Solvents Consumer Safety Assessment Tool, EGRETv2
Questions & Answers from the webinar held on 7th April 2016

A. List of questions raised

1. How is EGRET different from other consumer assessment tools?
2. Has EGRET been peer reviewed?
3. Will the assessment conducted with previous version of EGRET require to be updated?
4. Can EGRET be used in the ECHA's Chemical safety assessment and reporting tool Chesar?
5. Can EGRET be used with Specific Consumer Exposure Determinants (SCEDs) if available?
6. Can EGRET be used to assess consumer exposure to substances in articles?
7. Why are some cells in the tool locked?
8. Whether and how the assessment of infrequent exposures has been addressed in EGRET?
9. During the Partner Expert Group (PEG) consultation on ECHA's IR&CSA R15 Guidance revision in 2015-2016 the approach to the assessment of infrequent exposures from application of consumer products has considerably changed several times and no longer supports application of the frequency banding approach developed by ECETOC. What do you think about ECHA's proposed approaches and how are you going to take this into account since the annual use frequency of a product in EGRET v2 cannot be changed by users?
10. Does EGRET generate Exposure Scenarios? Are these ES for the CSR and not for communication?
11. Will the tool be able to model exposures from mixtures?
12. Could you specify what the target RCR's (0.9, 0.5, and 0.2) are based on?
13. Will the terminology in the tool change to align with ECHA? For example no 'Risk Management Measures' or 'Operational Conditions' but 'Conditions of use'?
14. Could you further clarify the reason behind having target RCRs? Are you considering the cumulative exposure?
15. Extending the exposure time will lower the exposure? The tool works counter intuitively for exposure duration in that extending the exposure time results in a lower exposure. I assume that the background of this is the amount use is assumed to instantly evaporate and the air exchange reduces total exposure over a longer period. However, this shows a limitation of the tool. Can you elaborate a bit more on this?
16. Modified exposure determinant for amount used of a coating included in cell AO25 is based on US EPA data and not EU data. Is this acceptability for EU Authorities?
17. Does EGRET consider the consumer exposure well controlled if RCR yearly <1, but RCR daily >1?
18. Do the presented OCs and RMMs in your example (row) 14, bring down also the RCR systemic (all routes, daily) below 1?

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B. Answers

1. *How is EGRET different from other consumer assessment tools?*

EGRET is a tier 1.5 consumer risk assessment tool. It maintains the quickness and ease of use of Tier 1 tools (e.g. TRA) while providing some refinement to exposure predictions and additional functionalities to meet REACH information requirements. Based on the ECETOC TRA consumer module (a tier 1 tool), in addition to refined parameter values , it includes scenarios beyond TRA to cover all scenarios in the ESIG consumer GES library. Additional functionalities to meet REACH requirements more efficiently include the capabilities to auto-populate RMMs for safe use conditions and auto- generate narratives with standard phrases for easy supply chain communication. These features also contribute to consistency in output across users.

2. *Has EGRET been peer reviewed?*

The development and evaluation of the tool has been published in a peer-reviewed journal (http://www.nature.com/jes/journal/v24/n1/full/jes2012128a.html). The tool has been widely used for 2010 REACH registrations. The CSAs developed using EGRET have undergone evaluations.

3. *Will the assessment conducted with previous version of EGRET require to be updated?*

Please refer to the "Updates" worksheet in the tool for details and potential updates of the assessment.

4. *Can EGRET be used in the ECHA's Chemical safety assessment and reporting tool Chesar?*

Currently, exposure predictions and use conditions from EGRET can be manually entered into Chesar for each exposure scenario separately. Automated import of EGRET assessment into Chesar via XML transfer files is being worked out. It is planned that the import of whole consumer GESs (i.e. multiple product use scenarios) will be possible.

5. *Can EGRET be used with Specific Consumer Exposure Determinants (SCEDs) if available?*

Some of the SCEDs data (both the parameter values and justifications) can be manually entered into EGRET to refine the exposure assessment. Please refer to the user manual for details on the parameters that can be modified with SCEDs data.

6. *Can EGRET be used to assess consumer exposure to substances in articles?*

No. Currently, EGRET can only be used to assess potential exposure from use of consumer products/formulations not articles.

7. *Why are some cells in the tool locked?*

A few cells (e.g. air exchange rate, room volume) in the EGRET exposure parameter table were protected to maintain the integrity of the tool in case users accidentally delete or change the cell content.

8. *Whether and how the assessment of infrequent exposures has been addressed in EGRET?*

The ECETOC TRA use frequency bands have been implemented in EGRET v.2.0 to enable the assessment of consumer exposure from infrequent events, when comparison with a long term systemic DNEL is needed. This frequency banding approach developed by ECETOC is a more conservative means than averaging based upon the actual frequency values (as in ConsExpo, E-FAST and the previous EGRET version).

9. *During the Partner Expert Group (PEG) consultation on ECHA's IR&CSA R15 Guidance revision in 2015-2016 the approach to the assessment of infrequent exposures from application of consumer products has considerably changed several times and no longer supports application of the frequency banding approach developed by ECETOC. What do you think about ECHA's proposed approaches and how are you going to take this into account since the annual use frequency of a product in EGRET v2 cannot be changed by users?*

ESIG is aware of the most recent IR&CSA R.15 Guidance updates made by ECHA to the assessment methodology for infrequent consumer uses and communicated to PEG member in February 2015 in a cross-check document. The changes introduced in the updated R.15 Guidance address the need to align temporal aspects of exposure and hazard benchmark used for risk characterization. Instead of adjusting the exposure side based on the ECETOC frequency banding approach, ECHA suggests adjustments to be done on the hazard side, i.e. to derive adjustment factors for short-term or/and infrequent exposure in chronic DNEL derivations. Detailed analysis will be carried out once the final version of the IR&CSA R.15 Guidance is officially released to investigate the impact of changes on risk characterization outcomes in EGRET.

10. *Does EGRET generate Exposure Scenarios? Are these ES for the CSR and not for communication?*

EGRET generates Exposure Scenarios (ES) in REACH format that is laid down in Annex II of REACH. The generated ESs can be copy-pasted directly into the Chemical Safety Reports (CSRs) and annexed to the extended Safety Data Sheets (eSDS) for communication to downstream users.

11. *Will the tool be able to model exposures from mixtures?*

ESIG does not plan to extend EGRET computational capabilities beyond the assessment of substances (e.g. to formulated mixtures). Complex substances (e.g. UVCBs) are considered under REACH as single substances and their hazard is characterized following the conventional approach

for individual chemical substances. Thus, the assessment in EGRET for UVCBs would be similar to that for mono-constituents.

12. *Could you specify what the target RCR's (0.9, 0.5, and 0.2) are based on?*

If the exposure levels are below the appropriate DNEL (derived no effect level) (i.e. RCR<1), the risk to human is considered to be controlled based on ECHA REACH guidance R15 (Consumer Exposure Assessment) and R8 (Risk characterization). The three target RCRs built in EGRET (0.9, 0.5, and 0.2) provide users additional flexibility. EGRET is positioned as a Tier 1+ screening assessment tool. The target RCR of 0.9 has been set as a default risk control level to provide extra conservativeness in any assessment conducted in EGRET.

13. *Will the terminology in the tool change to align with ECHA? For example no 'Risk Management Measures' or 'Operational Conditions' but 'Conditions of use'?*

The terminologies of operational conditions (OCs) and risk management measures (RMMs) used in EGRET are consistent with ECHA definitions provided in R.12 Use Description and R15 Consumer exposure assessment guidance documents. "Conditions of use" is a general term used to describe either the typical use conditions (i.e. OCs) or additional controls (i.e. RMMs) required ensuring a safe use condition.

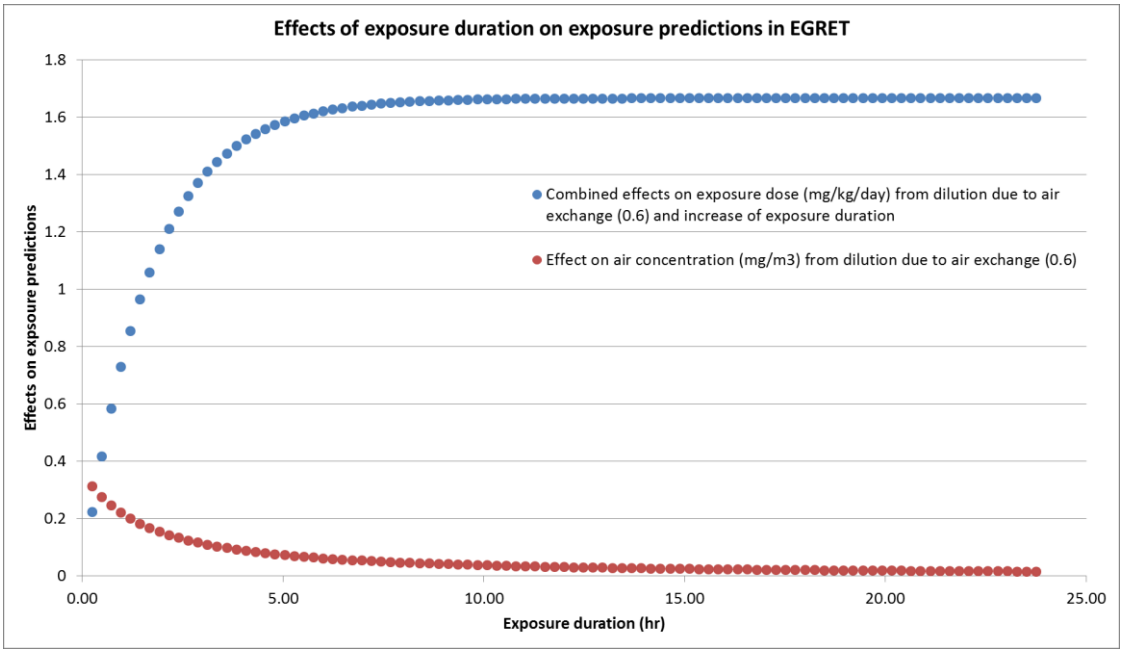
14. *Could you further clarify the reason behind having target RCRs? Are you considering the cumulative1 exposure?*

This feature was not added to intentionally address cumulative or aggregate exposures specifically. The risk control banding approach in EGRET v.2.0 was enhanced with a target RCR drop-down menu option. This was done to enable the tool's user to have greater flexibility in providing safety margins while maintaining automated selection of RMMs. The RMM autopopulation feature as implemented in EGRET is based upon comparison of the total RCR, summed across exposure routes for a given scenario, to the DNEL. More stringent RCR target values embedded in EGRET as compared to a traditional safe use indicator of RCR=1 may be used when there are concerns with regards to uncertainty in exposure estimates or when e.g. aggregate exposure (i.e. exposure to a single substance from multiple sources) needs to be evaluated.

[1] ESIG adheres to the WHO/IPCS Framework terminology for aggregate and cumulative exposure and risk definitions, which are as follows:
Aggregate exposure: The demographic, spatial and temporal characteristics of exposure to a single chemical through all relevant pathways (e.g. food, water, residential uses, occupational) and routes (e.g. oral, dermal, inhalation). **Aggregate risk** is the risk associated with multiple pathways/routes of exposure to a single chemical.
Cumulative exposure: the aggregate exposure (see above) to multiple chemicals. **Cumulative risk** is the combined risk from aggregate exposure to multiple chemicals (and may be restricted to chemicals that have a common mechanism of toxicity).

15. *Extending the exposure time will lower the exposure? The tool works counter intuitively for exposure duration in that extending the exposure time results in a lower exposure. I assume that the background of this is the amount use is assumed to instantly evaporate and the air exchange reduces total exposure over a longer period. However, this shows a limitation of the tool. Can you elaborate a bit more on this?*

Inhalation exposure predictions have been expressed in two units in EGRET: air concentration in mg/m3 (to be consistent with unit of inhalation DNEL used in REACH) and external dose in mg/kg/day. Similar to TRA, EGRET estimates worst-case air concentration (mg/m3) by assuming that the substance applied is released into air instantaneously (regardless of exposure duration). The maximum air concentration that can be achieved, however is capped by the saturated vapor concentration limit. The dilution due to air exchange ($dilution\ effect = \frac{\int_0^t e^{-air\ exchange * t} dt}{t}$) is introduced to refine this worst-case air concentration estimation. The total external dose (mg/kg/day) an individual receives, however will depend on the exposure duration directly and also the dilution due to air exchange. The combined effect of both factors ($combined\ effect = \frac{\int_0^t e^{-air\ exchange * t} dt}{t} * t$) on the external dose (mg/kg/day) is an increasing function, i.e. the external dose will increase with the exposure duration. The figure below simulates the effects of exposure duration on two types of exposure predictions (external dose in mg/kg/day, air concentration in mg/m3).



Modified exposure determinant for amount used of a coating included in cell AO25 is based on US EPA data and not EU data. Is this acceptability for EU Authorities?

16. *Modified exposure determinant for amount used of a coating included in cell AO25 is based on US EPA data and not EU data. Is this acceptability for EU Authorities?*

EGRET is thought of as a Tier 1+ consumer exposure model. The default parameters in EGRET were refined based on the review of available research data from peer-reviewed literature and databases on consumer products use. Each of the exposure scenarios was developed by considering the scenario as a whole to be conservative.

The EGRET has been published in a peer-reviewed journal: Journal of Exposure Science and Environmental Epidemiology together with tool evaluation results from various exposure scenarios (accessible at http://www.nature.com/jes/journal/v24/n1/full/jes2012128a.html). The tool has been widely used for 2010 REACH registrations.

17. *Does EGRET consider the consumer exposure well controlled if RCR yearly <1, but RCR daily >1?*

It depends on the health endpoint of the substance to be assessed. If the substance is classified for its chronic effects, the daily RCR <1 will indicate this risk is controlled based on REACH guidance. If the daily RCR>1 and the exposure event occurs less than once per week, a chronic RCR will be calculated in accordance with the use frequency banding approach. If the resulted chronic RCR is below 1, the risk will be controlled.

18. *Do the presented OCs and RMMs in your example (row) 14, bring down also the RCR systemic (all routes, daily) below 1?*

The example used in the demo (row 14) is PC1 glue DIY-use scenario. The RMMs introduced will bring down the total RCR for all routes (chronic) below 0.5 (in this hypothetical example, the target RCR = 0.5), not the total RCR on day of use.

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