

REACH Chemical Safety Assessment, Report and Exposure Scenario

Jacquie Berryman
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Performance you can rely on.



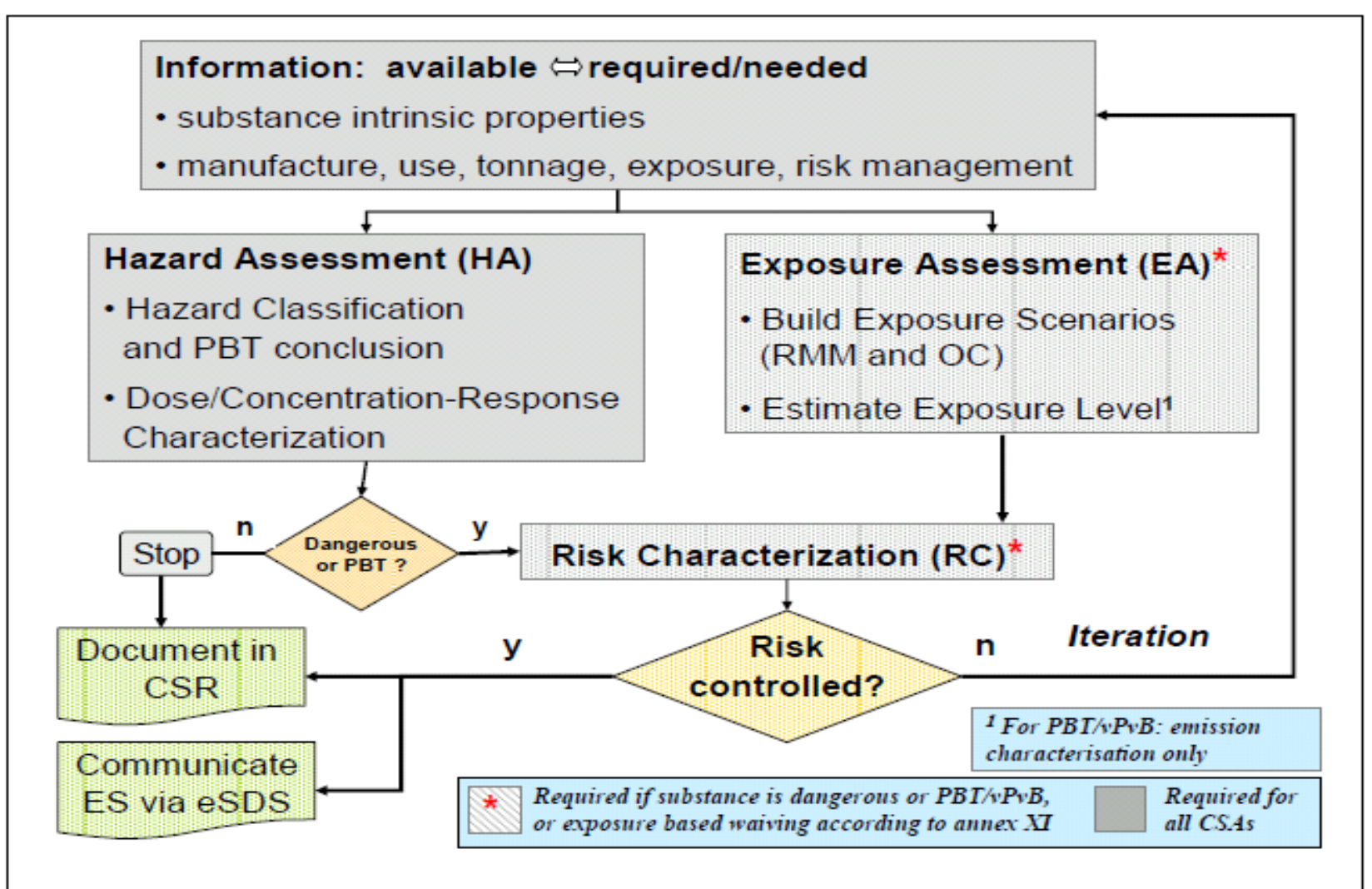
Presentation Outline



- Chemical Safety Assessment and Report
 - What and why
 - Process
 - Exposure Scenario's
- Lubricant Industry approach
 - ATC REACH Consortia
 - ATIEL / ATC GES Working Group
 - Next steps
- Back Up Slides
- Glossary of terms
- Information sources

- One of the basic principles of REACH is to ensure that substances manufactured or imported to Europe are used in a way which does not adversely impact human health or the environment.
- REACH requires that Manufacturers and Importers (MI's) assess the intrinsic hazards of the substance
 - Chemical Safety Assessment (CSA)
- For those substances that are classified as dangerous or PBT, vPvB the CSA also contains
 - Emission and exposure assessment throughout its life cycle.
 - Exposure Scenario
 - Risk characterisation
 - Identification of the operational conditions and risk management measures required to manage the risk
- A Chemical Safety Report (CSR) documents the CSA including its conclusions and results.

- The CSR is compiled by the MI for his own records and is also attached to the registration dossier.
- For substances classified as dangerous the MI is required to
 - Implement the OC and RMM's at his own facility
 - Communicate these down the supply chain
 - Exposure Scenarios
 - Extended Safety Data Sheet
- The Exposure Scenario is the key tool for communicating OC's and RMM's required to ensure risks are controlled.
 - Operation conditions can include application process, duration and frequency of use.
 - Risk management measures can include waste water treatment or local exhaust ventilation





Lubricant Industry Approach

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ATC REACH Consortia



- Technical Committee of European Petroleum Additive Manufacturers (ATC) is main trade association for petroleum additive manufacturers
 - Components suppliers
 - Formulators
- ATC REACH Working Group formed July 2004 to collaborate on regulatory projects that benefitted the Petroleum Additive Supply Chain
- Major Petroleum Additive Manufacturers have a history of working together on regulatory initiatives
 - US EPA High Production Volume Challenge
- REACH WG members
 - Afton
 - Chemtura
 - Chevron Oronite
 - Ciba
 - Infineum
 - Innospec
 - Lubrizol
 - Rhein Chemie

- Some early challenges in set up the consortia overcome with external independent help.
 - Confidentiality
 - Cost sharing
 - Anti trust
- Consortia currently working in 10 Task Forces to progress registration of over 50 priority substances for the lubricant additive industry.
 - Data gap analysis
 - Testing
 - Dossier preparation
 - CSA/CSR
 - SIEF communications
- Preparatory work for 2013 substances underway

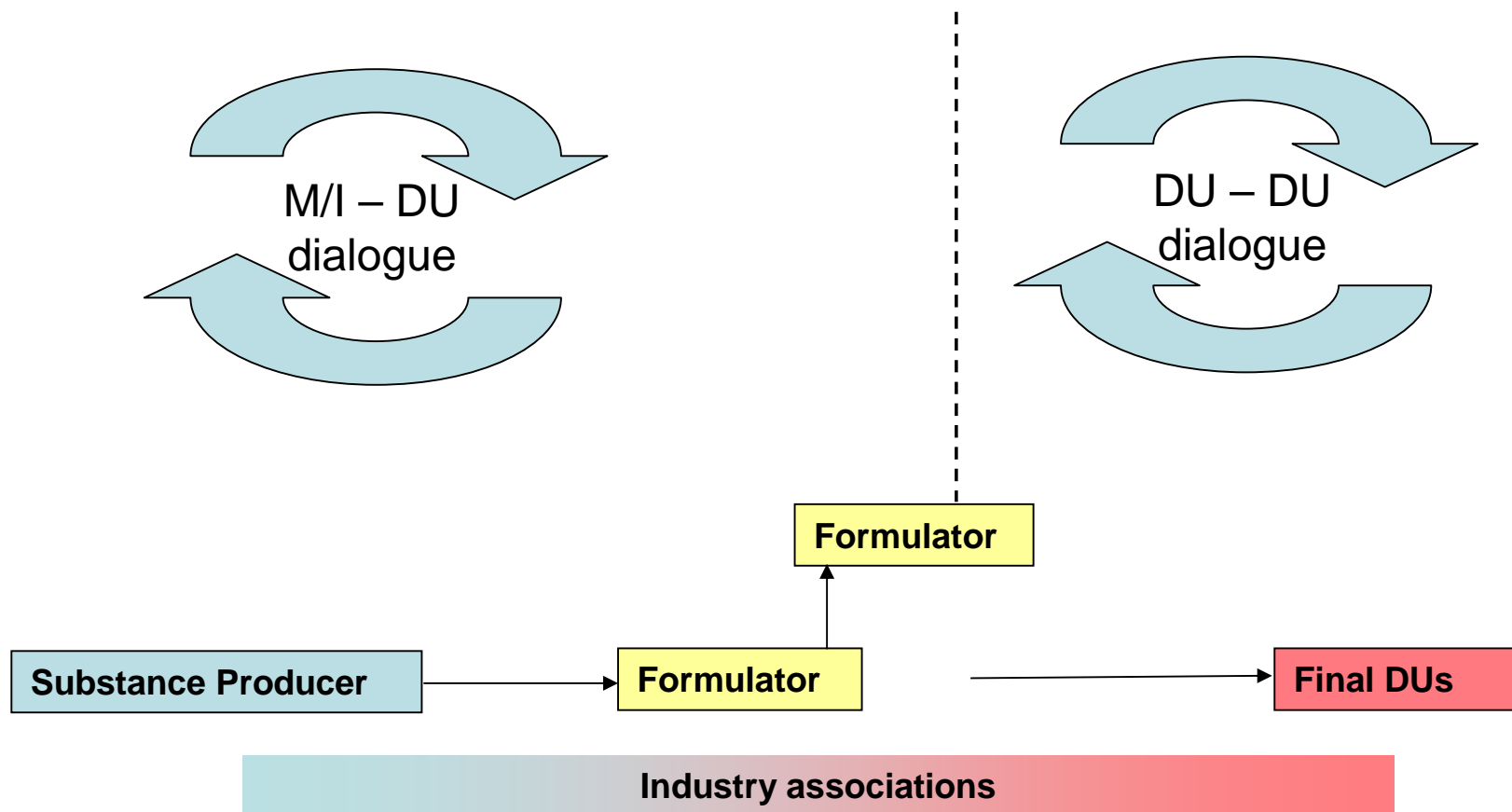
- ATIEL / ATC GES Working Group have been working to develop a standard industry approach to the development of Generic Exposure Scenario's.
- Initial output from the ATIEL / ATC REACH WG is posted on both trade associations web site
 - For lubes
 - Welcome to ATIEL
 - http://www.atiel.org/Reach_GES.htm
 - For fuels
 - Welcome to ATC
 - <http://www.atc-europe.org/reach-generic-exposure-scenario-ges.asp>
- The target audience for the information on these websites includes
 - Substance manufacturers and importers who need to prepare CSA/CSR's
 - Downstream Users who may want to verify the types of lubricant applications which are likely to be covered by lubricants and lubricant additive suppliers
- An example of the supplier-customer dialogue envisaged by ECHA guidance

Dialogue in the Supply Chain



- Identify uses
- Build exposure scenarios
- Conduct safety assessment

- Make uses known to M/I
- Inform on conditions of use
- Give feedback to exposure scenarios



- The working group are continuing activity to deliver
 - SPERCs (Special Environmental Release Categories) covering lubricant use
 - Intended to supersede ERCs in RIP guidance R.12 which are very conservative in their assumptions related to environmental release
 - Generic Exposure Scenario's for each Use Group
 - For mixtures
 - Habits and Practices information
 - Representative of consumer use of lubricants that can be used, in conjunction with the ECETOC TRA, to derive more accurate estimates of consumer exposure to lubricants.

There is still a long road ahead.....



**Thank you for your
attention**

Any ???

Back Up Slides

ATIEL / ATC DUCC Table



Revised 02_Aug_10	ATIEL-ATC EXPOSURE SCENARIO INFORMATION IN DUCC FORMAT		Compliant with ECHA guidance on use descriptors dated 22 March 2010						
Code	Short ES title	Short description of process or activity	Use Descriptors						
			Sector of use (SU)	Process Category (PROC)	Product category (PC)	Product Sub-category	Environmental Release Category (ERC)	SPERC	Article Category (AC)
ATIEL-ATC Group A (i)	Industrial formulation of lubricant additives, lubricants and greases. Includes material transfers, mixing, large and small scale packing, sampling, maintenance and associated laboratory activities.	Closed continuous processes at elevated temperature with sampling, including grease manufacture.	SU 3, 10* *maybe not applicable for use as intermediate	PROC 2	PC 17, 19*, 24, 25	n/a	ERC 2 ERC 6A*	under development	n/a
		Batch closed process with sampling. Blending and Filling processes (closed / dedicated). Includes both bulk and small quantity additions. May be at elevated temperature, e.g. grease manufacture.		PROC 3					
		Batch open process. Blending and Filling processes (open / non dedicated). Includes addition of both bulk and small quantity additions. May be at elevated temperature, e.g. Grease manufacture.		PROC 4, 5					
		Sample collection of formulation		PROC 4, 5					
		Sample collection of incoming raw materials		PROC 8b					
		Bulk transfers by fixed pipe or flexible hose		PROC8b					
		Small pack (drum/bag) transfers - dedicated facility.		PROC 8b					
		Small pack (drum/bag) transfers - non dedicated facility.		PROC 8a					
		Maintenance & cleaning		PROC 8b					
		Top filling of bulk containers (road cars etc)		PROC8b					
		Filling of drums and small packages		PROC 9					
		QC & Laboratory		PROC 15					
		Material storage		PROC 1, 2					

ATIEL Lubricants Application Table



LUBRICANT APPLICATION		ATIEL-ATC LUBRICANT USE GROUP
Family	Specific application	
Engine oils	Passenger car (gasoline & diesel)	B
Engine oils	Diesel (transportation, public works, agriculture)	B
Engine oils	Marine - MDCL	B
Engine oils	Marine - TPEO	B
Transmission fluids	Industrial gear oil (open)	C
Transport Greases	Chassis lubrication (e.g. includes aviation, heavy goods vehicles)	C
Metalworking	Quenching fluids (water based) - diluted	D
Total loss lubrication	Glass release agents	D
Metalworking	Soluble oil machining/grinding fluids - concentrate	E
Metalworking	Tapping and threading	F
Metalworking	Hobbing	F

Glossary of Terms



- ATC - Additives Technical Committee (Petroleum Additive Manufacturers in Europe)
- ATIEL - Association Technique de l'Industrie Européenne des Lubrifiants
- CSA - Chemical Safety Assessment
- CSR - Chemical Safety Report
- MI - Manufacturer and/or Importer
- PBT - environmentally persistent, bio accumulative and toxic substances
- vPvB - environmentally very persistent, very bio accumulative
- OC - Operating Conditions
- RMM - Risk Management Measure
- SIEF - Substance Information Exchange Fora
- GES - Generic Exposure Scenario
- ECHA - European Chemical Agency
- WG - Working Group
- SPERC - Special Environmental Release Category
- ERC - Environmental Release Category
- ECETOC – European Centre for Ecotoxicology and Toxicology of Chemicals
- TRA – Targeted Risk Assessment

- **Article – anything where the shape of surface properties is of greater importance to the function than the chemical composition (example: an inkjet cartridge)**
- **Downstream User - someone other than a manufacturer or importer who uses a substance either on its own or in a preparation in the course of his industrial or professional activities. (Article 3-13);**
- **Exporter - the last actor in the non-EU supply chain**
- **Formulator - someone who prepares preparations (rip 3-5-2);**
- **Importer - any natural or legal person established within the community who is responsible for import. (Article 3-11)**
- **Manufacturer - someone who manufactures a substance. (Article 3-9)**
- **Preparation - - a mixture or solution composed of two or more substances (example: ink – a mixture of pigments and solvents)**
- **Substance - single chemicals i.e. with a CAS number. A new chemical substance or chemical extract from its natural state (example: Pigments and Solvents) chemical entity, or the product of a manufacturing process.**
- **Third Party Registration - a company can choose to register anonymously through a third party while retaining all responsibilities' for the registration. (Article 4)**

- European Chemicals Agency Homepage:
 - http://ec.europa.eu/echa/home_en.html
- Full and Final REACH Text
 - http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf
- European Chemicals Bureau
 - <http://ecb.jrc.it/>
- IUCLID 5
 - <http://iuclid.eu>
- REACH Navigator Homepage – Guidance on obligations
 - <http://reach.jrc.it/>
- REACH Centrum – A REACH initiative started by CEFIC
 - <http://www.reachcentrum.org/>
- REACHReady, UK focussed REACH initiative from the UK CIA
 - <http://www.reachready.com/>
- “Automotive Industry Guideline on REACH” Version 2
 - http://www.acea.be/images/uploads/files/20080207_AIG-REACH_V2.pdf



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