Matching ES for substances with ES for mixtures – a perspective from the lubricants sector

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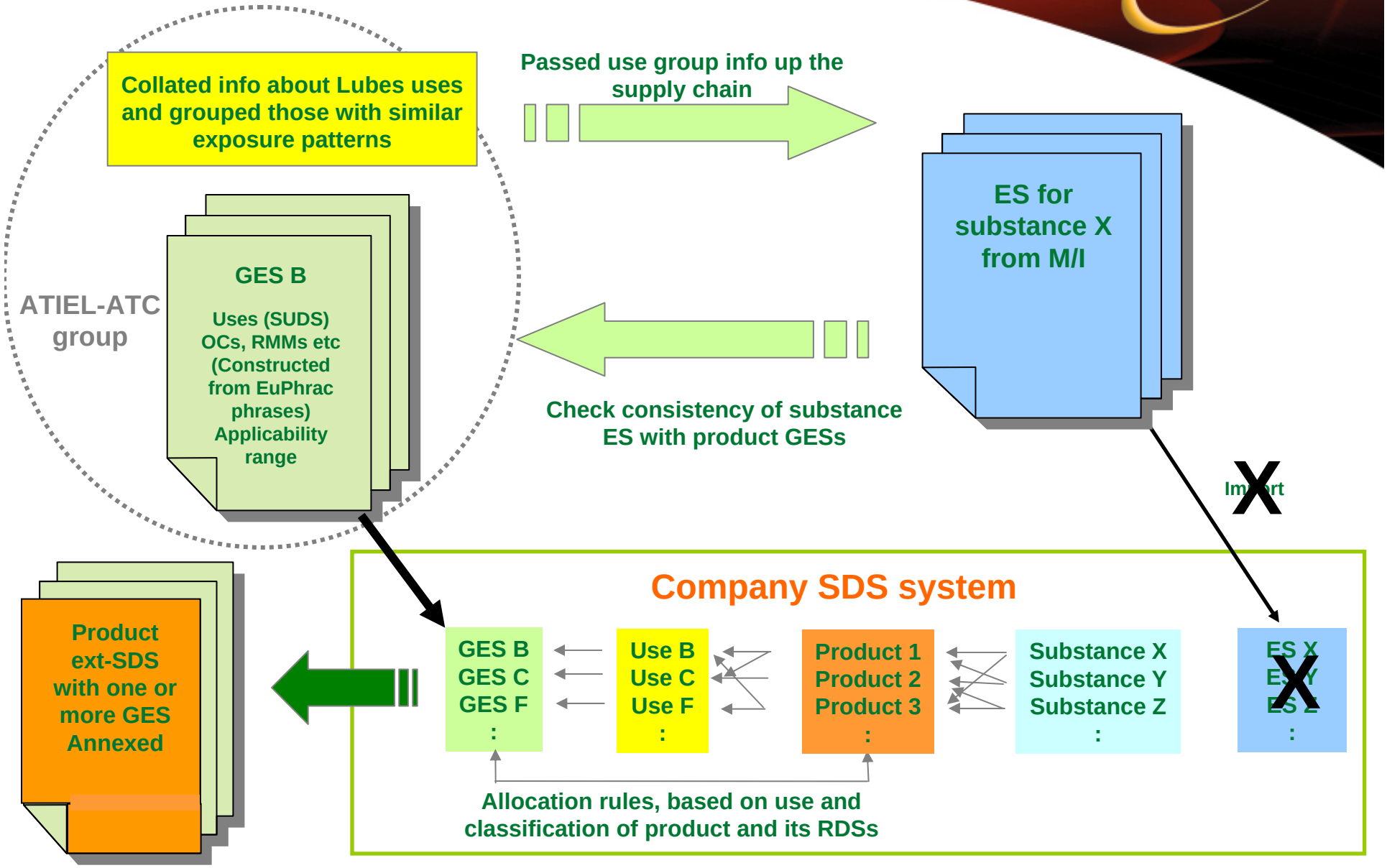
ATC

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



GESs – general comments

- **GES have been developed for each ATIEL/ATC use category**
- **The identified OCs and RMMs cover both human and environmental risks**
  - And can be traced to a quantitative CSA where appropriate
- **The GES structure is 'modular'**
  - Enables Health & Environment content to be "mixed and matched"
  - Facilitates ready manipulation in IT systems
- **New standard phrases have been identified 'by exception'**
  - And will be proposed for inclusion into the BDI library
- **GES and supporting documentation to be made available via ATIEL web site**
  - GES narratives, User Guide, Boundary condition matrices, SpERC documentation, Compliance flow charts etc.
  - Free of charge for members and non members alike

How were Environmental GESs developed?

- **Risk Determining Substances (RDS) identified for each use group**
  - Members canvassed for input on substances and typical concentrations in lubricant mixtures
  - RDSs chosen based on: hazard, multiple companies interested, availability of hazard data, need to cover all the use groups
  - 150+ substances distilled down to three for the environment
- **Gathered hazard data on chosen RDSs**
- **Ran initial ECETOC TRA calculations based on default emission fractions**
- **Gathered real exposure data and OC & RMM information via member questionnaire**
- **Obtained volume data for lubricant's supply chain**
- **Developed SpERCs for industrial uses**

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 approaches as the reference point
  e.g. concentration of the relevant hazardous substances
- CSAs conducted for each ATIEL Use Group supported by typical OCs and RMMs mapped in the DUCC table and Boundary Conditions
- GES narratives developed from CSAs

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

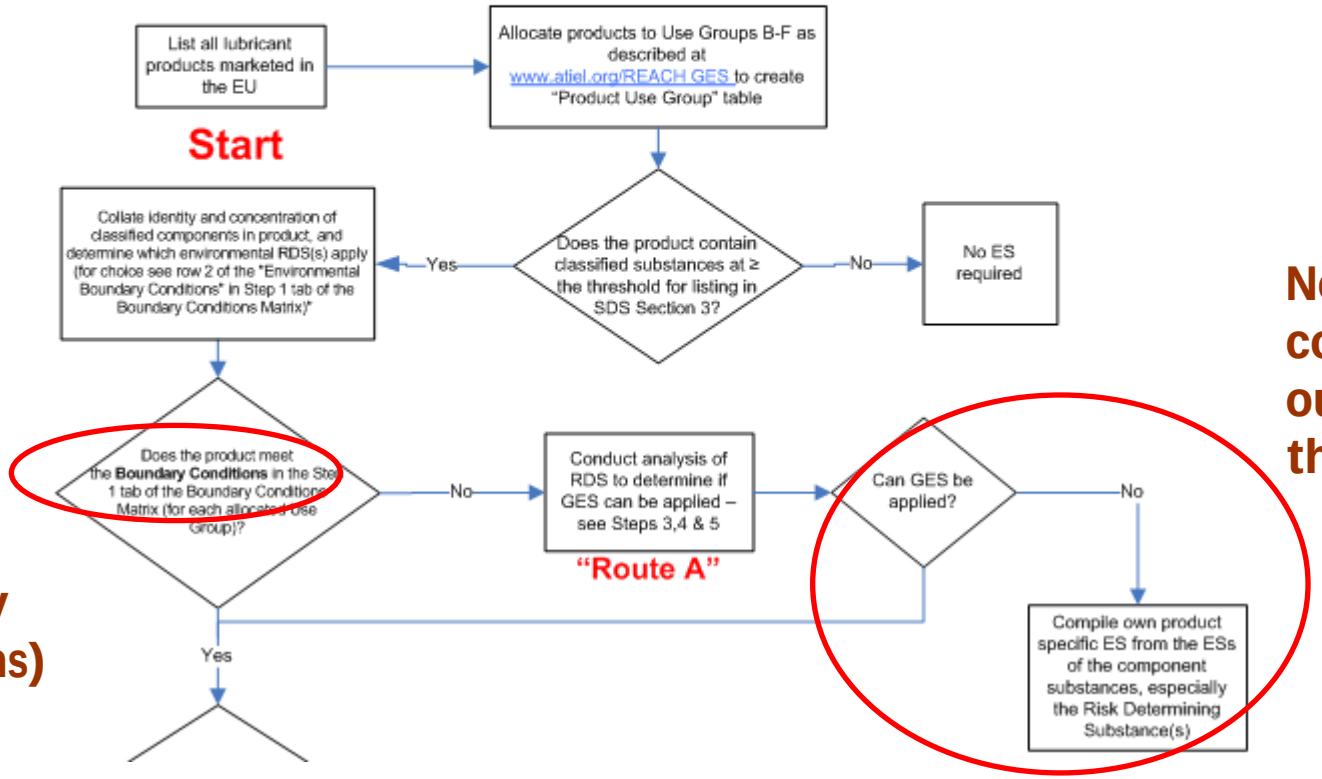
Detailed flowcharts for each step

Consistency checks between raw material ext-SDS and GESs

Allocation of GESs to products

Step 1

Allocate Products to Use Groups and Attach Annex to Product SDS



Check products are in scope (within boundary conditions)

Not all products covered – outliers need their own SES

*****DRAFT BOUNDARY CONDITIONS MATRIX
FOR USE WITH STEP 1 OF FLOWCHART (following Beta Test)*****

Health Boundary Conditions

Criteria / Boundary Conditions	ATIEL USE GROUPS / GES				
	B: General use in vehicles or machinery - Industrial - Professional	**C: Use in open systems - Industrial - Professional**	**D: Use in open high temperature processes - Industrial**	**E: Metal working fluid concentrates - Industrial**	**F: Use in high energy open processes - Industrial - Professional**
1. Product C&L covered by one or more of the listed R phrases (DPD human health):	R43 R36; R41 R38; R21 R20 Not classified	R43 R36; R41 R38; R21 R20 Not classified	R43 R36; R41 R38; R21 R20 Not classified	R43 R36, R41 R37 R38, R21 Not classified	R43 R36; R41 R38; R21 Not classified
2. For products classified as R43 (skin sensitiser), sensitising component is within the listed concentration range:	**Skin sensitiser** a)≥ 0.1 - 1% Strong b)≥ 1 - 3% Weak or Moderate	**Skin sensitiser** a)≥ 0.1 - 1% Strong b)≥ 1 - 3% Weak or Moderate	**Skin sensitiser** a)≥ 0.1 - 1% Strong b)≥ 1 - 3% Weak or Moderate	**Skin sensitiser** a)≥ 0.1 - 1% Strong b)≥ 1 - 3% Weak or Moderate	**Skin sensitiser** a)≥ 0.1 - 1% Strong b)≥ 1 - 3% Weak or M

Environmental Boundary Conditions

Criteria / Boundary Conditions	ATIEL USE GROUPS / GES				
	B: General use in vehicles or machinery	**C: Use in open systems**	**D: Use in open high temperature processes**	**E: Metal working fluid concentrates**	**F: Use in high en... open processes**
1. Product C&L covered by one or more of the listed R phrases (DPD environment):	R52/53 Not classified	R52/53 Not classified	Not classified	R50/53 R51/53 R52/53 Not classified	R50/53 R51/53 R52/53 Not classified
2. Boundary DSD classifications & concentrations for Environmental Risk Determining Substance(s) (RDS) in mixture	1) R51/53 - not readily biodegradable, present at ≤ 1.4% w/w in product, or 2) R50/53 - readily biodegradable, present at ≤ 1.0% w/w in product	1) R51/53 - not readily biodegradable, present at ≤ 1.4% w/w in product, or 2) R50/53 - readily biodegradable, present at ≤ 1.0% w/w in product	N/A	1) R50/53 - readily biodegradable, present at ≤ 2.0% w/w in product, or 2) R50/53 - not readily biodegradable, present at ≤ 40% w/w in product, or 3) Biocidal substance, present at ≤ 5% in product	1) R50/53 - readily biod... present at ≤ 1.0% w/w in... or 2) R50/53 - not readily biodegradable, present... w/w in product, or 3) Biocidal substance, ... ≤ 0.5% in product, or 4) R51/53 - not readily biodegradable, present... w/w in product
3. **M...** for product (for industrial use)	1) 45 tonnes/day 2) 2800 tonnes/day	1) 2 tonnes/day 2) 412 tonnes/day	N/A	1) 131 tonnes/day 2) 436 kg/day 3) not quantified (*see note 5)	1) 222 tonnes/day 2) 3.5 tonnes/day 3) not quantified (*see note 5) 4) 1.1 tonnes/day

Check GES is a good fit for the product:

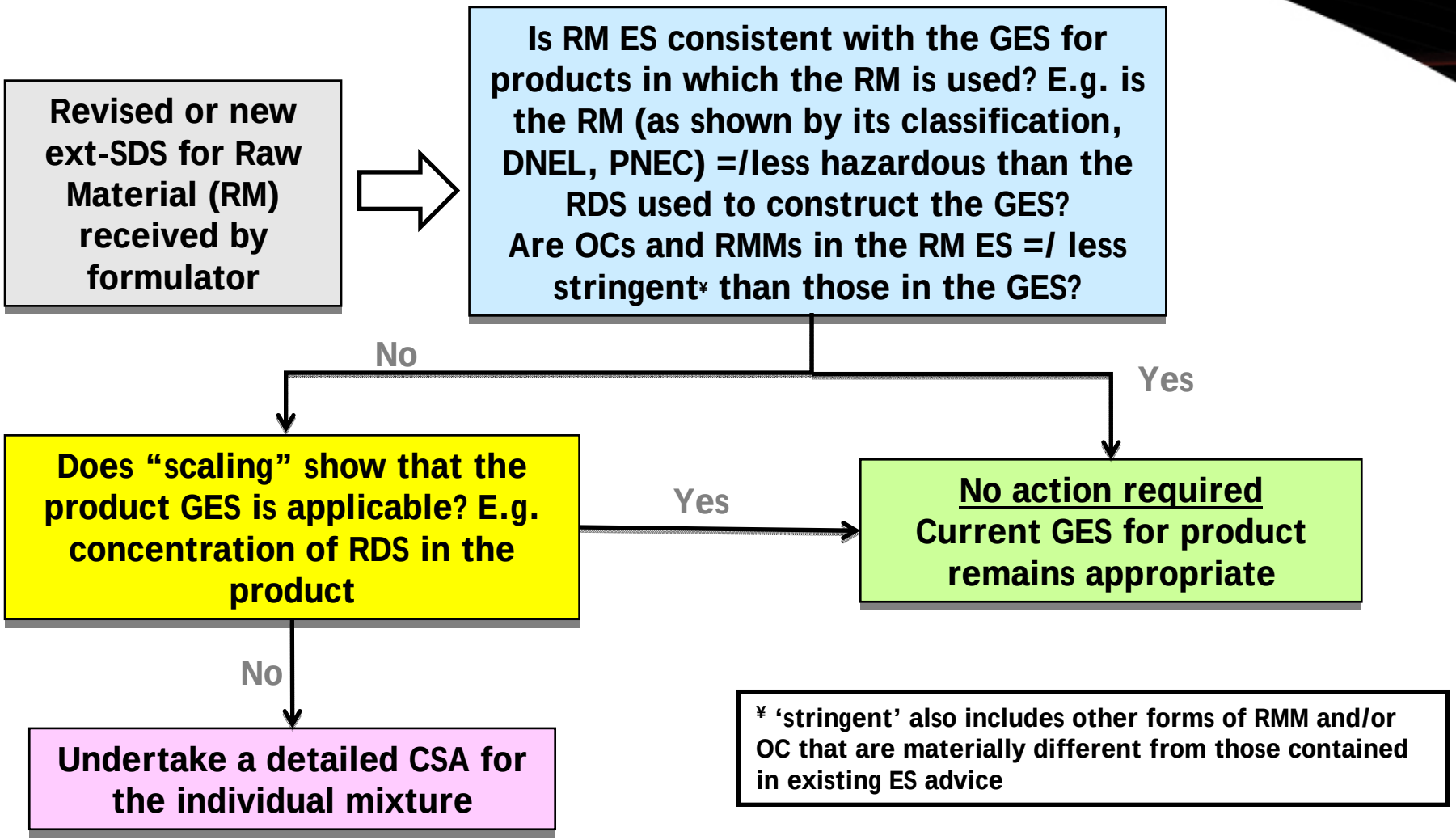
Use

C&L of mixture

C&L and concn of RDS

Product Msafe

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



Real life example 1
Substance ES vs GES (Use Fi) - Health

Despite the differences in RMMs we are confident ES & GES are consistent in terms of level of control – GES applies

Number of the contributing scenario
Contributing exposure scenario controlling worker exposure for PROC 8b

Further specification
assessment tool used: Chesar 1.1.3

Product characteristics
Liquid, vapour pressure < 0,5 kPa at STP
Covers percentage substance in the product up to 100 % (unless stated differently)

Frequency and duration of use
Avoid carrying out activities involving exposure for more than 4 hours

Human factors not influenced by risk management
Area potentially exposed: corresponds to palm of 2 hands (480 cm²)

Other given operational conditions affecting workers exposure
Indoor and outdoor use

Conditions and measures related to personal protection, hygiene and health evaluation
Wear suitable gloves tested to EN374. Wear respiratory protection (Efficiency: 90 %).

Section 2.1	Control of worker exposure
Product characteristics	
Physical form of product	Liquid, vapour pressure < 0.5 kPa [OC3].
Concentration of substance in product	Covers use of substance/product up to 100% (unless stated differently) [G13 update]
Frequency and duration of use	Covers daily exposures up to 8 hours (unless stated differently) [G2]
Other Operational Conditions affecting worker exposure	Assumes use at not > 20°C above ambient, unless stated differently [G15] Assumes a good basic standard of occupational hygiene is implemented [G1].
General measures applicable to all activities [CS135]	Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off any skin contamination immediately. Provide basic employee training to prevent/minimise exposures and to report any skin problems that may develop [E3]
	Use suitable eye protection. [PPE26] Avoid direct eye contact with product also via contamination on hands. [E73]
Filling / preparation of equipment from drums or containers. [CS45]. PROC 8b	No other specific measures identified. [EI20]
Equipment cleaning and maintenance [CS39]. PROC 8b	Drain down system prior to equipment break-in or maintenance [E35].Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). [E11] Retain drain downs in sealed storage pending disposal or for subsequent recycle [ENVT4].

Real life example 2
Substance ES vs GES (Use Bi) - Health

2.2 Contributing scenario controlling worker exposure for: PROC1, PROC2, PROC8a, PROC9

Product characteristics

Concentration of the Substance in Mixture/Article		Covers the percentage of the substance in the product up to 5%.
Physical Form (at time of use)	:	Liquid, vapour pressure < 0.5 kPa
classification	:	PROC1, PROC2, PROC8b, PROC9

Amount used

classification	:	Covers the percentage of the substance in the product up to 100 % (unless stated differently)., PROC1, PROC2, PROC8b, PROC9

Frequency and duration of use

Exposure duration	:	> 4 h
Frequency of use	:	220 days/year
classification	:	PROC1, PROC2, PROC8b, PROC9
Exposure duration	:	1 - 4 h
classification	:	PROC8b
Exposure duration	:	15 - 60 min
classification	:	PROC8b
Exposure duration	:	< 15 min
classification	:	PROC8b

Human factors not influenced by risk management

: None known.

Other operational conditions affecting workers exposure

: Handle in accordance with good industrial hygiene and safety practice.

: Assumes a good basic standard of occupational hygiene is implemented.

Technical conditions and measures

Technical conditions and measures	:	Provide extraction ventilation at points where emissions occur.

Conditions and measures related to personal protection, hygiene and health evaluation

Protective equipment	:	Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training., Safety glasses with side-shields conforming to EN166, PROC1, PROC2, PROC8b, PROC9

- **RMM applies to all PROCs including (inappropriately) PROC 1**
- **Clearly exceeds the RMMs for one or more contributing scenario in the GES**
- **Our GES delivers RCR <1**
  - **RCRs in supplier's ES are all < 0.01**

DU CSA according to Practical Guide - hence notification!

Real life example 3
Substance ES vs GES (Use Bi) - Environment

Parameter	GES Boundary Conditions (applicability range)	Raw Material X data (from ext-SDS)	Boundary Conditions met?
DSD Classification	R51/53	R51/53	Y
Concentration in product (%w/w)	≤1.4	< 5	Y
Biodegradability	Not readily biodegradable	Not readily biodegradable	Y
Log Kow	< 0.7	3.59 (from dissemination site)	N
Water solubility (mg/L)	≤ 1650	practically insoluble	Y
PNEC STP (mg/L)	≥ 1	3.8	Y
PNEC freshwater aquatic (mg/L)	≥ 0.004	0.004	Y
PNEC freshwater sediment (mg/kg)	≥ 0.024	0.0701	Y
PNEC marine water (mg/L)	≥ 0.0046	0.0046	Y
PNEC marine sediment (mg/kg)	≥ 0.0024	0.00701	Y
PNEC terrestrial (mg/kg)	≥ 0.0025	0.0548	Y
Conclusion	**Scale down Msafe on GES because of higher than assumed log Kow (or create another GES to cover raw materials with higher Kow)**		

DU CSA according to Practical Guide - hence notification!

Conclusions

- **Delivers soundly-based, understandable advice to DUs now**
  - No need to wait until 2018 Registrations for key information
- **Enables formulators to provide consistently useful advice 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
  - Not suitable if selling mixtures to other formulators

Learning Points & Questions (1)

- **Beta-testing showed that process works well in most cases; environment more difficult than health**
  - Bigger library of GESs required for Environment (i.e. additional RDSs)
- **Missing data (e.g. log K_{ow}, PNECS) on raw material ext-SDS created a problem at raw material boundary conditions check**
- **Some content of substance ESs is surprising /unrealistic**
  - air treatment for additive in formulated lubes;
  - statement requiring "closed system" for all contributing scenarios
- **Reverting to supplier will not necessarily provide a simple and quick answer – registrants will be constrained by consortium / joint submission considerations**
- **Watch out for confusion between "." and "," when reading values**
- **Spreadsheet developed to record results of raw material assessments & actions arising**

Learning Points & Questions (2)

- **Scaling instructions/boundaries often absent from supplier ESs**
- **"Scaling" requires expertise – not easy to delegate to non specialists**
- **Current draft of "Practical Guide" is very restrictive in terms of definition of scaling vs. DU CSA**

  We have found no examples where "scaling" (as defined by ECHA's draft guidance) clearly applies
- **What is the requirement for notifications if it is a DU CSA?**

  Is it really intended for each individual lubricant formulator using the same substance to notify ECHA of reliance on the ATIEL / ATC DU CSA (as currently defined in Draft Practical Guide)?