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Introduction to SCEDs
(Specific Consumer Exposure Determinants)

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Challenge for REACH Consumer CSAs

- Chapter R15 of the TGD is conservative. It is meant to be. It aims to ensure that no consumer uses exist that are unsafe.
- Only two consumer Tier 1 model available for developing CSAs i.e. Chesar and ECETOC TRA
- TRA takes the basic algorithms of the ESR TGD but adopts them to reflect the inherent precaution expressed by REACH ChR15
- Utility of TRA v2 limited. TRAv3 offers improved accuracy but is still constrained in the extent to which iteration is possible.

- So how can the process be improved?
- The solution is to move away from the standard TRA default values by allowing the use of relevant and justified exposure determinants

➢ ***Specific Consumer Exposure Determinants (SCEDs)***

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SCEDs : Basic Premise

- ECETOC understands the science of exposure assessment. But the TRA needs hard data to exploit the boundaries of exposure science
  - But only industry sectors really have knowledge of where (and how) their products are used
- Specific Consumer Exposure Determinants (SCEDs) serve as the vehicle for reliably, efficiently and consistently supplying these data
- SCEDs require clear and transparent justification in order that they can be seen to be reliable and representative for the described use
- SCEDs should be available to support the primary uses of the principle consumer products that contain chemicals
  - PCs and PC_sub categories covered by the TRA together with further sub categories where considered appropriate
  - SCEDs can also be developed to cover articles that contain chemical substances
- SCEDs need to be applied in a manner that aligns with the expectations of ChR15 of the TGD

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Principles Underpinning SCEDs (1)

1. The application of the information within a SCED will be consistent with the process described in ChR15 of the TGD
   - Tier 1 information will first be applied to determine the nature of any exposure/risk.
2. SCEDs should cover all relevant routes of exposure for the use.
3. SCEDs are developed by trade groups/associations.
   - the group commits to communicate and apply its contents
4. SCEDs are intended to be available for all circumstances where consumer exposures to chemicals are commonly encountered.
5. The format and content of the SCED uses the template described in Appendix F of ECETOC Technical Report 114.
6. The minimum content of the SCED addresses exposure determinants necessary to run the TRAv3 consumer module
7. Each data point within the SCED should be substantiated/ verified by reference to 'open access' information sources

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Principles Underpinning SCEDs (2)

8. Where habits and practices differ across countries/regions, then the SCED should reflect those areas with the highest uses/exposure conditions.
9. The trade group commits to routinely review the SCED's content to ensure it remains accurate and current.
   - And to close identified information deficiencies
10. DUCC commits to make available SCEDs in a publically accessible SCED library

DUCC/CONCAWE background document on SCEDs available at :

http://echa.europa.eu/documents/10162/12738969/enes4_pres_session5background_document_sceds_guidance_v10_en.pdf

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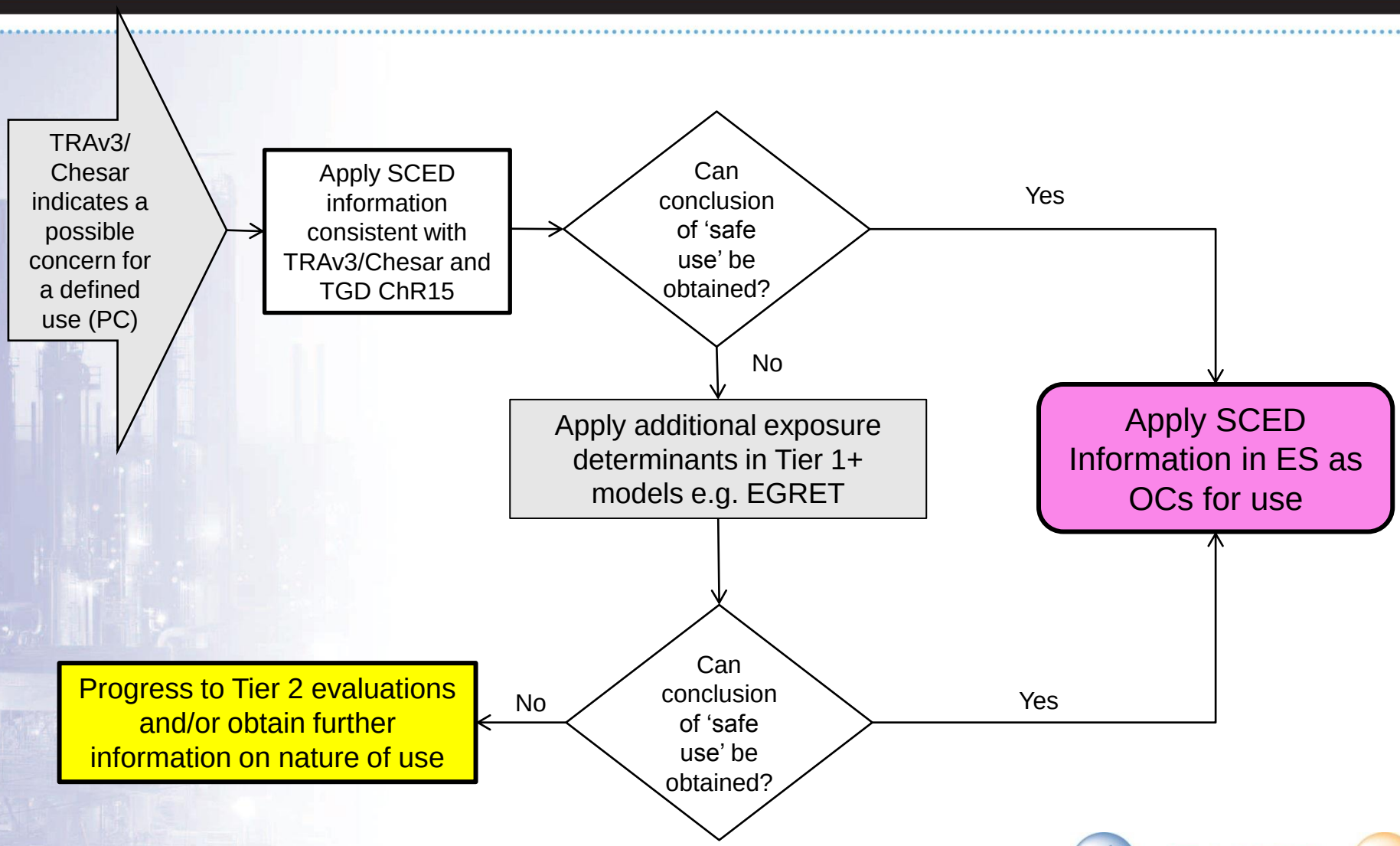
Format of SCEDs

Use descriptor or determinant: explanation		Relevance in ECETOC TRA v3[4]
Title of the use, generic description: e.g. ES short title		Standard TRA, extended TRA, other tools
Product/Article Use Category	The product category (PC) describes in which types of chemical products (substances as such or in mixtures) the substance is finally contained when it is supplied, in this case to consumers. The article category (AC) describes the type of article into which the substance has eventually been processed.	Standard TRA , Extended TRA
PC/AC Subcategory	If one of the product or article sub-categories used as entries to the ECETOC TRA is more suitable than a product category it shall be stated here.	Standard TRA, Extended TRA
Product Ingredient Fraction (by weight)	Concentration of the substance in the product, based on product-specific information.	Standard TRA, Extended TRA
Frequency of Use (events/day , and for an infrequently used product also provide days/year)	Number of times per day that a product is used, based on product-specific information.	Standard TRA, Extended TRA
Relevant Route(s) of Exposure	Consumer exposure estimation needs to consider three separate exposure routes: inhalation exposure, dermal exposure, oral exposure. Indication of which of these route is (are) relevant for the use of the product.	Standard TRA, Extended TRA
Product Characteristics / Properties	*In case there is a characteristic/property than can/will affect the value of some of the exposure determinants (e.g. volatility) it shall be stated here. Such physchem-based considerations may be relevant for certain sector, e.g. for the use of fuels of varying volatility.*	Extended TRA
Dermal Specific Parameters		
Skin Contact Area	Skin area (in cm^2) which is exposed to the product. This value can only be entered for either the adult or child, but not both.	Extended TRA
Skin Transfer Factor	Fraction (>0 to 1) of the substance transferred from the product to the skin. If the user has relevant, specific information or knowledge on the pattern of transfer, he can enter transfer fraction values to refine the exposure estimate. If no data is available, a conservative estimate of	Standard TRA, Extended TRA

Inhalation Specific Parameters		Standard TRA Extended TRA
Amount of Product used per application	Amount used, in g, based on product-specific information.	Standard TRA, Extended TRA
Exposure Time	Duration of the exposure, in hr, based on product-specific information and consumer habits.	Standard TRA, Extended TRA
Inhalation rate	In m^3/hr	Standard TRA, Extended TRA
Room Volume	Room volume, in m^3.	Standard TRA, Extended TRA
Is product use outdoors only?	Information on whether the use occurs only outdoors.	Extended TRA
Ventilation specified or likely due to properties (i.e., odour, etc.)- if so what type – (open window, fan)	Number of air changes per hour.	Extended TRA
Inhalation Transfer Factor	Fraction (>0 to 1) of the substance transferred from the product into the air. If the user has relevant, specific information or knowledge on the pattern of transfer, he can enter transfer fraction values to refine the exposure estimate (by varying the 'effective' amount of substance handled). If no data is available, a conservative estimate of 100% is assumed.	Standard TRA, Extended TRA
Oral Specific Parameters		
Volume Ingested	In cm^3.	Standard TRA, Extended TRA
Oral Transfer Factor	Fraction (>0 to 1) of the substance transferred from the product to the mouth, after mouthing of a product. If the user has relevant, specific information or knowledge on the pattern of transfer, he can enter transfer fraction values to refine the exposure estimate. If no data is available, a conservative estimate of 100% is assumed.	Standard TRA, Extended TRA

Inhalation Specific Parameters		
Amount of product used per application (g)	37500	Based on 50 litres and density of 750 g/l
Exposure Time (hr)	0.05	3 minutes, 97[th]% value from Vainiotalo *et al*, 1999
Is product used outdoors only?	Outdoor use	
Room Volume (m^3)	100	$100m^3$ used as default volume (consistent with Stoffenmanager)
Ventilation specified or likely due to properties (i.e. odour, etc.) – if so what type – (open window, fan)	0.6	Outdoor air exchange rate considered to equivalent to value cited by RIVM for garages (0 ftc)
Inhalation factor (fraction of total amount handles lost to air)	0.2%	Evaporative losses during refuelling expected to be <<1% based on mass balances

Use of SCED Information



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Consumer Uses of Petroleum Substances

- Many different PSs have common uses
  - Particularly as fuels and lubricants
- But the general use terms cover a range of specific uses
  - E.g. fuelling a car vs garden machinery vs indoor heater
- And different PSs can also be used very differently for a common use
  - LPG vs diesel vs gasoline in motor vehicles
- Historically, some PSs have also been used as 'general solvents'

- How many SCEDs are required to cover the range of PS uses?
- Are 'repeat SCEDs' required for the similar uses of different products?
- Are the exposure determinants contained in the TRAv3/ChR15 sufficient/appropriate to address PSs?
  - Are consumers really exposed to 70 litres of fuel when re-fuelling?
  - Are both hands coated with lubricants when oiling a bike chain?

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Scope of Current CONCAWE SCEDs

Product Category	Use Type	Product Type
Fuels	• Consumer re-fuelling of cars and similar vehicles	• Gasoline • LPG • Diesel
	• Garden equipment use	• Gasoline
	• Home space heating	• Kerosene • LPG
	• Recreational vehicles	• Gasoline
	• Lamp oils	• Gas oils • Foots oils
Lubricants	• Filling passenger vehicle engine	• Base oils • Kerosene • Gas oils • RAEs

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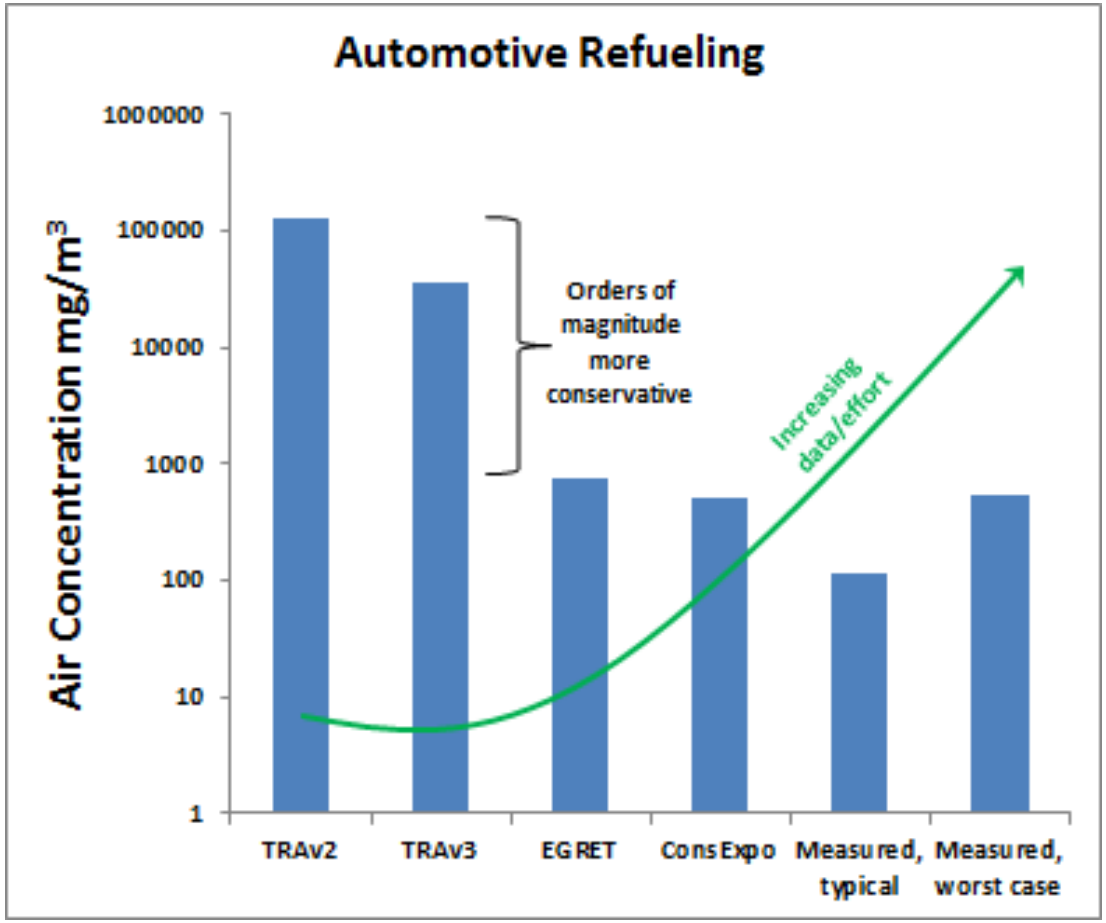
Impact of SCED Application

The information within the SCED is critical for enabling more realistic estimates of exposure to be obtained



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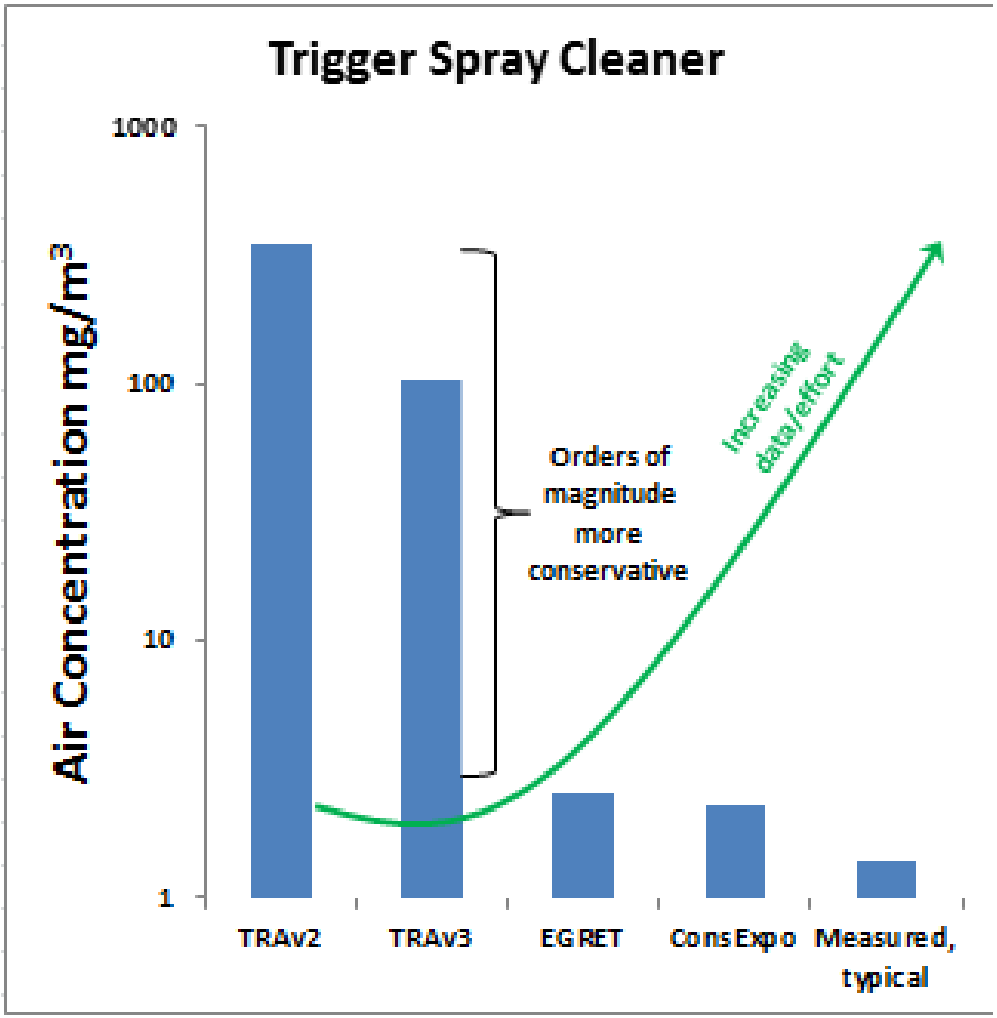
Impact of SCED Application

The number of SCEDs available for a sector is likely to be a reflection of the nature of the associated exposures and risks



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Summary

- DUCC has coordinated a cross-industry activity aimed at developing an initial SCED library
- Principles for SCEDs developed, piloted and tested
  - Endorsed by ECHA and the MSs at ENES4
- The SCED delivers the ability to exploit the new functionality of TRAv3 as well as companion tools (e.g. EGRET, CONSEXPO)
- ECETOC is now working with stakeholders to deliver an updated TRA that will efficiently process available SCED data
- There are gaps in the current coverage of SCEDs
  - Other sectors now need to offer their data
- But be aware that developing the SCEDs is a not an easy exercise
  - SCEDs highlight what is know and what is assumed about consumer exposures

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Questions ?

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