EUSES VERSION 2.1 | European Union System for the Evaluation of Substances
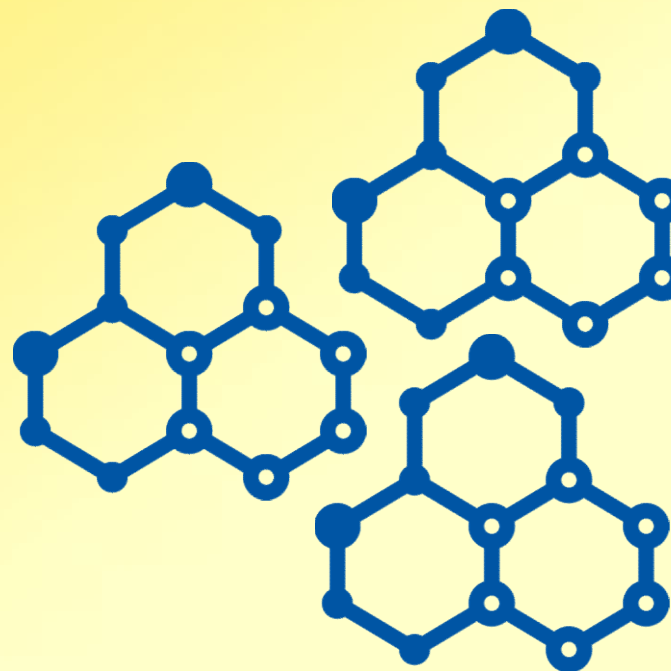
World Café

05 June 2018

Topics:

1. QSARs
17-18. Man via environment
25. Parallel assessment

1. QSAR

- Priority: OK
- Principles:
  - Option 4: remove QSARs from EUSES, allows user-input needed
  - Option 2: but
    - better guidance to user (decision tree embedded in EUSES)
    - Refinement e.g. log Kow cut-off, need pKa
    - Franco model: mono-valent, appl. domain, review or outdated?
    - Consider more recent CEFIC-LRI BCF model for ionizable substances + PPLFIR models for neutral organics
- Impact:
  - Assess reliability against measured
  - Expert group needed to decide on which model + develop guidance

17-18. Man Via Environment

- Priority: OK
- Principles: new additional considerations:
  - Parameterization local scenario (distance, 100% local consumption)
  - Update of food basket (EFSA)
  - Integrate biocide manure application (tbc)
  - Outcome needs: authorization (impact) versus risk
- Impact:
  - Assess whether it is worthwhile topic 17 (neutral org.)
  - Assess worthwhile food basket
  - Stakeholder group to agree on new scenario

25. Parallel assessment

- Priority: OK
- Principles:
    - Overall OK but for many "substances" need further consideration (not one model-fits-all)
    - User-friendly batch-modus; additional bonus: uncertainty and sensitivity analysis
    - IT dependent: need user-friendly parallel assessment in EUSES and as in CHESAR
    - For risk characterisation:
        - Flexibility on choice max RCR, sum of RCR, sum of selected RCR
        - For biocide mix, need import of trophic level hazard information
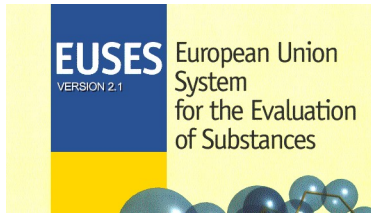
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Topics:

2. Relase scenarios
6. SimpleTreat
7. Sewer degradation
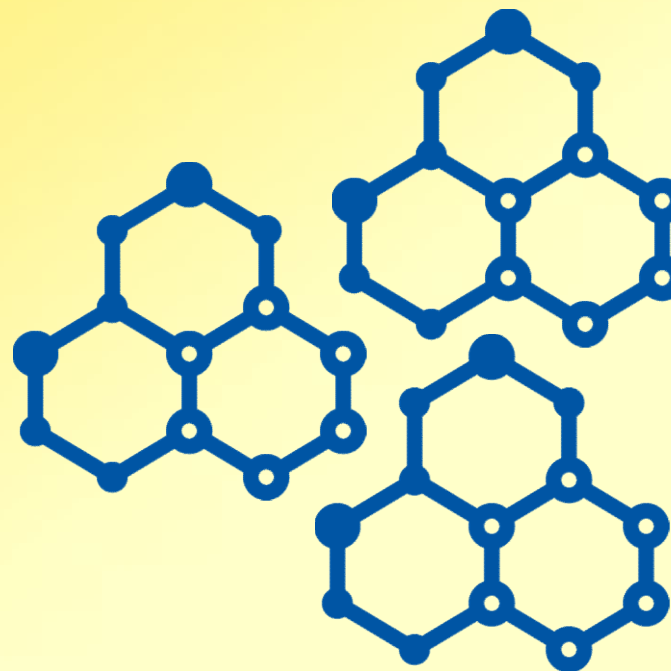
Topic 2 – Release scenarios

Do you agree with the priority assigned to the modification (if not to specify points of disagreement)?

- All groups agreed with priority assigned – important to be addressed

Topic 2 – Release scenarios

Do you agree with the principles of proposed modification?

- Including Spercs in EUSES: how to assure that correct data are included?

- **Easy way to change Spercs (=> not hard coded) in case of newly agreed values**

- ➢ **Same applies for biocides: should be easy to update since currently frequent changes/adaptations in scenarios**

- Direct release:
  - Specifically for co-formulants/additives release to soil is considered relevant (in addition also run off to surface water)
  - Reference was made to ECPA discussion for co-formulants in agrochemicals
  - Pesticide assumption: not all parameters applicable to REACH (e.g. sediment parameters)
  - **Some doubts were raised if biocides scenarios for direct release are applicable under REACH**
  - Biocides scenarios as refinement for conservative REACH approaches?

Topic 2 – Release scenarios

- More efforts to be done to make scenario more accessible for other legislation => before implementing something new, check what is in place for the other area in the future

- Different approaches are barrier between legislations

- Pharmaceutical scenarios (VETs) should be also included in EUSES

- Harmonisation needed since different spread sheets exists, should be but back in a common tool, speeding up process

- Biocides scenarios partly inconsistent, should be aligned

- Default values should be in general adjustable and not hard coded (to make refinements possible)

- Check carefully scenarios to be included in EUSES if developed for a specific substance group: are they really relevant in general also for other substances?
  - Possible solution: create specific EUSES sub-tools for specific substance groups (nanos, metals)

Topic 2 – Release scenarios

- vP substances are coming back, e.g. via groundwater => circular process in environment, however no link to release (covered by the background concentration?)
- Simple cross-use of scenarios should be carefully evaluated, why have scenarios been created, are they really applicable for other legislation
- Case by case decision: where is it sensible to apply scenarios cross-legal areas
- Every improvement of realism of scenario is considered helpful
- For REACH: certain data sets are missing to apply scenarios for biocides!
- Additives may be part in many biocides, therefore biocides scenarios are also considered relevant for these general chemicals since release pathway similar
- Applicability of consumption based scenarios to REACH, would require change in REACH thinking (partly to conservative)

Topic 2 – Release scenarios

How to carry out the "impact assessment" (sensitivity analysis) to decide on whether to implement the change?

- Impact is considered clear, compare with ERCS and Spercs – self explaining
- Does a change have really an impact on the protection goal
- Increase regulatory impact and costs for IND by potentially new data requirements
- How many uses and how many substances are used e.g. in co-formulants for which direct release would be assessed
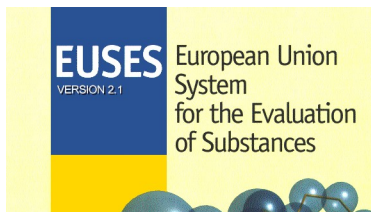
Topic 6 – SimpleTreat

Do you agree with the priority assigned to the modification (if not to specify points of disagreement)?

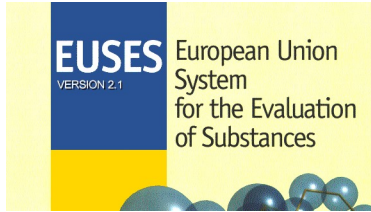- All groups agreed with priority assigned – important to be addressed

Topic 6 – SimpleTreat

Do you agree with the principles of proposed modification?

- **Industrial STP implemented in SimpleTreat 4 should also be included**
- Industrial version not yet downloadable from the Website
- See SETAC Rome (presentation/poster) validation exercise
- Big difference: temperature (sludge temp of 30 degrees in IND STP) and residence times
- SLR: Should be agreed before implementation (extend to European situation, not only based on one EU country)
  - Expert group to follow up
  - Look at research data which already exist EU wide/legal aspects on used data
  - Is the default value a medium or percentile?
  - Bioavailability factor to be considered
- Harmonisation between legislation and review default values for other parameters also in a broader context for REACH and Biocides - expert group to follow up?
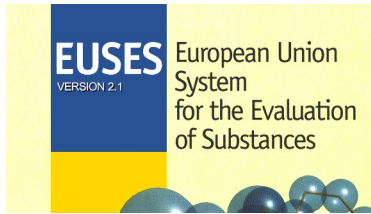
Topic 6 – SimpleTreat

- Old version should be accessible in EUSES as well (verification of „old" dossiers) – doubts expressed by other group if needed since SimpleTreat still available as stand alone tool
- Note that certain STP steps for specific industries (e.g. petrol) are not yet included in SimpleTreat
- Parameters should not be hard coded, should be possible to be changed (e.g. in case of side specific assessments)
- If you deviate from standard parameters should be highlighted in EUSES (implement a kind of side specific mode?)
- Probabilistic model instead of a deterministic model?
- Also degradation in sludge during storage before application to be considered (default value for storage time of stored sludge?)
- For hydrophobic chemicals additional removal processes to be taken into account

Topic 6 – SimpleTreat

How to carry out the "impact assessment" (sensitivity analysis) to decide on whether to implement the change?

- Compare with stand alone versions of SimpleTreat (work already done by some authorities, see UBA report/RIVM report, companies)
- Check if work was done for biocides is also relevant for REACH

Topic 7 – Sewer degradation

Do you agree with the priority assigned to the modification (if not to specify points of disagreement)?

- All groups agree with priority assigned – important to be addressed

Topic 7 – Sewer degradation

Do you agree with the principles of proposed modification?

- Technical challenge with regard to regions
- Is there a need for temperature correction: 12 degrees used for biocides in general acceptable?
- Is the residence time of 1 hour (biocides) acceptable? Expert group to follow up
- Incorporation in release module or fate and distribution module (i.e. STP): rather release module
- Reference was made to biocides, should be harmonised
- Taking into account degradation „twice" (biodegradation overestimated) /i.e. is kinetic description still correct: was not considered an issue since different substrate (mixing of sewer in STP with other substrates)
- **For 20% direct discharge very important to look at degradation in sewer => big impact for down the drain releases**

Topic 7 – Sewer degradation

- Should distance/residence time be handled flexible for REACH in case of side specific assessment (default parameter can always be overwritten if side specific assessment is done)
- Where to draw the line in what detail emission estimation should be considered (general structure of compartments to consider: sewer, STP, others? What about waste handling, recycling?) EUSES should be flexible enough to cover also potentially these –
- In relation to previous point:
  - waste treatment was not considered as that important by other group since waste treatment is very technospheric and differently handled.
  - Huge difference between MS
  - For biocides reference is made only to local waste legislation
- Mainly relevant for substances with DT50 less than one hour (taking into account the current default value agreed for biocides)
- Metabolites should be consequently assessed if substance degrades rapidly!

Topic 7 – Sewer degradation

- Already in SimpleTreat there was an increase of residence time
- Important for high volume chemicals which are very toxic to bacteria (important refinement)
- Is STP connection of 80% still relevant: for biocides is was increased to 90% based on new statistical data.
- Should non-connection of households to sewer be also taken into account? No since model city is considered where it is assumed that all houses are connected to sewer system (i.e. 100% connection)
- Rather considered relevant for wide dispersive uses

Topic 7 – Sewer degradation

How to carry out the "impact assessment" (sensitivity analysis) to decide on whether to implement the change?

- Change of software needs to be validated (e.g. based on already available biocides examples for rapidly reacting substances)
- CONCAWE project ongoing
- Check with detergents associations if monitoring data are available to compare model with
- Look at number of substances with a DT50 value less than one hour
- Look at sewer distributions in US / not clear if information is available in EU
- Check with hydrology labs on distance/time in the drain
- Check model complexity: are additional data needed?
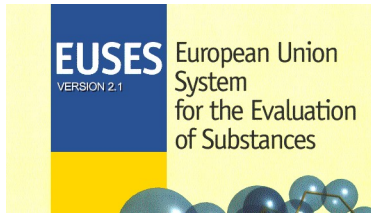
General comments

Impact assessment:

- Compare in principle cost/effort of change with regard to effect of change on the outcome of the risk assessment
- Impact assessment should be clustered, not looking only at one single changes/topics but overall picture of impact of clustered/all changes i.e. **holistic approach**

➢ ……Certain un-clarity what is meant with "Impact assessment" leading to different interpretations

Others:

- It was appreciated and considered important that ECHA took up EUSES including further developments in the future

- Harmonisation is **very** important!!!

- Example: e.g. each evaluation CA uses the same tool (ESD calculation sheets facilitated already mutual recognitions in some cases)
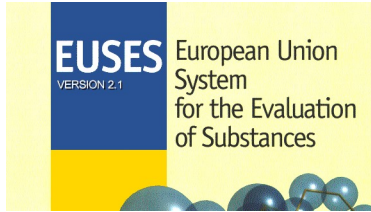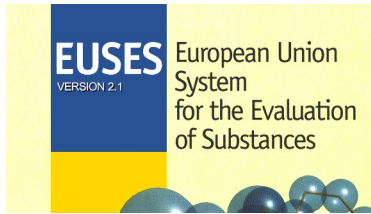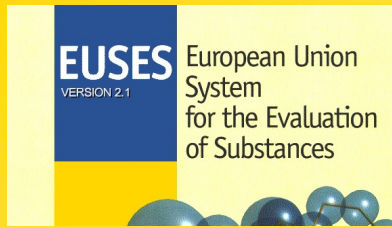
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Topics:
IT development
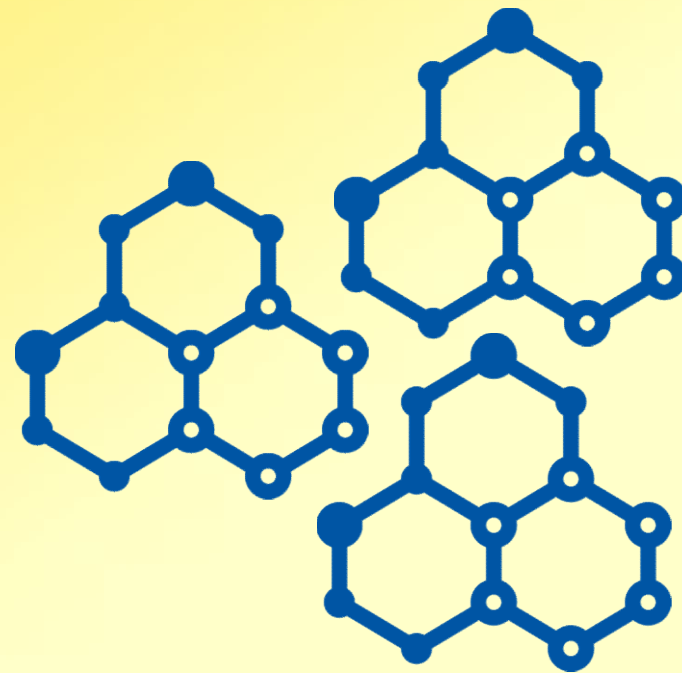
Where should most investment be made when updating EUSE

- Fix the bugs
- Make the tool more user friendly!
  - User interface more differentiated
  - See quicker the impact of changing a parameter (current workflow very long; RCR visualisation, more transparency)
  - Better support transparency when deviating from default (UI, explanation possibility, sensitivity: possibility to compare)
  - Support "tiering" approach
  - Save several version of the same assessment
  - Make applicability domain more transparent
  - Integrated help
- Update to account for recent scientific development:
- Extension for other substances
- Extension to other scenarios

EUSES
VERSION 2.1
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How EUSES should be used: own UI or integrated into Chesar

- Chesar contains a number of functionalities which are fit for purpose for EUSES
  - Reporting capacity (to be adapted to Biocides)
  - Connection to IUCLID
  - Tiering
  - UI more attractive
- BUT if EUSES would be made available via Chesar a number of changes would need to be implemented
  - Entering data directly (not via IUCLID)
  - Include ESDs from biocides
  - Make clear for which purpose the assessment is carried out (RECAH registration, biocide etc..)
  - Capacity to modify "all" data (including the capacity to change the definition of the environment e.g. US)
  - Capacity to see only the environmental aspects of the assessment (hide workers/consumers)
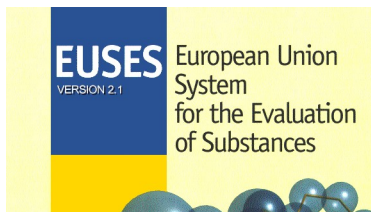
How should EUSES be distributed (local/on-line) + frequency of update

- On-line is the future! Easier to install and to update
  - Regular update would be good
- BUT
  - Security concern (fear of loosing control on data)
  - Need for internet:
    - No a problem anymore
    - Not always good/ Firewall
  - Need to keep the history (in case model/default changes)
- Need for distributed version
- Calculations should not be changed after version 3.0 (impact assessment critical). Only extensions
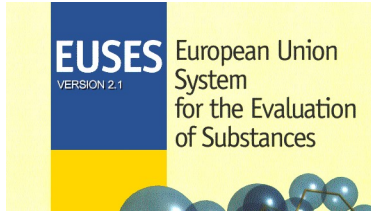
Should EUSES 3 calculation engine be open for re-use in other application

- Various views
- No need for several applications of the same tool
- Need to be able to connect for specific applications:
  - UK project GIS
  - Specific substances: Petrorisk
  - Batch running
- Make the code open source to enable modifications of calculation ?
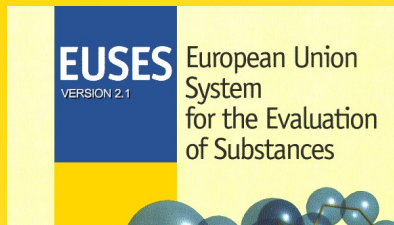
Thank you!

Email address if needed