

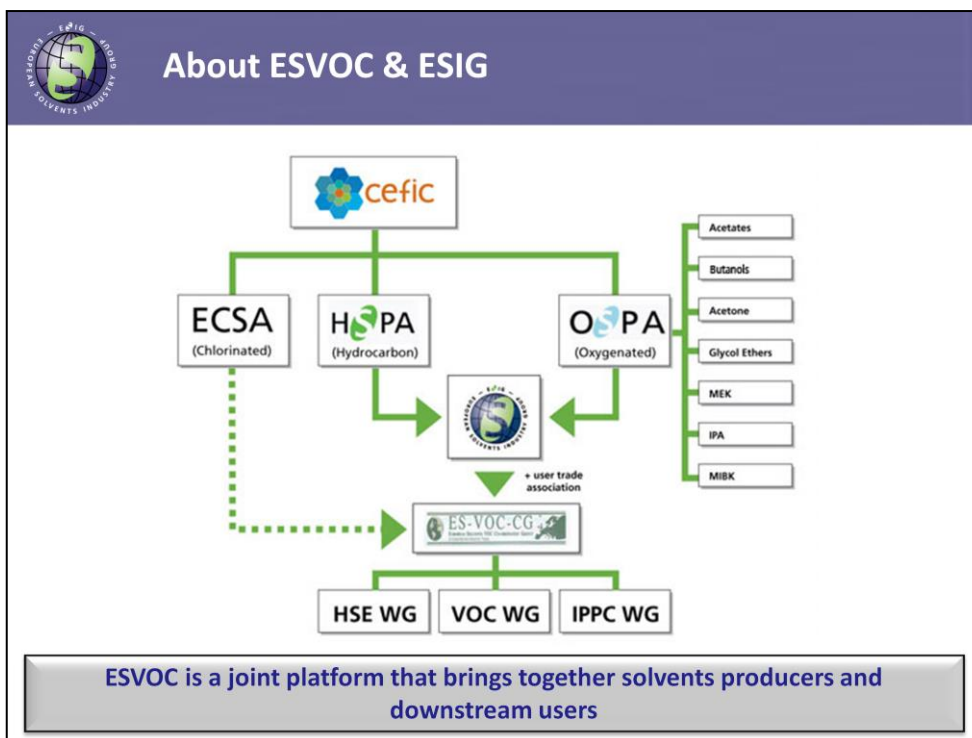


The European Solvents Industry Group
(ESIG) welcomes you to this webinar
on:

‘Safety Assessment of solvents for
consumer use with EGRET V2’

Brussels April 7th, 2016
Starting time 15:00 CET

1



This chart provides a little bit more background on the EU Solvent Industry Group (ESIG), the sponsor for development of the EGRET tool. ESIG is a joint activity of Oxygenated and Hydrocarbon Solvents Producers Association, i.e. two sector groups of The European Chemical Industry Council (CEFIC).



ESIG Members

	HSPA: 11 members	OSPA: 21 members	
	<ul style="list-style-type: none"> Cepsa Química 	<ul style="list-style-type: none"> Arkema 	
	<ul style="list-style-type: none"> DHC Solvent Chemie 	<ul style="list-style-type: none"> BASF 	
	<ul style="list-style-type: none"> Dow Haltermann 	<ul style="list-style-type: none"> Borealis 	
	<ul style="list-style-type: none"> ExxonMobil 	<ul style="list-style-type: none"> Celanese 	
	<ul style="list-style-type: none"> Galp 	<ul style="list-style-type: none"> Cepsa Química 	
	<ul style="list-style-type: none"> Hellenic Petroleum 	<ul style="list-style-type: none"> Clariant 	
	<ul style="list-style-type: none"> Neste Oil 	<ul style="list-style-type: none"> Domo 	
	<ul style="list-style-type: none"> Petrochem Carless 	<ul style="list-style-type: none"> Dow 	
	<ul style="list-style-type: none"> Sasol Italy 	<ul style="list-style-type: none"> Eastman 	
	<ul style="list-style-type: none"> Shell Chemicals 	<ul style="list-style-type: none"> ExxonMobil 	
	<ul style="list-style-type: none"> Total Fluides 	<ul style="list-style-type: none"> Ineos Oxide 	
		<ul style="list-style-type: none"> Ineos Phenolchemie 	
		<ul style="list-style-type: none"> LyondellBasell 	
		<ul style="list-style-type: none"> Oxea Chemicals 	
		<ul style="list-style-type: none"> Oxochimie 	
		<ul style="list-style-type: none"> Perstorp 	
		<ul style="list-style-type: none"> Polimeri Europa 	
		<ul style="list-style-type: none"> Novacap 	
		<ul style="list-style-type: none"> Sasol 	
		<ul style="list-style-type: none"> Sekab 	
		<ul style="list-style-type: none"> Shell Chemicals 	

Most of ESIG members are global chemicals players

ESIG brings together Europe's major solvents producers, most of which are global chemical players.



EGRET version 2

- A Tier 1.5 Consumer Risk Assessment Tool

Tatsiana (Tanya) Dudzina
Rosemary T. Zaleski
Hua Qian

ESIG webinar on Safety Assessment of Solvents for Consumer Use
April 07, 2016

4

Good afternoon ladies and gentlemen.

Thank you for joining us today. My name is Tanya Dudzina, and I am an exposure scientist with a vast experience in consumer and worker exposure modelling predominantly for regulatory risk assessment.

Today I will be giving an introductory presentation on the updated version of EGRET consumer exposure and risk assessment model.

The tool was specifically developed for solvents by the European Solvent Industry Group in a format consistent with the concept of Generic Exposure Scenarios.

The model is positioned as a Tier 1+ tool that falls in between the worst-case scenario low tier tools like ECETOC TRA and more sophisticated higher tier models such as ConsExpo.



Outline


- Introduction
 - What is EGRET?
 - Why EGRET?
 - Tool snapshots
 - Technical details
 - Tool recognition
- New features in Version 2
- Demo
- Summary
- Future plans

5

The presentation will start with some background information on the tool development, and then will go on to introduce the new features that have been implemented in its second version.

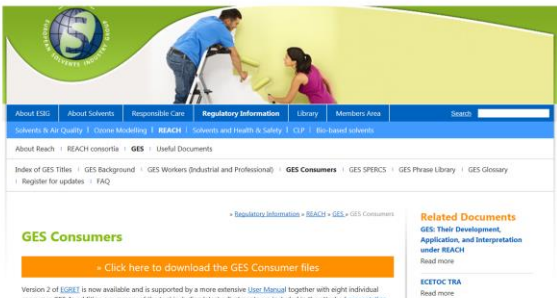
Afterwards, we will have a about 15 minutes live demonstration session, followed by a quick wrap up and future plans outline.


At the end of the presentation there will be half an hour Q&As session.



Introduction

- What is EGRET?
 - The European Solvents Industry Group (ESIG) Generic Exposure Scenario (GES) Risk and Exposure Tool (EGRET)
 - A tier 1.5 risk assessment Excel-based tool for consumer exposure assessment under REACH
 - Called “ESIG GES consumer tool” when it was released in July 10, 2010
 - Available for free at: <http://www.esig.org/en/regulatory-information/reach/ges-library/consumer-gess>





EGRET 2 master template Nov 2015 updated.xls

6

Next slide highlights basic things the user needs to know about EGRET.

The EGRET acronym stands for the European Solvents Industry Group (ESIG) Generic Exposure Scenario (GES) Risk and Exposure Tool.

It is an Excel spreadsheet-based model developed by ESIG to support European manufacturers and importers of chemical substances in the development of Exposure Scenarios for REACH registrations.

As you might have noticed EGRET naming contains reference to the generic exposure scenarios or GES. This is the concept that has been developed by ESIG in cooperation with downstream user associations shortly after REACH came into force in 2007. The idea was to develop a generic approach for exposure assessment that would address the variety of solvents on the market and their diverse applications as well as to enable harmonized communication of safe use conditions throughout the supply chain.

An individual GES title links multiple related individual product exposure scenarios into one overall larger category (e.g. Coatings GES that contains individual product scenarios including spray paint, hobby glues, and other related products). Such a grouping enables same individual product use scenarios to be used for every GES they might be relevant. What is more important, it provides greater consistency in exposure and risk assessment among different users of the tool.

Later in 2010 ESIG sponsored the development of a consumer exposure modelling tool that was based upon the ECETOC TRA consumer module. The tool was named “ESIG GES consumer tool” to reflect the fact that it adopted the GES approach and included some additional technical refinements described in the ECETOC TRA documentation, that were not yet, however, implemented in the TRA model. The ease and quickness of using the TRA tool, including the capability to assess multiple use scenarios at once, was maintained in the ESIG model. The tool also allowed to perform exposure assessment and risk characterization consistent with REACH information requirements.

Since its first release in 2010 EGRET has been used for consumer exposure and risk assessments under REACH for a number of solvents and solvent-like products, including:

- Hydrocarbon solvents
- Oxygenated solvents
- Fuels and lubricants

Today we will be focusing on the updated second version of EGRET, which is now freely available for downloading on ESIG web-site. The model may be of interest mainly to suppliers and registrants of solvents, but can be as well useful for solvent users, who also wish to learn how to perform safety assessments for their products.



Consumer Use Titles covered by EGRET

- Developed by ESIG in conjunction with solvents end users

	CSA workbooks	GES Use Titles	Product Categories Codes
1	Coating.xls	Use in coatings	PC1, PC4, PC8 (excipient only), PC9, PC15, PC18, PC23, PC24, PC31, PC34
2	Cleaning.xls	Use in cleaning agents	PC3, PC4, PC8 (excipient only), PC9, PC24, PC35, PC38
3	Lubricants.xls	Lubricants	PC1, PC24, PC31
4	Agrochemical.xls	Use in agrochemicals	PC12, PC27
5	Fuels.xls	Use as a fuel	PC13
6	FunctionFluid.xls	Functional fluids	PC16, PC17
7	Deicing.xls	De-icing and anti-icing applications	PC4
8	WaterTreatChem.xls	Water treatment chemicals	PC36, PC37

Source of table: modified from <http://www.nature.com/jes/journal/v24/n1/full/jes2012128a.html>

7

The tool exists in the form of a master template featuring exposure scenarios for all product categories (PCs) addressed in EGRET.

To make the life of the tool users' easier, ESIG also developed eight individual GES consumer workbooks that cover only the associated PCs as illustrated on slide #7.

For example, in the case of Coatings GES the PCs covered include PC1 adhesives, PC4 deicing and anti-freeze products, PC9 coatings and paints as well as others that might be associated with use in coatings. All the GES workbook files can be downloaded from ESIG website.



Introduction

• Why EGRET?

- Runs on MS Excel
- Requires minimal user inputs (MW, VP, DNELs)
- Evaluates multiple exposure scenarios at the same time
- Delivers exposure assessments (EAs) beyond Tier 1
- Conducts a chemical safety assessment (CSA)
- Auto-populates risk controls for safe use conditions
- Generates narratives in REACH format
- Uses standard phrases from CEFIC ESCom Phrase library for easy communication

Tools	Tier 1 Exposure Estimation	Tier 2 Exposure Estimation	Conducting a CSA	Efficient Iteration capability*	Risk Communication
EPA E-Fast	✓	✓	x	x	x
ConsExpo	✓	✓	x	x	x
TRA	✓	x	✓	x	x
Chesar	✓	x	✓	x	✓
AISE REACT	✓	x	✓	x	x
EGRET	✓	(✓)	✓	✓	✓

* Efficiency in specifying RMMs and scaling with minimal manual intervention

✓ – with this capability
x – without this capability

Source of table: <http://www.nature.com/jes/journal/v24/n1/full/jes2012128a.html>

Source of table:

8

Next slide discovers the advantages of using EGRET.

It is one of many existing consumer exposure modelling tools developed for REACH, but it is one of a few that enables efficient generation of the consumer exposure and risk information in accordance with REACH requirements.

EGRET stands in between existing Tier 1 or Tier 2 models, like TRA or ConsExpo, because the predictions are somewhat refined as compared to Tier 1 models, but the input required from the user is really minimal (the only info required to run the assessment includes substance molecular weight, vapor pressure and route-specific Derived No Effect Levels). Consequently, use of EGRET can minimize the need to go to a higher, more resource intensive tier of exposure modelling.


Since originally EGRET was based on the ECETOC TRA, it is logical that there exist some similarities between the two models:

- First of all, both run on a common platform, Microsoft Excel.
- Both models require input to be provided once; exposure and risk estimates will be generated in seconds simultaneously for multiple scenarios.
- Route specific Risk Characterization Ratios and the total RCR across all routes of exposure will be provided for each product scenario individually.

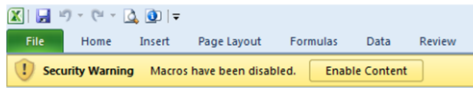
A unique aspect of EGRET is that it auto-populates RMMS in accordance with the risk control banding concept that will be discussed later.

Furthermore, the tool generates exposure scenario narratives consistent with REACH Annex II format, and clearly differentiates between operational conditions and risk management measures. The ESs can be then directly copy-pasted into Chemical Safety Reports and annexed to extended Safety Data Sheets.

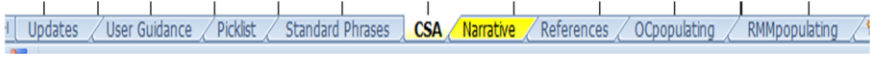
Finally, EGRET develops its output based on the standard phrases contained in the EuPhrac (or CEFIC ESCom phrase) library, which is an essential means for consistent and efficient communication of safe use information across multiple suppliers.

 Tool Snapshots: Getting Started

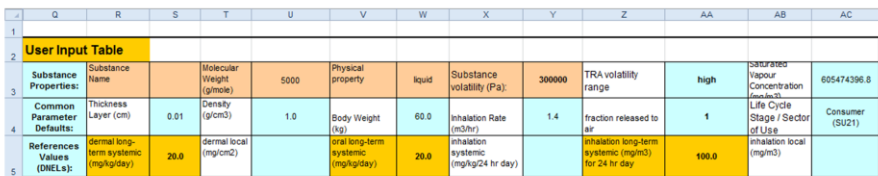
- **Enable macro**



- **Select “CSA” worksheet to start an assessment**



- **User Inputs**



9

The next few slides introduce EGRET’s interface.

When the user first opens the tool, he is prompted to enable the embedded macro. This is required in order to be able to run the model.

Within the model workbook there are nine individual spreadsheets. Most of them are for information only. The only two worksheets the user will need to work with are the “CSA” for exposure and risk assessment and the “Narratives” for ESs generation.

The user input tables comes up on the top of the screen in the CSA tab. The fields are color coded to facilitate the interaction with the tool.

- The tan colored cells indicate required information; these include substance name, MW, phys property (for liquids only), and substance VP. For MW and VP, the preset defaults enable the model to be run even when this information is not available – in this case the worst case exposure estimates will be generated.

- Adding substance specific values will result in more realistic exposure estimates and will also enable a saturated vapor concentration to be used as a worst-case upper bound for air concentration.

- The bright orange cells represent areas where route-specific Derived No Effect Levels should be entered as appropriate.

Tool Snapshots: Outputs

EGRET provides alongside ECETOC TRA based exposure and risk predictions

Table 1: Mapping Consumer Uses in the Supply Chain														
Generic Exposure Scenario				TIER1 Predicted Exposure - ECETOC TRA based on defaults						Risk Characterization based on defaults				
Short Title	Area of Application / UD	Relevant Use Sentinel Product	Product sub Category Sentinel	Predicted Dermal Exposure (mg/kg/d)	Predicted Oral Exposure (mg/kg/d)	Predicted Inhalation Exposure (mg/kg/d)	Predicted Inhalation Exposure (mg/m ³)	Predicted Inhalation Exposure - upper bounded with SVC when available (mg/m ³)	Total Predicted Exposure (mg/kg/d)	RCR (dermal)	RCR (oral)	RCR (inhalation mg/kg/d)	RCR (inhalation upper bounded with SVC when available mg/m ³)	RCR (all routes)
USES	Consumer-S002	PC1Adhesives, sealants	Glues, hobby use	1.0	n/a	12.3	15.0	15.0	14	0.09	n/a	n/a	1.93	2.82
DESCRIPTIONS	Consumer-S002	PC1Adhesives, sealants	Glues DIY use (carpet glue, tile glue, wood/joint glue)	214	n/a	3025.0	22500.0	22500.0	30046	1.87	n/a	n/a	3214.29	3216.36
PC LISTS	Consumer-S002	PC1Adhesives, sealants	Glue from spray	1.0	n/a	343.4	3025.0	3025.0	351	0.09	n/a	n/a	54.54	54.73
	Consumer-S002	PC1Adhesives, sealants		1.0	n/a	1543.0	15850.0	15850.0	1536	0.09	n/a	n/a	83.57	83.66

10

10


Moving forward to the output tables brings us to consumer exposure and risk predictions.

For transparency, alongside with Tier 1+ exposure predictions EGRET provides Tier 1 TRA-based defaults and outputs.

In addition to the exposure estimates, Risk Characterization Ratios are also provided for each product use scenario.

The RCRs lower than 1 indicate safe use conditions, i.e. the predicted exposure is lower than the hazard benchmark.

RCR greater than 1 indicate unsafe use and are highlighted in red. For these scenarios refinement of exposure is needed, which can be achieved by introducing appropriate RMMs.



Tool Snapshots: Outputs

EGRET assesses additional types of risk (other than long-term systemic)

Table 1: Mapping Consumer Users in the Supply Chain				TRA Tier1- Risk Characterization - refined estimates											
				Local Use		On Day of Use				Chronic Considering Yearly Use Frequency					
Generic Exposure Scenario		Relevant Use Sentinel Product		Product sub Category Sentinel		TRA Tier1- Risk Characterization - refined estimates									
Short Title	Area of Application / UD			Mean Inhalation Concentration Yearly (mg/m ³)	Total Predicted Exposure (mg/kg/d) (day of use for TRA comparison only)	RCR dermal local (based on mg/m ³)	RCR inhalation local (based on Activity TVA mg/m ³)	RCR systemic (dermal, daily, based on mg/kg/d)	RCR systemic (oral, daily, based on mg/kg/d)	RCR systemic (24h TVA inhalation mg/m ³)	RCR systemic (all routes, daily)	RCR systemic (dermal, chronic, based on mg/kg/d)	RCR systemic (oral, chronic, based on mg/kg/d)	RCR systemic (inhalation, yearly, based on mg/m ³)	RCR systemic (all routes, chronic)
GES USES	Consumer SUCE	PC1Adhesives, sealants		0.525	5.46	n/a	n/a	0.09	n/a	0.12	0.21	0.09	n/a	0.12	0.21
				Glues, hobby use											
DESCRIPTIONS	Consumer SUCE	PC1Adhesives, sealants		14.744	355.46	n/a	n/a	0.28	n/a	0.24	0.27	0.08	n/a	0.32	0.33
				Glues (DIY use) (carpet glue, tile glue, wood/parquet glue)											
PC USTS	Consumer SUCE	PC1Adhesives, sealants		3.222	45.50	n/a	n/a	0.09	n/a	1.05	1.24	0.08	n/a	0.05	0.05
				Glue from spray											
	Consumer SUCE	PC1Adhesives, sealants		0.243	21.50	n/a	n/a	0.09	n/a	0.58	0.59	0.09	n/a	0.58	0.59

11



Tool Snapshots: OCs and RMMs

OCs and RMMs are autopopulated to achieve safe use (i.e. chronic systemic RCR < target level; other effects would need to be looked at manually)

Operation Conditions (OCs)	Risk Management Measures (RMMs)	Indicator for Basis of Exposure Estimate	Risk Characterization - needed (subst)	
	RMMs for communication - Consolidate into GES or e-SDS REACH ADVISED: phrase [RMM code] Recommended: phrase [RMM code]		RCR systemic (dermal, based on mg/kg/d)	RCR systemic (oral, based on mg/kg/d)
			d	o
Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 364 days/year [ConsOC3]; covers use up to 1 time on day of use [ConsOC4]; covers skin contact area up to 35.73 cm ² [ConsOC5]; for each use event, covers use amounts up to 9g [ConsOC2]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m ³ [ConsOC1]; for each use event, covers exposure up to 4.00hr/event [ConsOC14];	No specific RMMs identified beyond those OCs stated	Based upon daily use	0.09	n/a
Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 1 day/year [ConsOC3]; covers use up to 1 time on day of use [ConsOC4]; covers skin contact area up to 110.00 cm ² [ConsOC5]; for each use event, covers use amounts up to 6390g [ConsOC2]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m ³ [ConsOC1]; for each use event, covers exposure up to 6.00hr/event [ConsOC14];	Avoid using at a product concentration greater than 10% [ConsRMM1];	Based upon infrequent use + RMM	0.00	n/a

12

As shown in the next slide, for these scenarios both Operational Conditions (OCs) and appropriate Risk Management Measures (or RMMs) will be autopopulated to achieve RCRs for long term systemic effects <1 or any other preselected target value. All this information will be documented in a separate table in the CSA tab.

It is worth reiterating that EGRET can differentiate between Operational Conditions and RMMs.

OCs include parameters that represent typical use scenarios (e.g. concentration, use amount) They cover changes of input parameters made in the EGRET table.

RMMs represent boundaries of typical Ocs. They are implemented to reduce exposure and are populated based on the target RCR. The most typical RMM for consumers would be a restriction of the maximum weight fraction of a substance that can be used in a given product type, followed by controlling the product use amount (normally done by the product manufacturer).

In addition to being reflected in the CSA worksheet, both OCs and RMMs get copied to the Exposure Scenario narrative, that will be shown on the next slide.



Tool Snapshots: ES Narrative

Section 1		Exposure Scenario Title
Title		GES USES
Sector of Use (SU code)		21
Use Descriptor (PC codes)		PC LISTS
Processes, tasks, activities covered		DESCRIPTIONS
Environmental Release Category		0
Specific Environmental Release Category		0
Section 2		Operational conditions and risk management measures
Section 2.1		Control of consumer exposure
Product characteristics		
Physical form of product		liquid
Vapour pressure (Pa)		300000
Concentration of substance in product		Unless otherwise stated, cover concentrations up to 100% [ConsOC1]
Amounts used		Unless otherwise stated, covers use amounts up to 37500g [ConsOC2]; covers skin contact area up to 6600cm ² [ConsOC5]
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to 365 days per year [ConsOC3]; Unless otherwise stated, covers use frequency up to 4 times per day [ConsOC4]; covers exposure up to 8 hours per event [ConsOC14]
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures [ConsOC15]; assumes use in a 20 m ³ room [ConsOC11]; assumes use with typical ventilation [ConsOC8].

The ES generated in EGRET based on the results of the Chemical Safety Assessment are consistent with the in REACH Exposure Scenario format, and can be used for downstream communication of safe use advice in a consistent and harmonized way.

As seen here on slide 13,

- Section 1 of the narrative contains information on the GES USE title, associated PCs, the processes and activities. The ERC and SPERC will need to be filled in separately based on the environmental assessment, that is not covered by the EGRET tool.
- The first part of the section 2 captures the information on control measures for consumer exposure. It lists basic phys/chem properties of the substance as inputted by the user in the beginning of the assessment, as well as the maximal use information across all PCs covered by the selected GES use title.



Tool Snapshots: ES Narrative

Section 2		Operational conditions and risk management measures
Section 2.1		Control of consumer exposure
Product characteristics		
Physical form of product		liquid
Vapour pressure (Pa)		300000
Concentration of substance in product		Unless otherwise stated, cover concentrations up to 100% [ConsOC1]
Amounts used		Unless otherwise stated, covers use amounts up to 37500g [ConsOC2]; covers skin contact area up to 6600cm ² [ConsOC5]
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to 365 days per year [ConsOC3]; Unless otherwise stated, covers use frequency up to 4 times per day [ConsOC4]; covers exposure up to 8 hours per event [ConsOC14]
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures [ConsOC15]; assumes use in a 20 m ³ room [ConsOC11]; assumes use with typical ventilation [ConsOC8]
		room size of 20m ³ [ConsOC11]; for each use event, covers exposure up to 4.00hr/event[ConsOC14];
		RMM No specific RMMs identified beyond those OCs stated
PC1:Adhesives, sealants-- Glues DIY-use (carpet glue, tile glue, wood parquet glue)		OC Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 1 day/year[ConsOC3]; covers use up to 1 time/on day of use[ConsOC4]; covers skin contact area up to 110.00 cm ² [ConsOC5]; for each use event, covers use amounts up to 6390g [ConsOC2]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m ³ [ConsOC11]; for each use event, covers exposure up to 6.00hr/event[ConsOC14];
		RMM No specific RMMs identified beyond those OCs stated

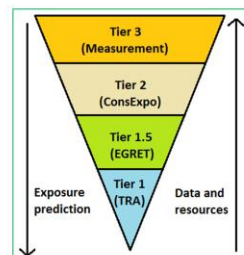
14

The 2nd part of section 2 of ES, shown on slide 14, covers the output from the chemical safety assessment for each individual product category individually. It provides detailed OCs and RMMs for each PC including the parameters under which safe use is warranted. The recipients of ESs are expected to take into account this information and ensure conformity with communicated advice on safe use of products.

To reiterate, all OCs and RMMs are generated based on the standard phrases developed by CEFIC for flawless supply chain communication.

- **Tool technical details**

- Designed for solvents
- Based on ECETOC Targeted Risk Assessment (TRA)
- For product categories only (not articles yet)
- Refinements based on latest TRA developments
- Additional exposure scenarios and subscenarios to cover ESIG GES library
- Various enhanced functionalities (e.g. risk control banding)



- **Tool recognition**

- A peer-reviewed publication
- Widely used in 2010 REACH registrations
- EGRET-based CSAs have undergone evaluations



<http://www.nature.com/jes/journal/v24/n1/full/jes2012128a.html>

15

We will now explore a bit more the tool's technical characteristics.

As mentioned earlier, exposure modeling can be performed in tiers or levels of different complexity and data quality requirements. The lowest tier 1 will require the least data and minimal computational resources to predict exposure, but will also result in the most conservative exposure estimate. Higher tier models will require robust and often personalized exposure datasets, that would enable prediction of more realistic values.

EGRET is considered to belong to an intermediate modelling tier as it provides refined exposure estimates compared to the worst-case scenario TRA tool. At the same time, EGRET predictions have been proven (for some, i.e. not all scenarios) to be more conservative than higher Tier modelling results or measured data.

Deliberately developed for solvents, EGRET accommodates additional solvent-specific ESs and can generate exposure predictions for all REACH PC codes included in the ESIG GES library. However, it does not (yet) include exposure scenarios for substances in articles.

In addition, EGRET was enhanced with a number of key functionalities, for example risk control banding approach, that we will talk about in more detail in a few minutes.

Finally, the performance of EGRET has been investigated in a peer-reviewed publication. The paper is freely accessible following the link provided at the bottom of the slide. It has been widely used for 2010 REACH registrations and the CSAs (e.g. CONCAWE's) supported with EGRET-based consumer exposure modelling have successfully undergone regulatory evaluations.



New Features in version 2

The Tool's functionality has been improved based on both the users' and stakeholders' (e.g. MSCAs) feedback.

New features include:

1. **Enhanced control banding** with **automated selection** of Risk Management Measures (**RMMs**) to provide an extra margin of safety
2. **TRA use frequency bands** to assess risks for infrequent exposure
3. Use with Specific Consumer Exposure Determinants (**SCEDs**)
4. Unlocked two additional parameters (skin contact area and amount swallowed)
5. Assessment of additional types of risk (other than long-term systemic)
6. Updated air exchange rate for outdoor scenarios to match TRA
7. Simplified user interface for output in a CSA format

16

The updated second version of EGRET accompanied by a comprehensive user manual has been released in December 2015. The tool's functionalities were improved based on feedback from users and other interested stakeholders including regulators. (NOTE: MSCA = Member State Competent Authorities)

There are a number of substantial updates compared to the previous version. Key new features listed on slide 16 include:

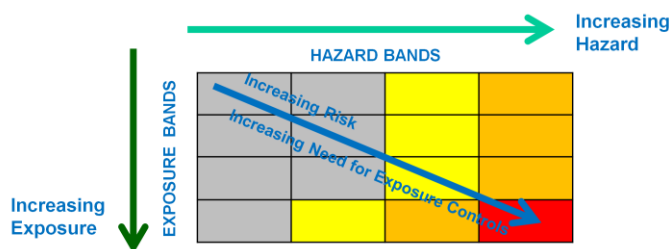
- The enhanced control banding with automated selection of RMMs
- The frequency banding approach to address infrequent exposures. This was specifically implemented to align EGRET with the most recent consumer TRA update v.3.1.
- In addition the number of exposure parameter in EGRET table has been extended to accommodate data from specific consumer exposure determinants (SCEDs).
- Consequently, we unlocked two additional exposure parameters to afford the user with a greater flexibility in adjusting the default values when they have rationale to do so (e.g. based on SCEDs)
- Also we simplified the logistics of the tool – in previous version there four CSA tabs and the user had to first select an appropriate tab depending on the vapour pressure of the substance and then continue with the assessment.
- In fact, there are a few other new features in the updated EGRET version. I think a lot of them we already covered earlier.

In the interest of time only the first three bullet points will be explained in more detail.



1. Enhanced control banding

- What is control banding?
 - A generic technique that determines control measures (e.g. ventilation) based on a range ("band") of hazards and exposures
 - Used widely in various worker risk assessment tools (e.g. COSHH Essentials, EMKG, ECETOC TRA, EASE, and StoffenManager)
 - Additional information can be found at <http://www.cdc.gov/niosh/topics/ctrlbanding/>



17

The first one is the control banding approach as illustrated in slide #17.

Control Banding is a generic approach that determines risk control measures based on the combination of ranges of hazards and exposure. The risk matrix shown at the bottom of the slide has exposure on the vertical axis, increasing towards the bottom of the box. Hazard is depicted in the horizontal axis, increasing from the left to the right. The risk potential, as well as the need and the level of exposure control measures, increases towards the lower right corner of the matrix.

Each of the boxes in the risk matrix represents a band of exposure and hazard (that is a risk). Red box corresponds to the highest risk situation.

It's then seem kind of logical to predetermine a range of typical control measures for each risk band a range. One utility of this banding approach is that predefined controls can then be applied for any substance that falls within a given risk band. Such an approach is much more efficient than the substance-specific evaluation, that also takes a look at each individual use. In addition, it provides more consistent recommendations for control measures.

As such, the control banding concept is widely supported and utilized in occupational settings. It has been implemented in several worker exposure assessment tools such as the UK COSHH Essentials, ECETOC TRA and Stoffenmanager. More information on the approach can be found at the website of the Centers for Disease Control by following the link provided with this slide.



1. Enhanced control banding cont'd

- How is control banding applied in EGRET?
 - Control bands were developed to cover the wide range of general population **chronic systemic** Derived No Effect Levels (DNELs) for typically encountered solvents.

Control bands	Chronic systemic DNEL: inhalation (mg/m3)	Chronic systemic DNEL: dermal/oral (mg/kg/day)
Band1: very low	≥0.5, <5	≥0.1, <1
Band2: low	≥5, <25	≥1, <5
Band3: medium	≥25, <100	≥5, <20
Band4: high	≥100	≥20

- How to use it?
 - When an exposure prediction based on operational conditions (OCs) for a substance exceeds DNEL value (i.e. RCR>1), RMMs will be automatically specified to reduce the exposure below the most stringent (lowest) DNEL value of the band.
 - EGRET autopopulates RMMs based upon DNEL bands to meet an Risk Characterization Ratio (RCR) target value.


18

In EGRET the control banding concept has been implemented for consumer exposures. To our knowledge EGRET is the only consumer exposure model that integrates it.

In the model the hazard component of the risk is taken as a starting point. Four consumer DNEL bands were developed and incorporated into EGRET (as illustrated in the table) to cover the ranges of possible route-specific long-term systemic DNELs encountered by the general population for typical solvents. The lowest band1 covers the “most” hazardous substances having the lowest DNELs. The exposure bands are based upon vapor pressure ranges, consistent with the approach in the ECETOC TRA for consumers.

Practically, for the EGRET assessment it means that if the predicted exposure, estimated based on the operational conditions, ends up being greater than the chronic systemic DNEL specified by the user, adequate risk management measures (RMMs) will be auto-populated to control the exposure below the most stringent DNEL value of the corresponding DNEL band.

It may sound a bit complicated in the beginning, but in fact the workflow is quite straightforward. The next slide is called to visualize the process step-by-step.



1. Enhanced control banding cont'd

• An example

$$RCR_A = \frac{Exposure_A (=20mg/m^3)}{DNEL_A (=10mg/m^3)} = 2 > 1$$

↓

DNEL of 10mg/m³ is in **band 2** (5-25mg/m³)

↓

RMMs will be provided automatically →

$$RCR_{RMM} = \frac{Exposure\ with\ RMM\ (<5\ mg/m^3)}{DNEL_{lowest\ in\ band2}\ (5mg/m^3)} < 1$$

↓

$$RCR_{A\ final} = \frac{Exposure\ (<5mg/m^3)}{DNEL\ (10mg/m^3)} \leq RCR_{RMM} < 1$$

(to ensure the RMMs provided are consistent and conservative)

Control bands	Chronic systemic DNEL: inhalation (mg/m ³)	Chronic systemic DNEL: dermal/oral (mg/kg/day)
Band1: very low	≥0.5, <5	≥0.1, <1
Band2: low	≥5, <25	≥1, <5
Band3: medium	≥25, <100	≥5, <20
Band4: high	≥100	≥20

- To reduce exposure
- To demonstrate safe use based upon chronic systemic effects
- To meet selected target RCR

19

Slide #19 provides an illustrative example on the risk control banding approach as implemented in EGRET.

Example: Let's assume we have a substance with an inhalation DNEL of 10 mg/m³ and predicted inhalation exposure of 20 mg/m³.

In this example a target RCR of 1 is used. The exposure of 20 mg/m³ divided by the DNEL of 10 results in an RCR=2, i.e. >1 based upon the tool default operational conditions.

First, EGRET will find out that DNEL=10 is in the DNEL band #2. The lowest DNEL in the band is 5 mg/m³.

In the next step, EGRET will automatically come up with RMMs to reduce the exposure to that lowest value of the low DNEL band, which is 5 mg/m³.

Please note that this DNEL band value is lower (and thus more stringent) than the 10 mg/m³ value specified initially by the user. That practically means, that the control banding approach provides an extra degree of conservativeness in risk assessment.



1. Enhanced control banding cont'd

- What's the enhanced control banding in EGRET version ?
 - The enhanced banding allows users to select a **target RCR** from three options: **0.9** (by default), **0.5**, or **0.2**
 - Based on the selected **target RCR**, appropriate control measures will be specified automatically by the control banding to provide the associated safety margin.
- What are the benefits?
 - A systematic approach to risk assessment
 - Flexible in providing different safety margins
 - Efficient identification of control measures
 - Consistency with RMM hierarchy
 - Added assurance for CSA outcomes



20

In the updated version of EGRET v.2.0 the control banding feature was further enhanced to allow the user to define a target RCR. This feature is implemented with a drop-down menu option shown on slide 20. By default the RCR is set to 0.9; two more stringent options were also made available based upon user feedback.

To achieve the target RCR a set of appropriate RMMs will be automatically selected following the approach described previously.

The enhanced CB in EGRET v.2.0 provides:

- a systematic and consistent approach to selection of RMMs preserving hierarchy of exposure control practices
- flexibility in specifying different safety margins
- efficient identification of control measures
- additional assurance for CSA outcomes given the built-in conservatism

The key message related to CB in EGRET is that it provides an extra degree of conservatism in risk assessment and enables the user to be flexible in determining margin of safety if considered appropriate.

The necessary RMMs will be pulled out automatically - no human intervention is needed. By this, consistent, common safe use conditions can be provided, allowing greater consistency across suppliers in communicating safe use information downstream.



2. TRA Frequency Bands

- **Concept**

- Developed by ECETOC TRA Task Force to better match exposure and hazard durations when an infrequent exposure is to be compared to a long term hazard benchmark.
- Aligned with ECHA's IR&CSA R.8 guidance on risk characterization: temporal aspects of exposure and hazard should match

Frequency bands	Description	Multiplier
Band 1: frequent	≥ 1/week	1
Band 2: occasional	1/month ~ 1/week	0.2
Band 3: infrequent	1/ 6 months ~ 1/month	0.04
Band 4: very infrequent	<1/6 months	0.01

- The banding approach is more conservative than linear averaging used in other consumer exposure models (ConsExpo, E-FAST).
- It is implemented in the TRA v3.1.
- EGRET v.2 replaced the actual use frequency values (i.e. linear averaging) with frequency bands to be consistent with TRA.

21

Another new feature that was added to the new version of EGRET to align it with the most recent update of the TRA consumer tool v.3.1 is the frequency banding.

Human exposure to some consumer products can occur infrequently, say on a yearly basis, or happen once in a few years. Typical examples would be painting a room, or installing a carpet. The problem arises when such infrequent exposures are to be compared to a long-term hazard benchmark that was derived based on a daily life-time exposure.

One of the approaches that has been proposed in the past and implemented in many commonly used higher tier consumer modelling tools implies linear averaging of exposure, i.e. normalizing the predicted event exposure with the actual annual use frequency.

Recently, ECETOC has developed an alternative more conservative approach called “frequency banding”, that is to be applied to the assessment of infrequent exposures. Four frequency bands were proposed (as shown in this table), each reflecting a certain periodic use of a consumer product. To be able to use this feature in TRA the user has to first add a new PC, for which the annual use frequency is known. This actual use freq is then assigned to one of the four frequency bands and, a corresponding multiplier is applied to adjust the calculated event exposure.

In EGRET, the frequency multipliers along with the justification for each PC are provided in Table 2b in the CSA tab. It should be noted that this parameter has been locked and cannot be modified.



3. Use with SCEDs

- Specific Consumer Exposure Determinants (SCEDs)
 - sets of **refined** exposure determinants (or factors) for more realistic exposure prediction (DUCC SCEDs guidance).
- **Six** input parameters (including justifications) can be modified **directly** within existing exposure scenarios in EGRET v.2 based on SCEDs data
- The adjustment for other (protected) parameters involves manual follow-up recalculation of the predicted exposure

22

Finally, EGRET v.2 can now be fed with the data reported by the DU Sector organizations for their relevant end use products in the format of Specific Consumer Exposure Determinants, or SCEDs.

For information, SCEDs are sets of realistic exposure factors compiled into a single factsheet document to be used as “information input” in consumer exposure assessment. A SCED identifies a specific exposure scenario for a consumer product or article in use. A SCED is populated with the data mined from e.g. peer-reviewed literature, reported trade groups activities, product databases. They allow more realistic consumer exposure predictions. A number of SCEDs have been already developed by trade associations for certain types of consumer products (e.g. fuels, adhesives, and household cleaning agents).

In the updated EGRET six input parameters can be directly modified based on the data from relevant SCEDs. These parameters are: concentration, use amount, skin contact area, swallowed volume, dermal and inhalation factors.



Demo

- Estimate ~10mins
- A hypothetical substance with coating GES use
 - **Inputs:**
 - MW=500g/mole, VP=200Pa
 - DNEL inhalation long term = 100mg/m³; dermal long term=20mg/kg/day
 - Target RCR = 0.5
 - **Outputs:**
 - PECs, RCRs, OCs, RMMs, and Narratives


23

With that the presentation part of the webinar is terminated. My colleague Dr. Rose Zaleski will guide you through the updated version of EGRET and demonstrate how it can be used.

Slide 23 We will run the tool with a hypothetical case study. For the purposes of this webinar, I will be using screen shots and walking through the process step by step. While the EGRET tool runs calculations extremely quickly, we experienced some delays and connection issues when moving between powerpoint and the excel file in a test of the webinar system. Because of this, I will be talking from screen shots. If there is time left after the Q&A session, I am happy to go through an example actually running the tool for anyone interested.

As listed here, for this example we are using a hypothetical substance with a molecular weight of 500 grams per mole and vapor pressure of 200 Pascals. The substance has systemic long term Derived No Effect Levels, referred to as DNELs, available for both the inhalation and dermal exposure routes, as listed here. The target Risk Characterization Ratio, or RCR for the example is 0.5

I will explain how the tool is set up, how to enter input, and the types of output that are provided as we move forward. Output includes Predicted Exposure Concentrations, the Risk Characterization Ratios which represent the ratio of the predicted exposure concentrations to the DNELs, Operational Conditions, Risk management Measure and Exposure Narratives, which is the summary of the exposure input and results in the REACH exposure scenario format.



Demo – getting started

- Step 1: download a copy of the coating GES consumer workbook at <http://www.esig.org/en/regulatory-information/reach/ges-library/consumer-gess>

GES Consumers

» Click here to download the GES Consumer files

Version 2 of EGRET is now available and is supported by a more extensive [User Manual](#) together with eight individual consumer GES. In addition a summary of the tool including latest adjustments are included in the attached [presentation](#).

- Step 2: enable macro

File Home Insert Page Layout Formulas Data Review

Security Warning Macros have been disabled. Enable Content

- Step 3: select “CSA” worksheet

Updates
User Guidance
Picklist
Standard Phrases
CSA
Narrative
References
OCpopulating
RMMpopulating

24

To get started, first a copy of the Generic Exposure Scenario of interest is downloaded from the ESIG website. Once downloaded, the user can reuse the file as many times as desired.

The master template of the EGRET tool with all product codes, not just the ones in a specific Generic exposure scenario, can also be downloaded. The user can hide any PCs not needed for an assessment. For REACH purposes, however, it is easiest and quickest to use the GES files which already are set to include only the relevant product codes for that generic exposure scenario.

The downloaded file is an excel spreadsheet, and when you open it you will get a message indicating macros have been disabled. For the tool to run properly, the user must click on enable content so that the macro can be run.

You will see that the tool contains a number of worksheets, and I will briefly review the types of content in each later in this demonstration. For the purposes of this example, however, only the CSA, or Chemical Safety Assessment worksheet, and narrative worksheets will be shown in detail. This is because these two worksheets are the only ones the user needs to perform a substance assessment and see all relevant input and output. The other sheets are included to provide more information and greater transparency on the tool.


The CSA is the main worksheet of interest, being the sheet where input is entered, and also tool default values and results can also be found.

Demo – CSA and Narrative spreadsheets									
<div> <div> </div> <div> <div>U3</div> <div>5000</div> </div> </div> <div>Copy of egret-2-coating demo file.xls2 [Compatibility Mode]</div>									
1	T	U	V	W	X	Y			
2									
3									
4	Molecular Weight (g/mole)	5000	Physical property	liquid	Substance volatility (Pa):	300000	TRA vo range		
5	Density (g/cm3)	1.0	Body Weight (kg)	60.0	Inhalation Rate (m3/hr)	1.4	fraction air		
6	dermal local (mg/cm2)		oral long-term systemic (mg/kg/day)	20.0	inhalation systemic (mg/kg/24 hr day)		inhalation systemic for 24 hr		
7									
8									
9									
10	ECETOC TRA based on defaults			Risk Characterization based on					
	Predicted Inhalation Exposure (mg/m3)	Predicted Inhalation Exposure - upper bounded with SVC when available	Total Predicted Exposure (mg/kg/d)	RCR	RCR (oral)	RCR (inhalation)	RCR (upper bound)		

Copy of egret-2-coating demo file.xls1 [Compatibility Mode]		
A	B	C
Section 1		
1	Exposure Scenario Title	
2	Uses in Coatings	
3	Sector of Use (SU code)	21
4	Use Descriptor (PC codes)	PC1, PC4, PC8 (exipient only), PC9, PC15, PC18, PC23, PC
5	Processes, tasks, activities covered	Covers the use in coatings (paints, inks, adhesives, etc) incl and preparation, application by brush, spray by hand or simil
6	Environmental Release Category	
7	Specific Environmental Release Category	
Section 2		
8	Operational conditions and risk management measures	
9	Field for additional statements to explain scenario if required - pending better understanding from ECHA	
10	Control of consumer exposure	
11	Product characteristics	
12	Physical form of product	liquid
13	Vapour pressure (Pa)	300000
14	Concentration of substance in product	Unless otherwise stated, covers concentrations up to 100% [C]
15	Amounts used	Unless otherwise stated, covers use amounts up to 13800g [C]
16	Frequency and duration of use/exposure	Unless otherwise stated, covers use frequency up to 365 day use frequency up to 1 times per day [ConsOC4] covers expos
17	Other Operational Conditions affecting exposure	Unless otherwise stated assumes use at ambient temperat [ConsOC11] assumes use with typical ventilation [ConsOC2
18	Section 2.1.1	
19	PC1 Adhesives, sealants-Glues, hobby use	OC Unless otherwise stated, covers concentrations up to 30% [C covers use up to 1 time/on day of use [ConsOC4] covers skin event, covers use amounts up to 9g [ConsOC2] covers use i use in room size of 20m3 [ConsOC11] for each use event, co
20	PC1 Adhesives, sealants-Glues DIY-use (carpet glue, tile glue, wood parquet glue)	RMM No specific RMMs identified beyond those OCs stated
21	PC1 Adhesives, sealants-Glues DIY-use (carpet glue, tile glue, wood parquet glue)	OC Unless otherwise stated, covers concentrations up to 30% [C use up to 1 time/on day of use [ConsOC4] covers skin contact covers use amounts up to 1380g [ConsOC2] covers use in room size of 20m3 [ConsOC11] for each use event, covers at
22	PC1 Adhesives, sealants-Glue from spray	RMM Avoid using at a product concentration greater than 10% [Cor
	PC1 Adhesives, sealants-Glue from spray	OC Unless otherwise stated, covers concentrations up to 30% [C

At this point, on slide 26, before continuing with the step by step instructions I would like to give an indication of the ease of the assessment. Slide 26 is a split screen showing both the CSA and narrative worksheets. Each will be discussed in further detail as we continue with the demonstration.

So here we have just opened the CSA worksheet, without modification to any of the defaults. On the right hand side is the narrative based upon these defaults. Looking at the bottom right of the screen, we can see the results for the first two exposure scenarios in the coatings GES. I would like to bring your attention to the Risk Management measures for these scenarios. Here you can see that no additional RMMs are needed for the first PC category, and an upper bound weight fraction of 10% concentration is specified for the second PC category.



Demo – providing inputs

User Input Table									
Substance Properties:	Substance Name	Molecular Weight (g/mole)	500	Substance volatility (Pa):	200	TRA volatility range	high		
Common Parameter Defaults:	Thickness Layer (cm)	Density (g/cm3)	0.01	Inhalation Rate (m3/hr)	1.0	fraction released to air	1.4		
References Values (DNELs):	dermal long-term systemic (mg/kg/day)	20.0	dermal local (mg/cm2)	inhalation systemic (mg/kg/24 hr day)	inhalation long-term systemic (mg/m3) for 24 hr day	100.0			
TIER1 Predicted Exposure - ECETOC TRA based on defaults									
Predicted Dermal Exposure	Predicted Oral Exposure (mg/kg/d)	Predicted Inhalation Exposure	Predicted Inhalation Exposure	Predicted Inhalation Exposure					
					RCR				

#	A	B
1	Section 1	Exposure Scenario Title
2	Title	GES USES
3	Sector of Use (SU code)	21
4	Use Descriptor (PC codes)	PC LISTS
5	Processes, tasks, activities covered	DESCRIPTIONS
6	Environmental Release Category	
7	Specific Environmental Release Category	
8	Section 2	Operational conditions and risk management measures
9	Field for additional statements to explain scenario if required - pending better understanding from ECHA	
10	Section 2.1	Control of consumer exposure
11	Product characteristics	
12	Physical form of product	liquid
13	Vapour pressure (Pa)	200
14	Concentration of substance in product	Unless otherwise stated, cover concentrations up to 10%
15	Amounts used	Unless otherwise stated, covers use amounts up to 375g
16	Frequency and duration of use/exposure	Unless otherwise stated, covers use frequency up to 36 frequency up to 4 times per day [ConsOC4]; covers exposure up to 1 time/on day of use [ConsOC2]; covers use under by 20m3 [ConsOC11]; for each use event, covers exposure
17	Other Operational Conditions affecting exposure	Unless otherwise stated assumes use at ambient temperature with typical ventilation [ConsOC8]
18	Section 2.1.1	Product categories
19	PCI Adhesives, sealants—Glues, hobby use	OC Unless otherwise stated, covers concentrations up to 3 use up to 1 time/on day of use [ConsOC4]; covers skin use amounts up to 9g [ConsOC2]; covers use under by 20m3 [ConsOC11]; for each use event, covers exposure
20	PCI Adhesives, sealants—Glues DIY-use (carpet glue, tile glue, wood parquet glue)	RMM No specific RMMs identified beyond those OCs stated
21		OC Unless otherwise stated, covers concentrations up to 3 use up to 1 time/on day of use [ConsOC4]; covers skin contact use amounts up to 6390g [ConsOC2]; covers use under 20m3 [ConsOC11]; for each use event, covers exposure
22		RMM No specific RMMs identified beyond those OCs stated

In slide #27 by simply modifying the inputs to that of our hypothetical substance, the tool in a second updates all outputs within the CSA worksheet and then automatically updates the RMM section of the narrative worksheet. It does this for ALL scenarios within the Generic Exposure Scenario workbook.

So bringing your attention again to the first two Product codes in this coatings GES, you can see that for both of them it is now indicated that no RMM is needed.

As Tanya has already indicated, this all happens very quickly and very consistently across substances. This quickness is a very great time savings as compared to higher tier tools that are generally run a single scenario at a time.

So after setting this big picture perspective of the tool, I would like to continue with the step by step process of using it for the hypothetical example by moving to slide 28.

Demo – inputs: closer look

- Step 4: user Inputs

Information on the substance

User Input Table												
Substance Properties:	Substance Name	Testing	Molecular Weight (g/mole)	500	Physical property	liquid	Substance volatility (Pa):	200	TRA volatility range	high	Saturated Vapour Concentration (mg/m ³)	40365.0
Common Parameter Defaults:	Thickness Layer (cm)	0.01	Density (g/cm ³)	1.0	Body Weight (kg)	60.0	Inhalation Rate (m ³ /hr)	1.4	fraction released to air	1	Life Cycle Stage / Sector of Use	Consumer (SU21)
References Values (DNELs):	dermal long-term systemic (mg/kg/day)	20.0	dermal local (mg/m ²)		oral long-term systemic (mg/kg/day)		inhalation systemic (mg/kg/24 hr day)		inhalation long-term systemic (mg/m ³) for 24 hr day	100.0	inhalation local (mg/m ³)	

DNELs

Note: Oral DNEL not specified as the route is not relevant

	BY	BZ
Target RCR		0.5

The target safety level

We are at the point where we have completed the first three steps, that is we have downloaded the coating GES file, opened it and enabled the macro, and then made sure we are in the CSA worksheet.

At this point, we modify the information in the User input table which shows up on the top of the screen when you open the CSA worksheet. As indicated previously, these are the orange shaded cells. The substance specific name, Molecular weight and vapor pressure are updated simply by typing over the default values. Similarly, the relevant substance specific DNELs are added by typing over any existing values. Values that are not relevant can also be removed or left blank, and in this hypothetical example the oral route is not relevant.

The tool's capability to autopopulate RMMs needed to meet a specific Risk Characterization Ratio apply to the long term system DNELs. However, the tool is also capable of calculating RCRs for other endpoints, and so these may also be entered if they are relevant for the substance. For the purpose of this example, however, no other endpoints are entered.

In this example, we have indicated that we would like to use a target RCR of 0.5. The tool default is 0.9, and so this value must also be changed. The target RCR cell is changed further to the right in the worksheet, in the columns with the identities shown here, rather than with the other user inputs. This is because the CSA worksheet columns start on the left with input and move to the right towards outputs. By positioning the target RCR cell in the columns associated with the output section, the user can instantly see the RMMs associated with a specific RCR. After entering the substance specific information in the user input section and also selecting an RCR if a value other than the tool default is desired, the tool automatically performs all exposure and risk calculations.



Demo – TRA-based assessment

- Step 5: TRA defaults

Supply Chain		Table 2a: Characterising the Risk - based on defaults (ECETOC TRA ver2 Consumers)									
		all	all			all	d	o	i	i	i
Relevant Use Sentinel Product	Product sub- Category Sentinels	Product ingredient (g/g)	adult / child	Product is spray? (S)	frequency (events per day)	Skin surface contact area (cm ²)	Amount Swallowed (g)	Amount Used per event (g)	room volume (m ³)	exposure time (hr)	
			d	o	i						
PCI Adhesives, sealants	Glues, hobby use	0.3									
			A	A	1	35.73		9	20	4	
PCI Adhesives, sealants	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	0.3									
			A	A	1	428.75		15000	20	6	

29

Slide #29 gives an overview of the rest of the content in the CSA worksheet. On the slide title these are listed as steps in the assessment, but at this point the assessment is completed, they are really just an overview of the information contained in the CSA worksheet.

In the rows under the user input table, the product codes and subcategories associated with the Generic Exposure Scenario are listed. The columns to the right start by first providing the ECETOC consumer TRA (ver2) defaults for each product code.



Demo – TRA-based assessment

• Step 6: TRA exposure and risk predictions


Only systemic exposure on day of use is modelled

e Supply Chain											
Relevant Use Sentinel Product	Product sub Category Sentinels	TIER1 Predicted Exposure - ECETOC TRA based on defaults						Risk Characterization based on defaults			
		Predicted Dermal Exposure (mg/kg/d)	Predicted Oral Exposure (mg/kg/d)	Predicted Inhalation Exposure (mg/kg/d)	Predicted Inhalation Exposure (mg/m ³)	Predicted Inhalation Exposure - upper bounded with SVC when available (mg/m ³)	Total Predicted Exposure (mg/kg/d)	RCR (dermal)	RCR (oral)	RCR (inhalation mg/kg/day)	RCR (inhalation upper bounded with SVC when available mg/m ³)
PC1Adhesives, sealants	Glues, hobby use	18	n/a	12.3	125.0	125.0	14	0.89	n/a	n/a	1.35
PC1Adhesives, sealants	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	214	n/a	30625.0	225000.0	40385.0	30846	1.87	n/a	n/a	403.65

Cells in red highlight
RCR>1, i.e. need to
control exposure

30

We are now continuing to the right in the worksheet, and can see the predicted exposure and risk characterization ratios that result if the TRA were to be used are presented. As you can see for this example, for the first two product code subcategories the RCRs are both well above 1.



Demo – EGRET-based assessment

- Step 7: EGRET defaults

Supply Chain

Relevant Use Sentinel Product	Product sub Category Sentinels	Table 2b: Characterising the Risk - after refinement of exposure estimate			
		all		dermal	
		Product ingredient (weight fraction) (g/g)	Frequency multiplier based on TRA frequency band, if < 1, only used for chronic assessment	Skin surface contact area (cm²)	
		Value	Comments	Value	Comments
PCI Adhesives, sealants	Glues, hobby use	0.3	TRA default	1	TRA default, daily
PCI Adhesives, sealants	Glues DRY-use (carpet glue, tile glue, wood parquet glue)	0.3	TRA default	35.73	RIVM do it yourself use, parquet and floor glue at < 1g, here used 11g
PCI Adhesives, sealants		0.3	USEPA 2009 draft PFH Table 17-4	100.00	RIVM, (however, est. 35.7 fingertips may be more realistic for an adhesive product)

Inhalation ECETOC TRA TIER1 - exposure modifiers

Room Volume (m³)	Exposure time (hours)
Value	Comments
20.00	TRA default
20	4
20	6

Clicking the unlocked cell will prompt a message box asking to provide reference for modified default parameter

Multipliers based on TRA frequency banding

References are provided for any change to the TRA default

In slide #31 we continue on towards the right in the worksheet. Now the EGRET default input values are presented. Any modifications to the TRA default values are substantiated with a justification for the change, and the reference for this justification. As indicated already, the user does have the capability to modify some of the EGRET input parameters. So the user can incorporate SCEDs data if available. If the user chooses to do so, a message box pops up to prompt the user to provide justification for this change.

Also on this slide, you can see the introduction of the frequency banding feature found in the current TRA version. The multiplier based upon the frequency banding approach is shown. For the purposes of this slide, not every single column of the EGRET default parameters is depicted.

The important thing to consider when using the tool and before making any modification, is that each scenario has been designed so that the scenario as a whole is intended to provide a conservative estimate of exposure. Some parameters are dependent upon each other, for example for a do it yourself type product such as wallpaint, use amount will depend upon room size. Therefore it is important that the user carefully consider and justify any modification to the default values.



Demo – EGRET-based assessment

• Step 8: EGRET exposure predictions

Range of exposures can be modelled:

- local vs. systemic
- on day of use vs. chronic

		dermal			oral		inhalation					
Relevant Use Sentinel Product	Product sub Category Sentinels	TRA Tier 1- Predicted Exposure - ECETOC TRA - refined estimates										
		Predicted Dermal Exposure, Daily (mg/kg/d)	Predicted Dermal Exposure, Chronic (mg/kg/d)	Predicted Dermal Exposure, Local (mg/cm2)	Predicted Oral Exposure, daily (mg/kg/d)	Predicted Oral Exposure, Chronic (mg/kg/d)	Predicted Inhalation Exposure, daily (mg/kg/d)	Mean Inhalation Event Concentration (mg/m³)	Indicator for Basis of the Inhalation Event Concentration (SVC 8 Saturated Vapor)	Mean Inhalation Concentration (24hr TWA) on Day of Exposure (mg/m3)	Mean Inhalation Concentration Yearly (mg/m3)	Total Predicted Exposure (mg/kg/d)- day of use for TRA
		day of use	chronic	event	day of use	chronic	day of use	event		day of use	chronic	
PCLAdhesives, sealants		1.79	1.79	3.00	n/a	n/a	4.67	51.15		8.52	8.525	6.46
	Glues, hobby use											
PCLAdhesives, sealants		5.50	0.06	3.00	n/a	n/a	3547.96	25897.51		6474.38	64.744	3553.46
	Glues DIY-use (carpet glue, tile glue, wood parquet glue)											

32

In slide 32 as we continue to move to the right in the CSA worksheet we next come to the EGRET exposure predictions based upon the EGRET inputs in the previous section. As discussed earlier, exposure predictions are provided for a range of REACH relevant exposures, including local and systemic effects, and day of use and chronic scales.



Demo – EGRET-based assessment

• Step 9: EGRET risk characterization

		Local Use		On Day of Use					Chronic Considering Yearly Use Frequency		
Relevant Use Sentinel Product	Product sub Category Sentinels	TRA Tier1- Risk Characterization - refined estimates									
		RCR dermal local (based on mg/cm2)	RCR inhalation local (based on Activity TWA mg/m3)	RCR systemic (dermal, daily, based on mg/kg/d)	RCR systemic (oral, daily, based on mg/kg/d)	RCR systemic (24hr TWA inhalation mg/m3)	RCR systemic (all routes, daily)	RCR systemic (dermal, chronic, based on mg/kg/d)	RCR systemic (oral, chronic, based on mg/kg/d)	RCR systemic (inhalation, yearly, based on mg/m3)	RCR systemic (all routes, chronic)
				20	0	100		28.9	0.0	100.0	
PC1Adhesives, sealants	Glues, hobby use	n/a	n/a	0.09	n/a	0.09	0.17	0.09	n/a	0.09	0.17
PC1Adhesives, sealants	Glues DIY-use (carpet glue, tile glue, wood parquet glue)	n/a	n/a	0.28	n/a	64.74	65.02	0.00	n/a	0.65	0.65

Cells in red
highlight
RCR>1

Cells in yellow highlight
RCR> target RCR
(0.5 in this case)

Target
RCR


0.5

0.6
0.5
0.4

33

In slide 33 further continuing to the right, we next find the EGRET Risk Characterization Ratios calculated from the exposure predictions and the substance specific DNEL values that have been entered. These are again based upon the EGRET inputs provided earlier in the tool. I would like to point out that for the first two exposure scenarios, RCRs are greater than 1 only for the second one a daily use basis. In comparison, based upon the TRA defaults these RCRs were much higher. Here, you can also see that RCRs are provided by exposure route and also as a summary of all routes for systemic effects.

Using the frequency bands, which consider that infrequent uses are being compared to chronic Derived No Effect Levels, the RCRs are not less than one for either of the first product subcategories. The tool uses changes in color highlighting to help the user understand cases in which the RCR is above value of interest. Cells in red denote an RCR > 1, and cells in yellow highlight an RCR that exceeds the target RCR.



Demo – OCs and RMMs in EGRET

- Step 10: EGRET OCs/RMMs

Relevant Use Sentinel Product	Product sub- Category Sentinels	TRA Tier- Risk	Operation Conditions (OCs)	Risk Management Measures (RMMs)	Indicator for Basis of Exposure Estimate	Risk Characterization - including RMMs when needed (substance Specific)			
		RCR systemic (all routes, chronic)		RCR systemic (dermal, based on mg/kg/d)		RCR systemic (oral, based on mg/kg/d)	RCR systemic (inhalation based on mg/m ³)	RCR systemic (all routes)	
						d	o	i	t
PC1Adhesives, sealants	Glues, hobby use	0.17	Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 364 days/year [ConsOC3]; covers use up to 1 time on day of use [ConsOC4]; covers skin contact area up to 35.73 cm ² [ConsOC5]; for each use event, covers use amounts up to 5g [ConsOC6]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m ³ [ConsOC11]; for each use event, covers exposure up to 4.00h/event [ConsOC14].	No specific RMMs identified beyond those OCs stated	Based upon daily use	0.09	n/a	0.09	0.17
PC1Adhesives, sealants	Glues DIY use (carpet glue, tile glue, wood parquet glue)	0.65	Unless otherwise stated, covers concentrations up to 30% [ConsOC1]; covers use up to 1 day/year [ConsOC3]; covers use up to 1 time on day of use [ConsOC4]; covers skin contact area up to 100.00 cm ² [ConsOC5]; for each use event, covers use amounts up to 6390g [ConsOC6]; covers use under typical household ventilation [ConsOC8]; covers use in room size of 20m ³ [ConsOC11]; for each use event, covers exposure up to 6.00h/event [ConsOC14].	Avoid using at a product concentration greater than 23% [ConsRMM1].	Based upon infrequent use - RMM	0.00	n/a	0.50	0.50

RMMs are automatically populated to:

- demonstrate safe use based upon long-term systemic effects
- meet target RCR (0.5 in this case)

34

On slide #34, proceeding further to the right in the CSA worksheet, we now see for each scenario the operational conditions and RMMs. The operational conditions are the summary of all of the EGRET input values. Any additional Risk Management Measures that must be implemented to reduce the RCR to a value less than the target RCR are also specified. To the right of the RMMs, we also see the RCRs that result for scenario after including the RMMs in the exposure calculation.

So to summarize so far, we have reviewed how to enter user input into the CSA worksheet, as well as reviewed the structure, information, and where output is shown within this worksheet.



Demo – EGRET ES Narratives


- Step 11: EGRET ES Narratives

Section 1		Exposure Scenario Title
Title		Uses in Coatings
Sector of Use (SU code)		21
Use Descriptor (PC codes)		PC1, PC4, PC8 (excipient only), PC9, PC15, PC18, PC23, PC24, PC31, PC34
Processes, tasks, activities covered		Covers the use in coatings (paints, inks, adhesives, etc) including exposures during use (including product transfer and preparation, application by brush, spray by hand or similar methods) and equipment cleaning.
Environmental Release Category		0
Specific Environmental Release Category		0
Section 2		Operational conditions and risk management measures
<i>Field for additional statements to explain scenario if required - pending better understanding from ECHA</i>		
Section 2.1		Control of consumer exposure
Product characteristics		
Physical form of product		liquid
Vapour pressure (Pa)		200
Concentration of substance in product		Unless otherwise stated, covers concentrations up to 100% [ConsOC1]
Amounts used		Unless otherwise stated, covers use amounts up to 13800g [ConsOC2], covers skin contact area up to 857.5cm ² [ConsOC5]
Frequency and duration of use/exposure		Unless otherwise stated, covers use frequency up to 365 days per year [ConsOC3], Unless otherwise stated, covers use frequency up to 1 times per day [ConsOC4], covers exposure up to 6 hours per event [ConsOC14]
Other Operational Conditions affecting exposure		Unless otherwise stated assumes use at ambient temperatures [ConsOC15], assumes use in a 20 m ³ room [ConsOC11], assumes use with typical ventilation [ConsOC8]
Section 2.1.1		Product categories
PC1 Adhesives, sealants—Glues, hobby use	OC	Unless otherwise stated, covers concentrations up to 30% [ConsOC1], covers use up to 364 days/year [ConsOC3], covers use up to 1 time/on day of use [ConsOC4], covers skin contact area up to 35.73 cm ² [ConsOC5], for each use event, covers use amounts up to 9g [ConsOC2], covers use under typical household ventilation [ConsOC8], covers use in room size of 20m ³ [ConsOC11], for each use event, covers exposure up to 4.00hr/event [ConsOC14].
	RMM	No specific RMMs identified beyond those OCs stated
PC1 Adhesives, sealants—Glues DIY-use (carpet glue, tile glue, wood parquet glue)	OC	Unless otherwise stated, covers concentrations up to 30% [ConsOC1], covers use up to 1 day/year [ConsOC3], covers use up to 1 time/on day of use [ConsOC4], covers skin contact area up to 110.00 cm ² [ConsOC5], for each use event, covers use amounts up to 6390g [ConsOC2], covers use under typical household ventilation [ConsOC8], covers use in room size of 20m ³ [ConsOC11], for each use event, covers exposure up to 6.00hr/event [ConsOC14].
	RMM	Avoid using at a product concentration greater than 23% [ConsRMM1]

Finally, in slide 35, we are now moving to the narrative worksheet to see how this information is automatically summarized in the exposure scenario format for REACH. The worksheet includes the name of the Generic Exposure Scenario, in this case coatings, and the product codes associated with this GES. Moving further down, substance and product code specific information is automatically populated. The general operational conditions that prevail across all product codes and subcategories are also summarized.

Moving further down any additional operational conditions, and if needed, Risk management measure are shown for ALL of the individual subcategories within the GES. Both the Operational Conditions and Risk Management Measures are provided in standard phrases found within the (ESCom and EuPhrac) standard phrase library(ies), facilitating translation for use in extended safety data sheets.

At this time, the test demonstration is now concluded, but I would like to go back to one slide to provide some more general information on the tool structure.



Summary

- EGRET is a tier 1.5 risk assessment consumer tool
 - minimal user inputs
 - refined exposure predictions
 - assessment of multiple scenarios in one run
 - autopopulation of safe use conditions in REACH format
 - communication with standard phrases

GES

GES Background
GES Workers
GES Consumers
GES SPERCs
GES Phrase Library
GES Glossary

REACH Generic Exposure Scenarios (GES) - OVERVIEW

The ESIG GES library includes:

- 1) [Index of GES titles](#) (including scope and associated Use Descriptors)
- 2) [Worker](#) (Industrial and Professional) GES library
- 3) [Consumer](#) GES library
- 4) [Environmental SPERCs](#) library

The GESs contained within the ESIG/ESVOC library have been developed for solvents, although the underpinning principles are equally applicable to other solvent-like materials.

GES Consumers

[Click here to download the GES Consumer files](#)

Version 2 of [EGRET](#) is now available and is supported by a more extensive [User Manual](#) together with eight individual consumer GES. In addition a summary of the tool including latest adjustments are included in the attached [presentation](#).

GES Consumers


ID	FILE
	EGRET 2 Agrochemicals_Consumers
	EGRET 2 Cleaning_Consumers
	EGRET 2 Coating_Consumers
	EGRET 2 Deicing_Consumers
	EGRET 2 Fuels_Consumers
	EGRET 2 FunctionalFluids_Consumers
	EGRET 2 Lubricants_Consumers
	EGRET 2 WaterTreatChemicals_Consumers

To wrap up the presentation the key messages of today's webinar are highlighted in slide #37.

EGRET is a tool for consumer exposure and risk assessment developed by the European Solvent Industry Group for solvents and solvent-like products (e.g. fuels and lubricants). The tool can also be useful for formulators of solvent-containing mixtures when they want to carry out their own chemical safety assessments. Since the tool was specifically designed for solvents, the assessor of other consumer product ingredients, e.g. fragrances, are urged to check whether the generic exposure scenarios in EGRET reflect typical use of other substances.

Overall,

- EGRET is sought of as a Tier 1+ tool that requires minimal user inputs, but provides refined exposure predictions as compared to Tier 1 models.
- It is able to simultaneously run multiple exposure scenarios for individual PCs and asses various types of risks.
- In EGRET safe use conditions are derived automatically following the control banding approach; the user is also enabled to specify additional safety margin by selecting the target RCR.
- Most importantly, EGRET is fully compatible with REACH requirements: it automatically generates appropriately formatted ESs based on the outcomes of the CSA; in those ESs OCs and RMMs are communicated with standard phrases from ESCom library.



Future plans


- In 2016 – to develop EGRET assessment outputs in Chesar XML format to:
 - Enable utilizing ECHA's IT tool box features with EGRET Tier 1.5 assessment for CSA generation
 - Enable transfer of documented refined and justified OCs, RMMs and exposure predictions into Chesar in an automated secure manner
 - Facilitate direct communication of information with International Uniform Chemical Information Database (IUCLID):
 - By generating section 9 and 10 of the full chemical safety report
 - By populating use and exposure relevant fields of IUCLID

EGRET

⇒


XML

⇒



⇐

⇒



38

EGRET as any other tool is dynamic in nature and gets updated as necessary.

In terms of the plans for the near future, which are shown in the next slide, tool's recognition is considered to be the main priority. This webinar in particular was designed to increase public awareness of EGRET and promote its expert use.

In addition, ESIG has recently launched a project on the development of XML files that can be directly imported into ECHA's Chemical Safety Assessment and Reporting tool (Chesar). These XML files will allow the risk assessor to automatically transfer **all the information from EGRET** (incl refined and justified OCs and RMMs) directly into Chesar. Once in Chesar the EGRET-based CSA can be inherently integrated into the CSR generated with Chesar as well as provide basis for the population of use and exposure sections in IUCLID.

In the long-term perspective it would be also good to enhance the tool with the articles exposure scenarios. However, the exact timeline for that activity has not been defined yet.



Questions?

39

Thanks!