DRIVING STANDARDS
IN LUBRICANT TECHNOLOGY

The technical committee of petroleum additive manufacturers in Europe

Developing Mixture Exposure Scenarios – a perspective from the Lubricants' Sector

Alison Margary, Shell – on behalf of ATIEL/ATC

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Features of the Lubricant Sector

- **Lubricants are complex mixtures**
  - Frequently contain up to 20 substances
- **Lubricants are marketed for diverse applications:**
  - EU volume 5-6 Million tpa
  - Industrial (~30%), professional (~65%), and consumer (~5%) use
  - Totally closed to total loss; point use to wide dispersive
  - Automotive Lubricants (51%), Industrial Lubricants - including Marine Engine Oil (20%), General Industrial Lubricants - including Greases and Metalworking fluids (29%) [Kline report, 2008]
- **Formulators sell directly to distributors and end-users**
  - Products not generally sold to other formulators

Overview of the Lubricants Supply Chain

Additive Manufacturer & Formulator (Industrial)

- ZDDP (Manufactured)
- Calcium sulphonate (purchased EU)
- Hindered Phenol (manufactured)
- Performance package X (imported, non-classified)
- Base Oil X (purchased EU)

Additive Package 'A'

EU Lubricant Formulator (Industrial)

- Additive Package 'A' (purchased EU)
- Additive package 'B' (purchased EU/imported)
- Substance A/B/C (purchased EU/imported)
- Base Oil Y (manufactured/purchased EU)

Formulated, branded lubricant

Lubricant Use Groups (Industrial, Professional & Consumer)

- 120+ separate applications
- Consolidated into 6 Use Groups
- Based on similar Exposure patterns

Features of the Lubricants' Supply Chain

- Short supply chain
- Reasonably well-defined and structured sector
- Limited number of manufacturers and major formulators
  - Well-organised at the regional level
- Large number of smaller formulators
  - Loosely organised at the national level
- Formulations oriented towards (a limited number of) specific end uses
  - Passenger vehicles; industrial machinery; aviation; marine; etc.
- Stable formulations; not a high rate of change; not a trend for more hazardous mixtures over time

➢ Characteristics that enable generic-based solutions for the sector to be scoped, trialled and refined

ATIEL/ATC Use Groups

ATIEL/ ATC Use Group	Description of Use	Sectors Covered
A	Formulation of lubricant additives, lubricants and greases. Includes material transfers, mixing, large and small scale packing, sampling, maintenance and associated laboratory activities.	i
B	General use of lubricants and greases in vehicles or machinery. Includes filling and draining of containers and enclosed machinery (including engines)	i, p, c
C	Use in open systems. Application of lubricant to work pieces or equipment by dipping, brushing or spraying (without exposure to heat), e.g. mould releases, corrosion protection, slideways	i, p, c
D	Use of lubricants in open high temperature processes, e.g. quenching fluids, glass release agents	i
E	Handling and dilution of metalworking fluid concentrates	i
F	Use of lubricants in high energy open processes, e.g. in high speed machinery such as metal rolling / forming or metalworking fluids for machining and grinding	i, p

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B	General use of lubricants and greas… machinery. Includes filling and … and enclosed machinery (i… …ners	i, p, c
C	Use in open syste… …lubricant to work pieces or eq… …g, brushing or spraying (withou… …), e.g. mould releases, co… …, slideways	i, p, c
D	…cants in open high temperature processes, …enching fluids, glass release agents	i
E	Handling and dilution of metalworking fluid concentrates	i
F	Use of lubricants in high energy open processes, e.g. in high speed machinery such as metal rolling / forming or metalworking fluids for machining and grinding	i, p

Supported by Use Descriptors and mapping of typical OCs and RMMs (DUCC format)

Key features of the approach

- Development of Generic Exposure Scenarios for each Use Group
  - centred on CSA-based verification of conditions of use
- Description of safe use conditions for classified formulated mixtures aimed at providing reliable safe use advice
- Based on worst case human health classification (excluding CMRs) and environmental hazard
  - As a consequence are inherently conservative, but support provision of good practice advice with agreement of the industry sector
- Introduces major efficiency steps
  - GES may be applied to all classified mixtures that are within the boundary of application
  - Estimate most classified lubricants mixtures are covered
- Safe use information for non-classified mixtures but containing hazardous substances listed in Section 3 communicated via main sections of SDS
  - Supports DU expectation that ES relevant for classified products only

Key information requirements to apply the approach - Formulators

- To check against GES boundary conditions
  - List of classified products mapped to GES Use Groups
  - Concentration level of components driving the classification
  - Identification of environmental Risk Determining Substance(s) (RDS)
- To verify incoming ES for raw materials driving mixture classification are within the boundary of the GES
  - Raw materials mapped to GES Use Groups

  Human health
  - Comparison of GES OCs/RMMs against incoming ES, supported by raw material concentration, vapour pressure, DNEL

  Environment
  - Verification that correct GES has been selected on basis of raw material Vapour pressure, Kow, Biodegradability, PNEC (aq)
  - Comparison of GES OCs/RMMs and safe use rates against incoming ES

Key information requirements to apply the approach - DUs

GENERAL

- Understanding of the intended use of product
  - GES titles supported by simple explanatory statements

HEALTH

- Check that their own conditions of use (OCs and RMMs) are within the boundary of the communicated ES
  - Contributing Scenarios and associated PROCs

ENVIRONMENT

- Check that the communicated RMMs (or equivalent) are in use
- Check that their DU use rate of a product (kg/day) is less than Msafe value found on the ES

How were Health GESs developed ?

- Typical compositions and hazard classifications of products identified for each ATIEL Use Group
- Boundary conditions described using COSHH Essentials / EMKG control banding approaches and key Risk Determining Substances as the reference point

  e.g. concentration of the relevant hazardous substances, definition of exposure reference values
- CSAs conducted for each ATIEL Use Group supported by typical OCs and RMMs mapped in the DUCC table and Boundary Conditions
  - using ECETOC TRA for exposure estimates and Cefic Worker CSA Template
- GES narratives developed from CSAs using standard phrases

Health boundary conditions matrix - Screening (to check HH GES is applicable)

Row Number	Criteria / Boundary Condition	B: General use in vehicles or machinery B(i) - Industrial B(p) - Professional
1	Product Classification & Labelling (C&L) covered by one or more of the listed R phrases (DPD human health):	R43 R36; R41 R37 R38; R21 R20 R65; R66; R22 (see Note 1) Not classified
2	For products classified as R43 (skin sensitiser), sensitising component is within the listed concentration range:	Skin sensitiser (see Note 2) a) ≥ 0.1 - 1% Strong b) ≥ 1 - 3% Weak or Moderate

Check GES is a good fit for the product:

Use title

C&L of mixture

Concentration of skin sensitisers in mixture (if relevant)

Health boundary conditions matrix - Detailed (to confirm component ES within the GES boundary

Row Number	Criteria / Boundary Condition	B: General use in vehicles or machinery B(i) - Industrial B(p) - Professional
3	Boundary concentration of health Risk Determining Substance(s) in mixture/formulation	**Skin sensitisers:** ≤ 1% of strong sensitiser ≤ 3% of weak/moderate sensitiser **Other hazardous components except CMRs:** a) ≤ 25% (industrial) * b) ≤ 5% (professional) * * Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) c) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES.
4	Boundary Reference Value (RV), long term (8 hour) dermal and inhalation for health Risk Determining Substance(s)	**(i) RV inhalation vapour:** ≥ 5ppm OR Vapour Pressure ≤0.01 Pa. **(ii) RV dermal:** ≥ 0.5 mg/kg bw/day

Boundary concentration:

1. Skin sensitisers, if relevant
2. Other hazardous components with defined concentrations (ind/prof) (except CMRs)
3. Other, if component OCs/RMMs equal or less stringent

Boundary reference value:

- inhalation and dermal

How were Environmental GESs developed?

- Information gathered from Members:
  - Potential Risk Determining Substances (RDS)
  - Typical use rates
  - Exposure data
  - Typical OCs and RMMs used
- Obtained volume data for lubricants' supply chain
- Developed SpERCs (Specific Environmental Release Categories) for industrial and professional use groups

How were Environmental GESs developed?

- **Generic RDSs**
  - RDSs made generic by describing each as a set of key properties
  - Key properties identified were: Kow, vapour pressure, biodegradability and PNEC $_{FW\ aqua}$
  - Generic cut-off points determined for each property
  - 40 different profiles created, identified by RDS code

RDS code assigned on basis of four substance characteristics

Four substance parameters to determine RDS code				RDS Code
log Kow	VP (pa)	Biodegradability	PNEC mg/l	
<5	<1	Readily biodegradable	0.00001 ≤ - <0.0001	1.1
<5	<1	Readily biodegradable	0.0001 ≤ - <0.001	1.2
<5	<1	Readily biodegradable	0.001 ≤ - <0.01	1.3
TriPP, CAS 115-86-6, EC 204-112-2				1.3.1
<5	<1	Readily biodegradable	0.01 ≤ - <0.1	1.4
<5	<1	Readily biodegradable	0.1 ≤ - <1.0	1.5
<5	<1	Not biodegradable	0.00001≤ - <0.0001	2.1
<5	<1	Not biodegradable	0.0001≤ - <0.001	2.2

RDS codes assigned according to key parameters

How were Environmental GESs developed?

- **Generic Safety Assessments**
  - Safety Assessments carried out for all RDS codes and lubricant use groups using ECETOC TRA tool
  - Inputs into TRA:
    - Release fractions
    - Volumes
    - Worst case properties within each RDS code
  - Output from TRA:
    - Msafe values – maximum amount that can be used safely under given conditions
    - Removal efficiencies

How were Environmental GESs developed?

- GES compilation
  - TRA inputs and outputs provided as look-up tables
  - GES values selected from tables according to RDS code and lubricant use group
  - Values inserted alongside relevant OC/RMM standard phrases to create the GES

Release fractions (RF) to three environmental compartments for different use groups: WASTE WATER

RDS Code	ATIEL ATC Use group Release Fraction (RF) to water from process (after ty								
	Ai-add pack	Ai-lubes	Bi	Bp	Bc	Ci	Cp	Cc	Di
1.1	2.00E-10	2.00E-11	2.00E-11	5.00E-04	5.00E-04	2.00E-11	5.00E-04	5.00E-04	
1.2	2.00E-10	2.00E-11	2.00E-11	5.00E-04	5.00E-04	2.00E-11	5.00E-04	5.00E-04	
1.3	2.00E-10	2.00E-11	2.00E-11	5.00E-04	5.00E-04	2.00E-11	5.00E-04	5.00E-04	see
1.3.1	1E-10	1E-11	1E-11	5.00E					
1.4	2.00E-10	2.00E-11	2.00E-11	5.00E					
1.5	2.00E-10	2.00E-11	2.00E-11	5.00E					
2.1	2.00E-10	2.00E-11	2.00E-11	5.00E					

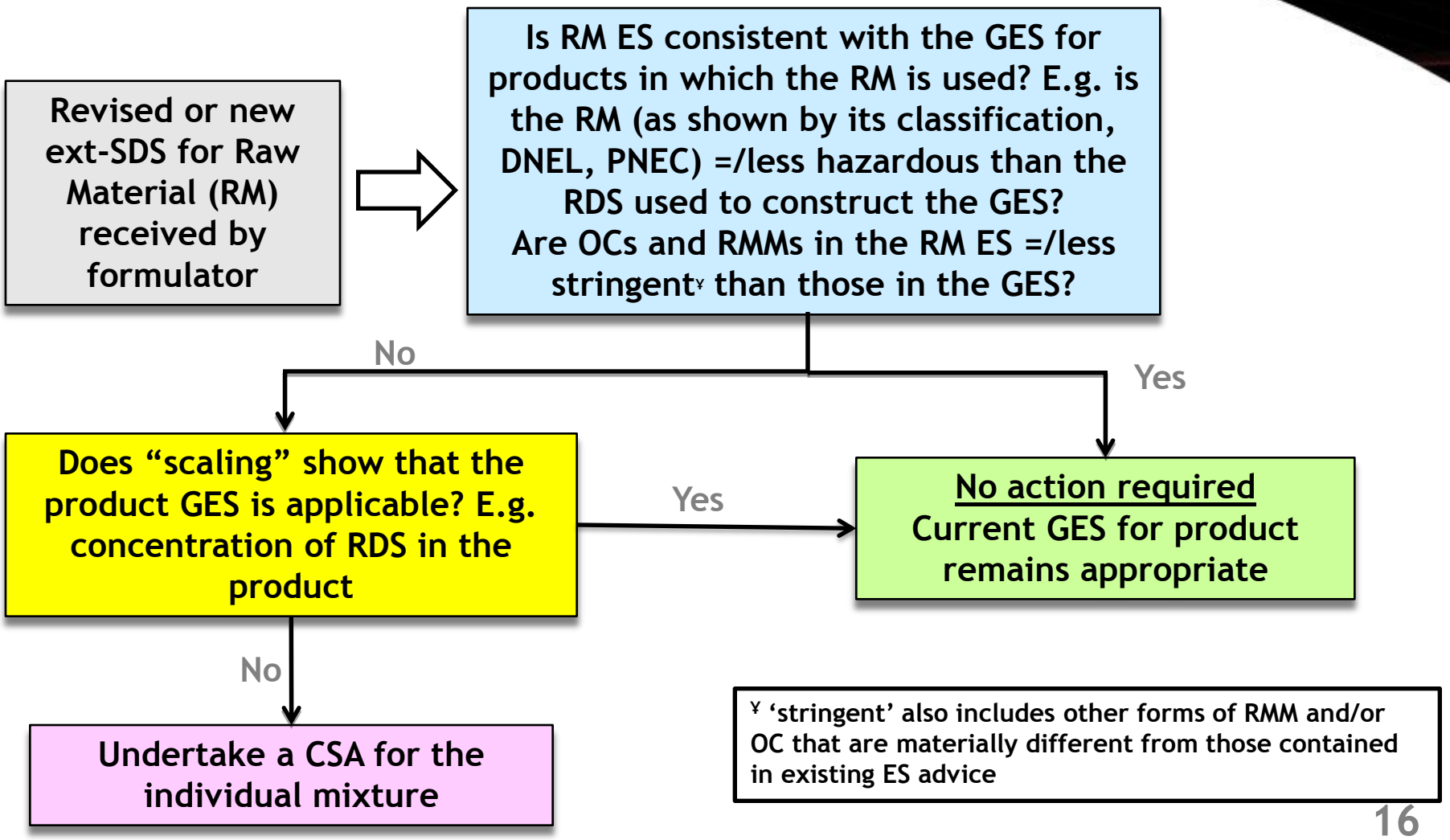
Example Input Table

Msafe values for generic products for different use groups at the product level using a treat rate of 2% except

RDS Code	ATIEL ATC Use group Msafe (kg day-1)								
	Ai-add pack	Ai-lubes	Bi	Bp	Bc	Ci	Cp	Cc	Di
1.1	66879	6694	1963	19	8	294.4	3	0.3	
1.2	668792	66942	19627	191	79	2944	28	3	
1.3	6687917	669420	196269	1911	793	29439	283	33	
1.3.1	485294116	1201229490	67209667	29351	9835	9729484	4873	3453	n a
1.4	66879165	6694195	1962694	19107	7934	294390	2835	325	
1.5	668791651	66941950	19626944	191071	79341	2943899	28348	3253	
2.1	33393	3343	1185	13	4	174	2	0.2	
2.2	333925	33425	11854	134	39	1737	15	2	

Example Output Table

Consistency check overview substance ext-SDS/ES vs.GES



Attaching GESs and checking raw materials - overview of process

- **Step 1:**
  - Allocate lubricant products to ATIEL-ATC use group(s)
  - Check that product meets product boundary conditions
  - Attach GES to product SDS for each required use group
- **Step 2:**
  - Allocate raw materials (RMs) to use groups
  - Link uses ↔ products ↔ raw materials
- **Step 3:**
  - Consistency check for uses
- **Step 4**
  - Consistency check for human health
- **Step 5**
  - Consistency check for environment

Consistency checks between raw material ext-SDS and GESs

- **Step 6**
  - Options if raw material ext-SDS is <u>not</u> consistent with the GES

Attaching GESs and checking raw materials - overview of proces

- **Step 1:**
  - Allocate lubricant products to ATIEL-ATC use gro
  - Check that product meets product boundary
  - Attach GES to product SDS for each rec
- **Step 2:**
  - Allocate raw materials (RMs
  - Link uses ↔ products
- **Step 3:**
  - Consister
- **Step 4**
  - Consistency nan health
- **Step 5**
  - Consistency check for environment
- **Step 6**
  - Options if raw material ext-SDS is not consistent with the GES

Detailed flowcharts for each step

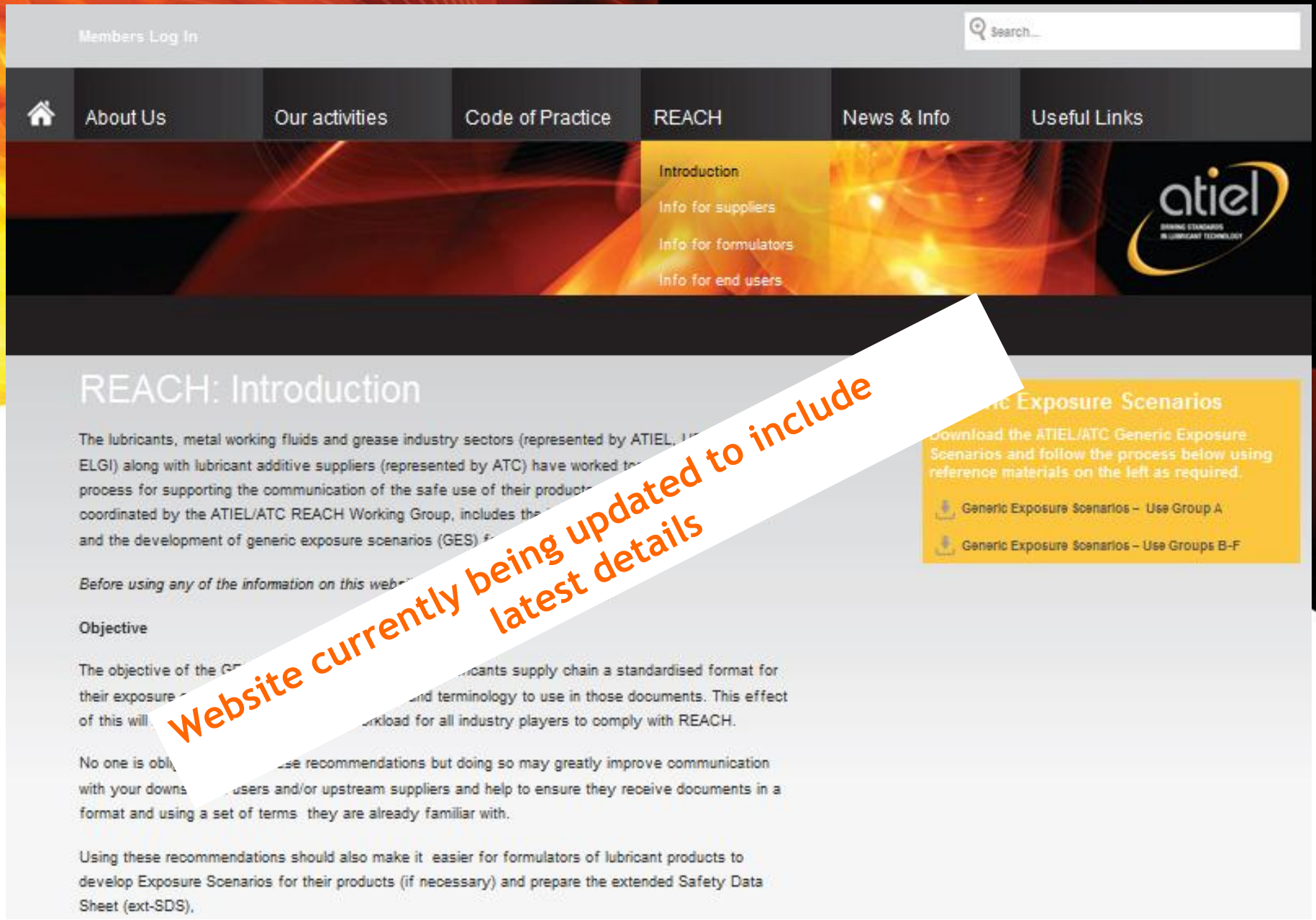
Consistency checks between raw material ext-SDS and GESs

Conclusions

- **Delivers sound, understandable advice to DUs now**
  - No need to wait until 2018 Registrations for key information
- **Enables formulators to provide useful safe use advice in a consistent manner to their customers**
- **Constrains the length of the ext-SDS to a manageable size**
- **Complements the nature of SH&E advice already being offered by lubricant suppliers e.g. technical advisory notes**
- **ATIEL/ATC has devoted significant time and effort to develop GESs and associated processes**
- **ATIEL/ATC solution will not necessarily be the one most suited to all supply chains**
  - Needs collaboration within the sector/supply chain

Roll out plan and documentation

- GES and supporting documentation to be made available via ATIEL web site by year end 2012
  - Guide to user document, GES narratives, Boundary condition matrix, SpERC documentation, Compliance flow charts etc.
  - Free of charge for members and non members alike
- New GES phrases to be incorporated into Cefic ESCom Phrase library
  - Translations and metadata funded by ATIEL
- Website help
  - Supporting documents; FAQs
- Workshop for members
  - Tentative dates to be organised at national level
- Further challenges
  - Translation of key documents into European languages
  - Training and initial support for formulators in applying the approach that have not been directly involved in the development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Info for end users
atiel
REACH: Introduction
The lubricants, metal working fluids and grease industry sectors (represented by ATIEL,
ELGI) along with lubricant additive suppliers (represented by ATC) have worked to
process for supporting the communication of the safe use of their product
coordinated by the ATIEL/ATC REACH Working Group, includes the
and the development of generic exposure scenarios (GES) f
Before using any of the information on this web
Objective
The objective of the GE
icants supply chain a standardised format for
their exposure
nd terminology to use in those documents. This effect
of this will
rkload for all industry players to comply with REACH.
No one is obl
se recommendations but doing so may greatly improve communication
with your downs
users and/or upstream suppliers and help to ensure they receive documents in a
format and using a set of terms they are already familiar with.
Using these recommendations should also make it easier for formulators of lubricant products to
develop Exposure Scenarios for their products (if necessary) and prepare the extended Safety Data
Sheet (ext-SDS).
ic Exposure Scenarios
Download the ATIEL/ATC Generic Exposure
Scenarios and follow the process below using
reference materials on the left as required.
Generic Exposure Scenarios – Use Group A
Generic Exposure Scenarios – Use Groups B-F
Website currently being updated to include
latest details

Thank you for your attention !

Backup

The challenges to be addressed

- **Existing DU Guidance envisages**
  - Detailed analysis of ext-SDS/ES for each hazardous substance
  - Evaluation of individual mixtures (some formulators make thousands)
- **Drawbacks**
  - Likely inconsistency between ESs of received substances
  - Incorrect assumptions made by registrants about emissions
  - Trickle down of information until 2018 and beyond
  - Significant churn of information placing massive burden on formulators
- **What is required?**

  Process for covering most (ca. 90%) of mixtures which:
  - is practical, science based, understandable to SMEs,
  - reflects the finished mixture today rather than wait for 2018
  - is efficient, and capable of being processed within companies' IT systems (both larger companies and SMEs)
- **Customers want simple, relevant, understandable advice**
  - That builds on prevailing exposure/risk control practices and
  - Reduces unnecessary complication for customers

The ATIEL-ATC Approach