections 2 and 4
  - included in calculation tool specified e.g. via reference to website(s)
  - unless limitations are provided to DU in eSDS-ES section 4
- **Setting boundaries of scaling is the responsibility of the registrant/supplier and can be done**
  - via standard phrases in section 4 (transfer to tool to include in reports)
  - by defining upper limits for $RCR_{DU}$
  - advise not to exceed $RCR_{Supp}$

  **=> Operating the tool beyond the boundaries => (simplified) DU CSA**

# User Interface for Worker (TRA)



**DU ES Conformity Tool**

| | | | |
|---|---|---|---|
| eSDS for: | Product X | Main User Group: | 22 |
| Supplier: | Suplier Y | SU | 16 |
| Substance name: | ECHAol | other information 1: | zzzz |
| Substance CAS #: | 1234-56-7 | other information 2: | - |
| ES # | 2 | ES name: | dsfhsfgjn |
| Worker CS # | 5 | Done by: | FS |
| | | Date: | 06 March 2013 |

**Scaling boundaries provided by supplier (eSDS-ES section 4) for Worker CS:**

Do not scale from TRAv3 to TRAv2.
Do not remove LEV in scaling.

General info

Input part
Supplier scenario

DU Part
DU scenario (yellow)

Scaling advise
(eSDS ES, Sec. 4)

| Supplier provided data | | DU actual OCs and RMMs | | |
|---|---|---|---|---|
| TRA version | 3 | 3 | Comments/instruction: | Warnings: |
| Scenario name | whatever the name is | whatever the name is | Not for change by DU | |
| Process Category (PROC) | PROC 7 | PROC 7 | Not for change by DU | |
| Type of setting (PROC 7 and 22 always industrial, PROC 11 and 20 always professional) | industrial | industrial | | |
| Is substance a solid? (yes/no) | No | No | | |
| Dustiness of solids (high/medium/low) OR Vapour Pressure of volatiles (Pa) at ambient or process temperature | 10 | 10 | | |
| Duration of activity [hours/day] | >4 hours (default) | 1 - 4 hours | | |
| Use of ventilation ? (addresses outdoor use, LEV and General ventilation) | Indoors with LEV | Indoors | Check whether removal of RMM is not restricted | => if so, DU CSA is required |
| Use of respiratory protection and, if so, minimum efficiency ? | No | 90% | Check whether removal of RMM is not restricted | => if so, DU CSA is required |
| Substance in preparation? | No | No | | |
| Dermal PPE / Gloves (outside of TRAv2 / part of TRAv3) Note: Gloves APF 20 for industrial only! | No | Gloves APF 10 | Check whether removal of RMM is not restricted | => if so, DU CSA is required |
| Consider LEV for dermal exposure? (conservative default is "No" if entry left blank) | Yes | Yes | Not for change by DU | |

Instructions/Warnings

| | | | |
|---|---|---|---|
| Risk Characterisation Ratio - Long-term Inhalation | 0.14 | 0.168 | DU Risk Characterisation Ratio - Long-term Inhalation |
| Risk Characterisation Ratio - Long-term Dermal | 0.14 | 0.28 | DU Risk Characterisation Ratio - Long-term Dermal |
| Risk Characterisation Ratio - Long-term Total Exposure | 0.28 | 0.448 | DU Risk Characterisation Ratio - Long-term Total Exposure |
| | | Use RCR upper limit for scaling | Select aproach to follow* |
| RCR upper limit for scaling - Long-term Inhalation | 0.5 | Conclusion Inhalation: | Scaling for inhalation route successful |
| RCR upper limit for scaling - Long-term Dermal | 0.4 | Conclusion Dermal: | Scaling for dermal route successful |
| RCR upper limit for scaling - Long-term Total Exposure | 0.9 | Conclusion Total RCR: | Scaling successful - print Scaling report |

Results /Conclu-sions

Example

Max. RCRs for scaling

Print Scaling Report

Print simplified quantitative DU CSR and add CS to list for notification to ECHA

Outputs

# User Interface for ENV (TRA)

**Environment**

| | |
|---|---|
| ES # | 2 |
| Environmental CS # | 1 |
| ERC: | ERC 2 |
| Scaling boundaries provided by supplier (eS | |

General info

Input part
Supplier scenario

DU Part
DU scenario (yellow)

Scaling advise
(eSDS ES, Sec. 4)

**SIMPLE ENVIRONMENTAL SCALING TOOL - "SENS" Tool (version 0.9)**

| | MI data (e.g. from TRA v3) | | DU actual OCs and RMMs | mandatory entries / optional entries |
|---|---|---|---|---|
| $M_{SPERC}$ or $M_{STE}$ (kg/d) | 200.0 | | 300 | |
| Receiving Water Dilution (Fresh or Marine) -or use receiving water flow rate in line 59 | 10 | | | |
| Wastewater treatment plant flow ($m^3$/d) | 2000 | | 2000 | |
| Receiving water body flow rate ($m^3$/d) -if no dilution factor is providede in line 57 | 18000 | | 38000 | |
| *Optional: Emission days per year* | *220* | | | |
| Onsite Removal Efficiency - Air (%) | 0 | | 50 | Check whether removal of RMM is not restricted => if so, DU CSA is required |
| Onsite Removal Efficiency - Wastewater (%) | 50 | | 60 | Check whether removal of RMM is not restricted => if so, DU CSA is required |
| Risk Driving Compartment (Code) | 2 | Water-driven | Water-driven | |
| $M_{SAFE}$ (kg/d) | 1314 | | 1111 | |
| Risk Driving RCR - Air compartment driven | 0.050 | | 0.0375 | DU Risk Characterisation Ratio - air driven compartments |
| Risk Driving RCR - Water compartment driven | 0.900 | | 0.2700 | DU Risk Characterisation Ratio - water driven compartments |
| RCR upper limit for scaling - Air driven | 0.800 | | Conclusion Air route: | Scaling for air route route successful |
| RCR upper limit for scaling - Water driven | 0.900 | | Conclusion Water Route: | Scaling for water route successful |
| | | | Overall conclusion: | Scaling successful - print Scaling report for ENV |
| *Assessment via daily release rates to compartments:* | | | | |
| *Release rate - Air (kg/day)* | *2* | | 1 | |
| *Release rate - Waste water (kg/day)* | *1* | | 1 | |
| *Release rate - soil (kg/day)* | *0.1* | | 0.01 | |

Instructions/Warnings

Results /Conclu-sions

*DRAFT - new element triggered by PEG discussions - to be discussed/elaborated*

**NOTE: This tool assumes that a municipal STP is requested and you are connected to a municipal STP. If you are not, please use the GEST tool for advanced scaling.**

*Risk-driving Compartment Number Code:*

1 - Wastewater Treatment Plant Microbes; 2 - Freshwater; 3 - Freshwater Sediment; 4 - Freshwater Secondary Poisoning;
5 - Marine Water; 6 - Marine Sediment; 7 - Marine Secondary Poisoning; 8 - Soil; 9 - Terrestrial Secondary Poisoning;
10 - Humans via Indirect Exposure (primarily inhalation); 11 - Humans via Indirect Exposure (primarily ingestion)

Max. RCRs

Print Scaling Report for ENV

Print simplified DU CSR for ENV and add CS to list for notification to ECHA

Output

# Next Steps

- **Alignment on rules to define boundaries of scaling (worker and environment)**
  **=> transition to “simplified DU CSA” as ONE way doing a DU CSA**

- **Evaluation of additional options for simplified DU CSA beyond quantitative TRA worker calculations**
  - RMM hierarchy approach
  - Qualitative assessments (at least for eyes, etc.)
  - Measured data

- **Define set of notification information in case of DU CSA**

- **Explore options for simple notification process with ECHA**

- **Further explore application of concept in compilation of safe use information for mixtures**
  **=> extend input for multiple (risk driving) substances**

# OUTLOOK: Extension for Mixtures

## Modified DU ES Conformity Tool using multiple inputs

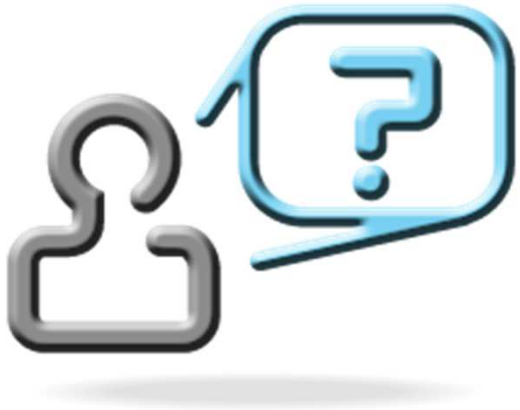
Two input columns: RDS Inh. + derm

Mixture parameters

| | Supplier Ocs and RMM for LS | | DU actual OCs and RMMs | |
|---|---|---|---|---|
| **Supplier provided data for** | **LS inhalation** | **LS dermal** | **Common parameters/conc. LS_I** | **concentration LS_Dermal** |
| **TRA version** | **3** | **3** | **3** | **Comments/instruction:** |
| Scenario name | whatever the name is | whatever the name is | whatever the name is | Not for change by DU |
| Process Category (PROC) | PROC 7 | PROC 7 | PROC 7 | Not for change by DU |
| Type of setting (PROC 7 and 22 always industrial, PROC 11 and 20 always professional) | industrial | industrial | industrial | |
| Is substance a solid? (yes/no) | No | No | No | |
| Dustiness of solids (high/medium/low) OR VP of volatiles (Pa) **at ambient or process temperature** | 10 | 10 | 10 | |
| Duration of activity [hours/day] | >4 hours (default) | >4 hours (default) | >4 hours (default) | |
| Use of ventilation ? (addresses outdoor use, LEV and General ventilation) | Indoors with LEV | Indoors | Indoors | Check whether removal of RMM is not restricted |
| Use of respiratory protection and, if so, minimum efficiency ? | No | No | 90% | Check whether removal of RMM is not restricted |
| Substance in preparation? | No | No | >25% | 5-25% |
| Dermal PPE / Gloves (outside of TRAv2 / part of TRAv3) Note: Gloves APF 20 for industrial only! | No | Gloves APF 5 | No | Check whether removal of RMM is not restricted |
| Consider LEV for dermal exposure? (conservative default is "No" if entry left blank) | Yes | Yes | Yes | Not for change by DU |
| | | | | |
| Risk Characterisation Ratio - Long-term Inhalation | 0.14 | 0.5 | 0.28 | DU Risk Characterisation Ratio - Long-term Inhalation |
| Risk Characterisation Ratio - Long-term Dermal | 0.14 | 0.1 | 0.3 | DU Risk Characterisation Ratio - Long-term Dermal |
| Risk Characterisation Ratio - Long-term Total Exposure | 0.28 | 0.6 | 0.58 | DU Risk Characterisation Ratio - Long-term Total Exposure |
| | | | **Use RCR upper limit for scaling** | |
| RCR upper limit for scaling - Long-term Inhalation | 0.5 | 0.5 | Conclusion Inhalation: | Scaling for inhalation route successful |
| RCR upper limit for scaling - Long-term Dermal | 0.4 | 0.4 | Conclusion Dermal: | Scaling for dermal route successful |
| RCR upper limit for scaling - Long-term Total Exposure | 0.9 | 0.9 | Conclusion Total RCR: | Scaling successful - print Scaling report |

# Questions ?

## An „appetizer“ only ...



## Thank you for your attention!

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