



The impact of REACH on Lubricants & Base Oils

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Who are ATIEL

- European Economic Interest Group
- Crankcase lubes focus
- 19 members (18 companies and 1 association)
- Representing very large fraction of European oil marketers
- Significant linkage to world markets
- Technical focus

BPCastrol

CEPSA

Chevron

ENI

ExxonMobil

Neste Oil

Fuchs

GALP

Kuwait Petroleum

Orlen Oil Ltd

Lotos Oil

Lukoil

Petronas

Repsol

Shell

Statoil Lubricants

Total

UEIL

Valvoline



REACH - topics

- *Introduction*
- *Registration and exposure scenarios*
- *Base oils*
- *ATIEL, ATC - Generic Exposure Scenario Library*
- *Enforcement*
- *Globally Harmonized System (GHS)*
- *Conclusions*

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Introduction



REACH

REACH is the European Union regulation covering the Registration, Evaluation, Authorisation & restriction of Chemicals

Came into force on 1st June 2007

Regulation EC1907/2006 contains over 840 pages plus many guidance documents!

What is the intention of REACH?

- Places responsibility on the 'chemical' industry to demonstrate the safety of its products throughout the supply chain
- It is designed to...
 - Provide a high level of protection to human health and the environment
 - Complete data gaps between EINECS (existing chemicals) & ELINCS (new substances)
 - Provide a single EU regulatory system with an efficient decision making process and clear timelines
 - Encourage innovation



REACH - where does it apply?

This European regulation impacts all substances *manufactured* in or *imported* into REACH impacted countries* in quantities greater than one tonne per year

**Austria, Belgium, Bulgaria, Cyprus, Czech Rep., Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, UK, Iceland, Liechtenstein, Norway, French Guiana, Guadeloupe, Martinique, Reunion, Channel Islands, Isle of Man, Dutch Antilles*

The European Chemicals Agency (EChA - based in Helsinki) has been established to manage REACH

What is regulated by REACH?

- Manufacture or import chemical substances or mixtures of chemical substances (preparations).
- Production or importation of articles (for example construction materials, electronic components, toys or vehicles) which contain substances included in a list of 'substances of very high concern' or which are released during their use.
- The processing of chemicals or formulation preparations (a mixture of substances) for end use (e.g. cleaning products, paints or motor oils)
- Use of formulated products professionally => a 'downstream user'.

Does REACH affect base oils & lubricants?

Base oils are substances

Base oils are manufactured in the EU

Base oils are imported into the EU

Blended lubricants are preparations

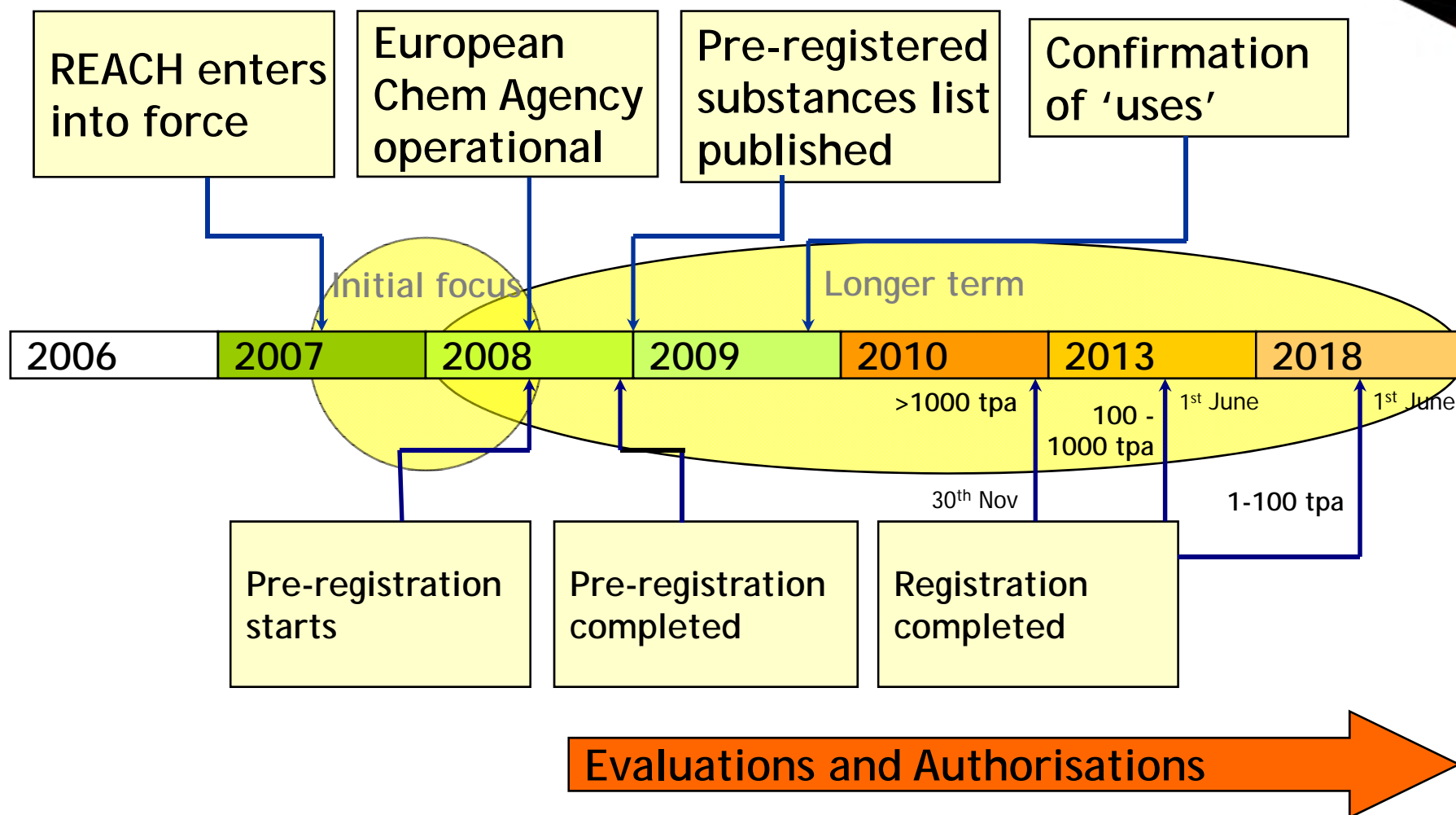
Blended in the EU

Imported into the EU

Blended lubricants may be used in 'articles'
e.g. vehicle gearboxes

} Yes!

The REACH timeline



REACH challenges

- *Pre-registration* phase closed on 1st December 2008 for all substances manufactured or imported at > 1 t / a
This enabled continued manufacture & / or importation
- Pre-registration is *substance and registrant specific* and needed for each manufacturing site (where sites are owned by different legal entities)
- *Registration* deadlines are tonnage specific up to 2018
Except substances of high concern (see ECHA candidate list) => Authorisation
Except for substances classified as CMR 1,2 and manufactured /imported above 1 t/a and for substances classified as R50/53 manufactured /imported above 100 t/a that must be registered in 2010

REACH challenges

- For each registration there will be a SIEF activity
One substance / one registration => no duplication of testing
- Base set hazard data + additional testing proposal for higher tonnage levels
- Registration activity requires compilation & submission of company specific & common information
- Fees have to be paid within 7 days of receipt of invoice
- Evaluation of registration dossiers will require further input by industry

REACH statistics

- Original estimate of 350,000 pre-registrations.
- Actually *2.7 million* pre-registrations submitted to ECHA by 1 December 2008.
- Total of 146,171 pre-registered substances information exchange groups (pre-SIEFs) formed from these to cover approx 150,000 substances relating to 65,000 legal entities.
- Large number of legal entities will require careful SIEF management
- To date an estimated 3,000 submissions have taken place

Importation into Europe

- Not too late for substances under 1,000 t /a
 - => Pre-registration can still take place within 6 months of first manufacture/importation but 12 months prior to registration date
 - => The deadline for late pre-registration of large volume, >1,000 t/a substances expired on 01 December 2009
- Importation of base oils into Europe and substances in finished lubricants requires registration
- Thus, it is necessary for,
 - A importer to have their own registration for the substances contained in a product (unless the substance originated from the EU, i.e. a re-importation)
 - and / or
 - The use of an EU located 'Only representative'

Re-importation - substances which have been registered, exported and then re-imported are exempted from a second registration and evaluation under certain conditions - they need to have been pre-registered



REACH & Exposure Scenarios

REACH & Exposure Scenarios

- REACH brings with it a new concept of exposure scenarios (ES)
- ES describes the practical use conditions which ensure safe use of a chemical
- This is required for all uses in the supply chain and *all of these 'uses' must be registered for it to continue*
- ES is to be developed by manufacturer/importer for >10t classified substances (Hazardous or vPvB etc.)

Exposure Scenario definition

Set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control exposure of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

REACH Article 3-37

A Generic Exposure Scenario is a consolidation of a number of ESs (individual tasks/activities) for a group of substances with a similar hazard profile for an area of operation within industry and are typically developed by manufacturers / importers in participation with DU associations. GESs can be set up as libraries for sector use.

Exposure Scenarios

- Exposure scenarios are required as part of the Chemical Safety Assessment for registered substances. The Chemical Safety Report documents the results of the assessment.
- The safety data sheet (SDS) communicates the conditions for use and required risk management measures (RMMs) (for sufficiently protecting human health & the environment)
- The exposure scenario considers,



Acceptable Safe Use

Chemical Safety Assessment

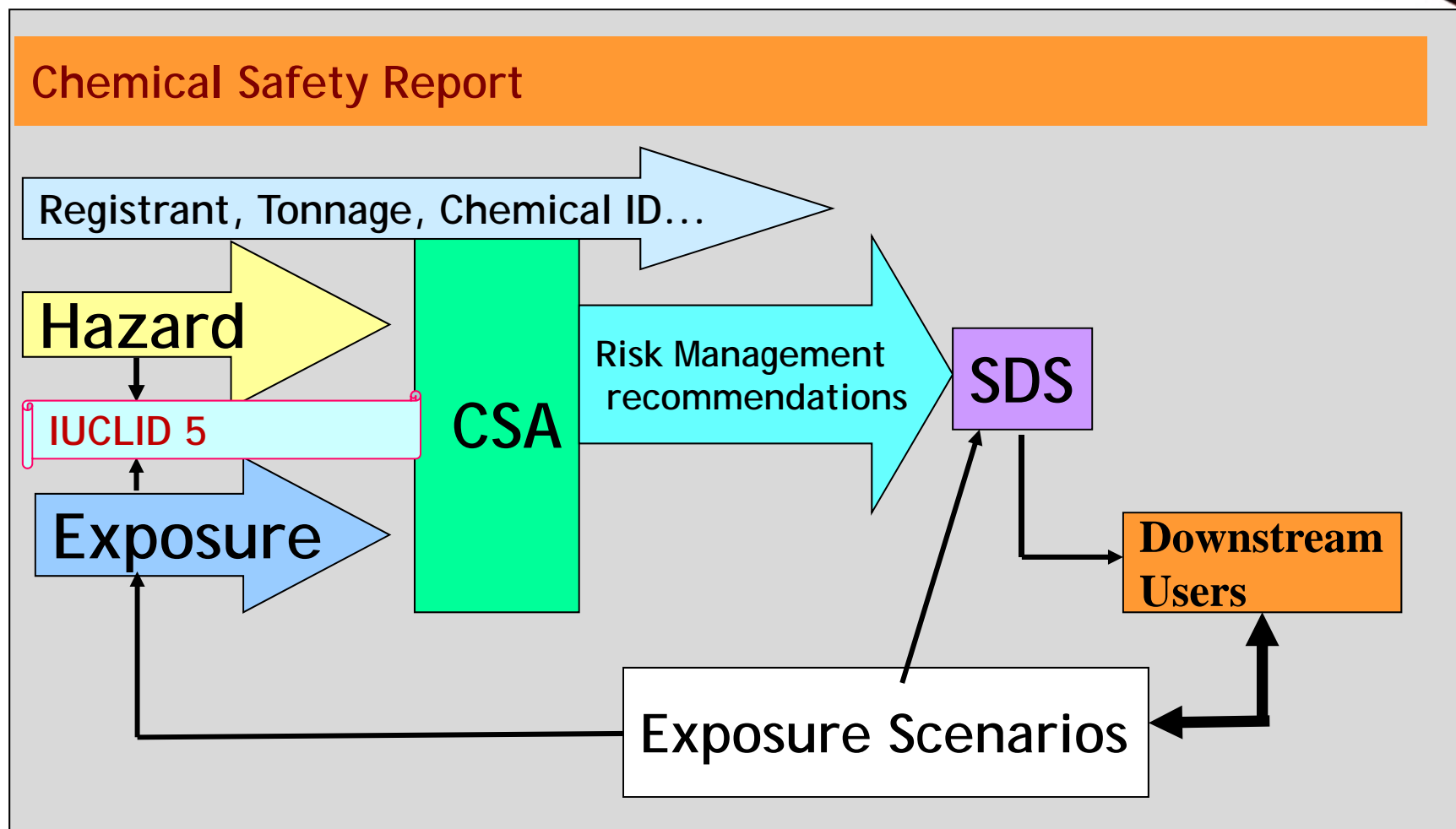
Chemical Safety Assessment is the process aimed at determining the risk posed by a substance and, as part of the exposure assessment, develop exposure scenarios including risk management measures to control the risks. Annex I contains general provisions for performing a CSA. The CSA consists of the following steps:

- Human health hazard assessment;
- Human health hazard assessment of physicochemical properties;
- Environmental hazard assessment;
- PBT and vPvB assessment.

If, as a result of this hazard assessment, the registrant concludes that the substance meets the criteria for classification as dangerous according to Directive 67/548/EEC (for substances) or has PBT/vPvB properties, this triggers further steps in the chemical safety assessment:

- Exposure assessment;
- Risk characterization. REACH Annex I.

The Chemical Safety Report



A closer look at Exposure scenarios

Pre-Registration

- Inform EChA* of intent to register
- SIEF** and consortia formation for data sharing

Registration

- **Chemical Safety Report to EChA**
- Testing proposals
- Allocation of Competent Authority
- Pay Registration Fees

Evaluation

- Dossier audit and/or evaluation
- Agree testing plans

Authorisation

- Risk management checks
- Socio-economic analysis
- Replacement plans
- Time limited Authorisation



REACH & Base Oils

Base Oils

- SIEF management and compilation of information for registration are being undertaken by CONCAWE. One of the product categories consists of 78 different base oil CAS numbers
- Access is granted by 'licence' to companies allowing use of the CONCAWE IUCLID5 files and CSR for the registration of virgin base oils.
 - This information is currently being used for registration & is known as 'Common information' - Phys/ Chem properties, Toxicology, etc.
 - Other data is known as 'Company specific' - Legal entity name, site/location, volumes, analytical data, etc.
- Base oils are UVCB substances

CONCAWE - CONservation of Clean Air and Water in Europe - www.concawe.be

(UVCB) Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances have additional identification requirements due to their unknown or variable composition. Identifiers such as source, manufacturing process and genetic code may be required to fully define the substance.



Base Oils REACH process

Step 1 - Use Identification & 'Table 1' mapping

The uses for lubricant base oils (Industrial / Professional / Consumer) have been identified

⇒ Communication through CONCAWE member companies via Petroleum Product Management Group (PPMG).

'Table 1' Mapping has been completed

⇒ Lifecycle key steps listed for each known use (contributing scenarios)

⇒ Ensured that each use/application is described in common terms using the standard REACH Use descriptor system, i.e. PROCS, & typical use conditions (Operational Conditions and Risk Management Measures)

⇒ Confirmed / discussed use mapping with downstream users associations and mapping revised based on feedback

⇒ Whole process and output extensively peer reviewed within CONCAWE

PPMG - Uses / STF-29 Human Health / EG - Environment

Base Oils REACH process

Step 2 - Completed 'Table 2' Chemical Safety Assessment (CSA)

1. Using ECETOC TRA tool, develop exposure estimates for each contributing scenario
Quantitative assessment will be for classified base oils only
Qualitative assessment to address R65 (Aspiration hazard - may cause lung damage if swallowed)
1. Obtain relevant DNELS (dermal and inhalation) and undertake the CSA to derive the Risk Characterisation Ratios (RCR), for both dermal and inhalation, for each contributing scenario.
2. Iterate the CSA where relevant (e.g. using TRA exposure reduction factors) to ensure all possibilities have been considered to reduce the RCR to <1.
3. Document the necessary risk management measures and operating conditions (to ensure the RCR <1) in a short narrative using standard phrase library.
4. If RCR cannot reasonably be reduced to <1, other approaches may need to be considered:
 - Use of higher tier model.
 - Applying measured data.
 - Not supporting the use.

Base Oils REACH process

Step 3 - Complete the Generic Exposure Scenario (GES) narrative for classified Base oils

- Using the information generated in Step 2 (i.e. risk management measures and operating conditions), transcribe into a narrative format using the BDI/ESVOC “library” of standard phrases
- Narrative will form basis of extended data sheet information for each exposure scenario
- For Base Oils classified as R65: the risk arising from aspiration hazard is solely related to the physical properties of the substance; a non-quantifiable hazard for which no DNEL can be derived. The risk can be controlled by implementing risk management measures tailored to this specific hazard e.g. ‘Do not ingest. If swallowed then seek immediate medical assistance’. Such a phrase will be included within the SDS to control this hazard

Base Oils REACH process

CONCAWE base oil product category use mapping

No	Base oil use mapping
1	Manufacture
2	Use as an intermediate
3	Distribution
4	Formulation & Re-packing
5	Coatings
6	Oil Field Drilling & Production
7	Metalworking Fluids
8	Release Agents & Binders
9	Agrochemicals
10	Road & Construction
11	Rubber Production & Processing
12	Polymer Processing
13	Fuel
14	Lubricants
15	Mining Operations
16	Water Treatment Chemicals
17	Explosives Manufacture & Use
18	Functional Fluids



ATIEL & REACH



ATIEL & REACH

- The ATIEL REACH committee has been involved with REACH since the original draft proposals
- ATIEL supports the principles outlined in REACH
- ATIEL believes that success for REACH will depend on close co-operation between supplier and customer and

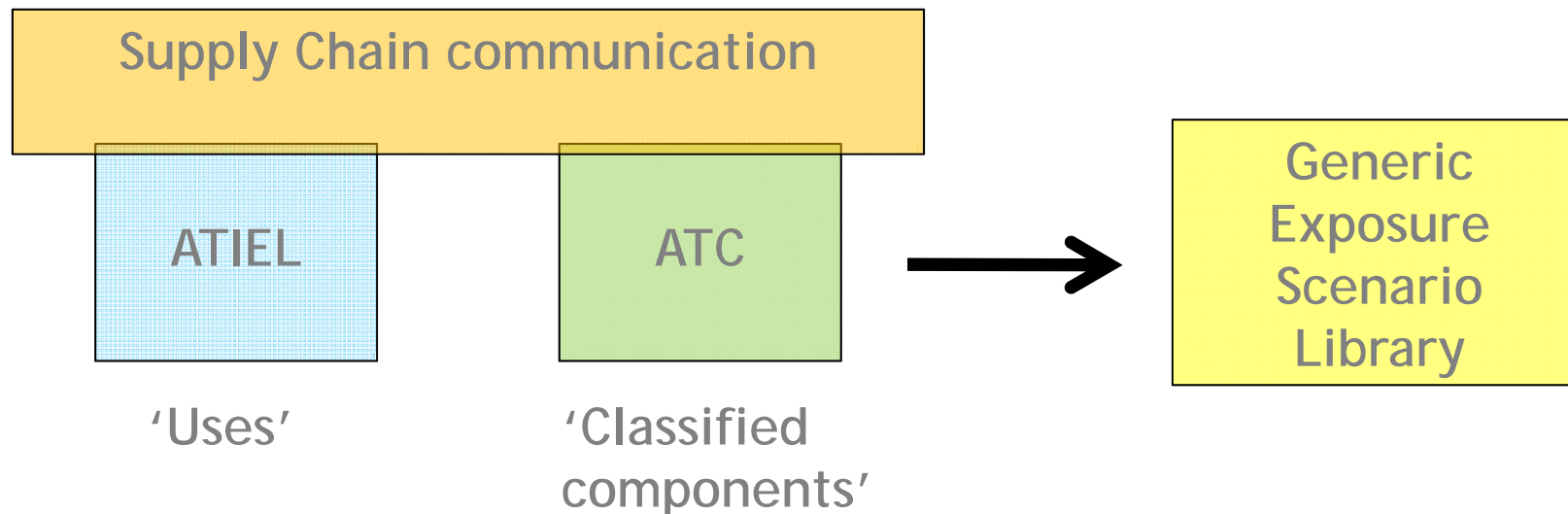
“that all participants need to recognise their role and responsibilities in providing information up and down the supply chain”

ATIEL Key issues for the Lubricants Industry

- ATIEL published a position paper* highlighting key issues for the lubricants industry...
 - Protection of Intellectual Property / Confidential Business Information
 - Maintaining 'level playing field' for Import and Export Business
 - Increased administrative and cost burden for information management imposed by REACH
 - Loss of Chemistry
 - => Hazardous components
 - => Low hazard, low risk chemistry may lead to the use of higher risk, lower performance chemistry.
 - => Chemistry requiring authorisation

ATIEL & ATC GES preparation

ATIEL and ATC are working together to produce a set of Generic Exposure Scenarios (GES) that will be hosted as a library for use by the lubricants industry

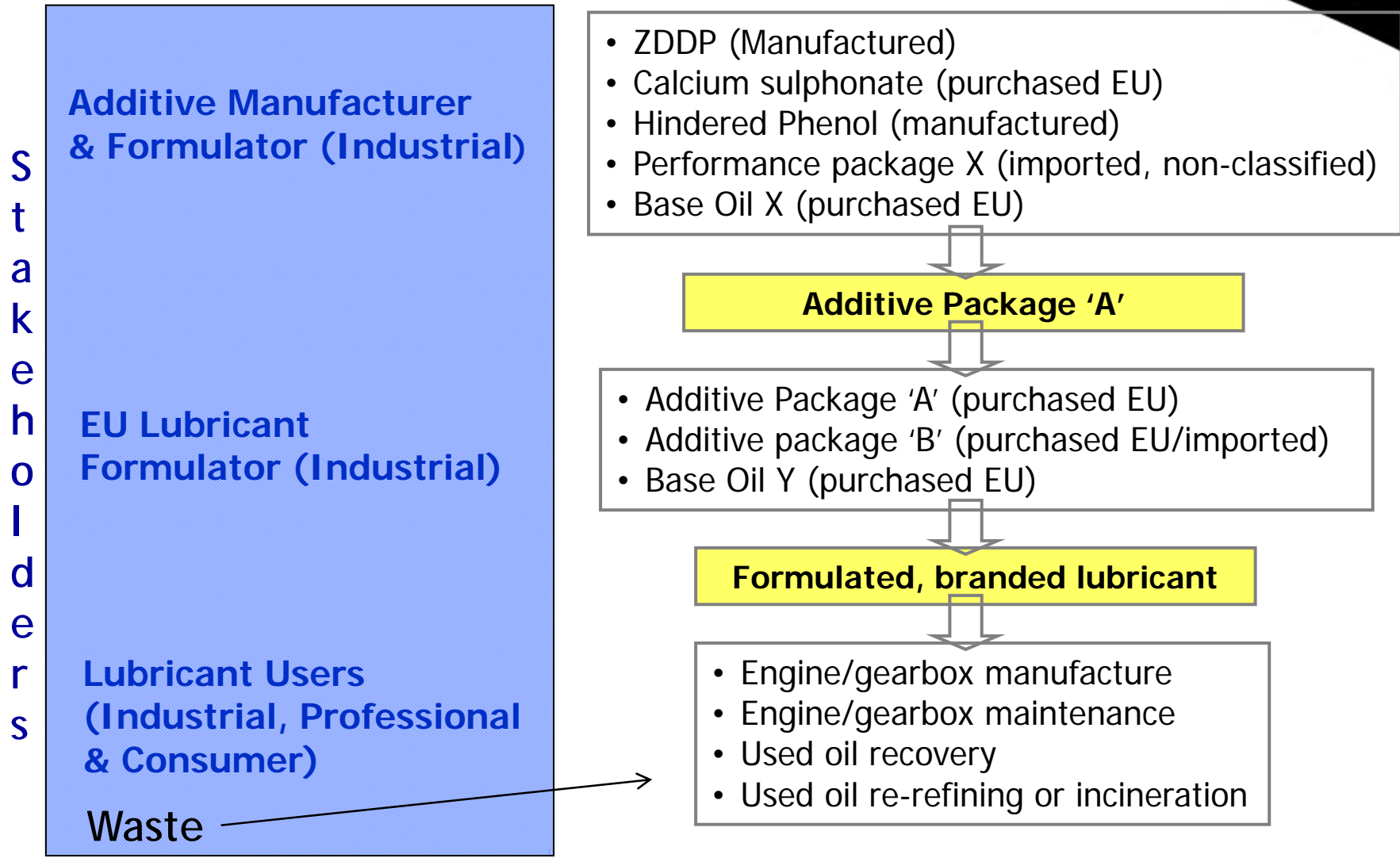


GES - Generic Exposure Scenario
ATIEL - Technical Association of the European Lubricants industry
ATC - Additives Technical Committee

Features of the Sector

- Lubricant additives are complex mixtures
Frequently contain 20 - 30 substances
- Numerous applications in most industry sectors
Automotive, industrial, greases
- Wide range of use types
Industrial / Professional / Consumer
Totally closed to total loss
Point use to wide dispersive
- Range of hazard profiles
Non-classified to a range of hazard classifications
Generally low volatility

Overview of the Lubricants Supply Chain



Lubricant Uses

- Matrix of lubricant uses and exposure determinants compiled
- Over 200 separate uses identified (so far), including:

Engine oils:	Cars, trucks, motor bikes, marine, railroad, outboard, aviation, etc
Transmission fluids:	Manual, automatic, CVT, industrial gear oils, axle lubricants, etc
Greases:	Vehicle bearings and universal joints, chassis lubricants, industrial bearings (open/closed), etc,
Industrial oils:	Turbine oils, compressor oils, hydraulic fluids, etc
Metalworking fluids:	Quenching, grinding, drilling, milling, etc, etc,
Total loss lubricants:	Chain saw oils, mould release agents, rock drill oils, slide-way lubricants, etc
Others:	Transformer oils, cable impregnation oils, heat transfer fluids, textile oils, etc



ATIEL ATC Use mapping

- Member companies surveyed for 'uses' - over 200 identified
- Identified uses grouped according to their shared exposure patterns
- Resulted in 6 general use groups labelled A to F

ATIEL Use group	Description
A	Formulation including greases
B	Closed uses
C	Open uses
D	Open high temperature processes
E	Soluble metalworking fluids
F	High energy open processes

Group A relates to formulation/manufacturing of lubricants
Group B to F the uses of finished lubricants



Development of Generic Exposure Scenarios

- Mapping of uses
- Communication of supported uses to DUs
- Calculation of exposure data - Human & Environment
- Refinement of exposure data - use of 'real' data
- GES authoring
- Refinement of GESs including areas of validity
- GESs made available to upstream (raw material suppliers) for inclusion in their ESs
- GESs made available via ATIEL website for stakeholder incorporation into ESs
- Incorporate ES risk management phrases into SDS systems



Benefits of ATIEL ATC approach

- GES development from communication within member companies and supply chain
- Involvement of majority of stakeholders
- Applicable to European Lubricants industry
- Simplification of participation in SIEFS
- Reduction in REACH costs

The initiative will result in significant benefits for the whole lubricants sector including SIEF/consortia activities

Information is freely available from ATIEL website

www.atiel.org - summary available in all EU languages



REACH Enforcement

Enforcement

- Member state competent authorities responsible for enforcement
- Numerous obligations are enforceable
- REACH-EN-FORCE-1 launched by ECHA
 - Enforcing core principle of REACH - “no data, no market”
 - National inspectors checking (pre)-registration and SDS provision
 - The project originally ran to January 2010 but its success resulted in it being extended to April 2011.
 - REACH-EN-FORCE-2 in planning to commence April 2011
- Many audits have already taken place & shipments have been halted at ports



Globally Harmonized System (GHS)

GHS - an introduction

- The United Nations GHS system is designed to provide a 'level playing field' for hazard communication
- It establishes international guidelines for:
 - Common form and content of Safety Data Sheets;
 - Common label language and symbols;
 - Common criteria for determining the safety, health and environmental hazards.
- Implementation:
 - Each country/region will adopt GHS through appropriate legislative processes - started in 2008.
 - Countries can adopt all or selected parts of GHS (- the 'Building Block Approach').
 - The EU has adopted GHS via the CLP (Classification, Labeling & Packaging) regulations, and has not adopted all of the 'building blocks' (e.g. Cat. 5 for Acute toxicity).
 - EU deadlines: 1st December 2010 (substances) and June 2015 (mixtures).

GHS - consequences

- New classification criteria means some products will now carry new/additional classifications.
- For example:
 - Introduction of STOT-SE (& STOT -RE) classifications
 - Increase in upper/lower limits for some hazards (e.g. aspiration hazard)
 - More emphasis on the difference between acute and chronic aquatic toxicity
- Changes in safety data sheets and labels:
 - New sub headers and data
 - New Hazard symbols, and the appearance of 'Signal Words'
 - Risk-phrases replaced by Hazard Statements
 - Safety phrases replaced by Precautionary Statements

(STOT-SE/RE - Specific Target Organ Toxicity - Single / Repeat exposure)

GHS - Hazard classification & symbols

The change to classification and hazard symbols needs to be considered.

The content and format of labels will change from the familiar orange rectangular symbols to a new triangular format





Conclusions

Finally...

- There continues to be a significant cost to industry for implementation of REACH
- The end of pre-registration was just the start of the process - the real work is now taking place for REACH and the lubricants industry!
- There is a requirement for ongoing data maintenance & reporting
- GHS aims to simplify
- Communication is key to success!



REACH Further information



REACH - further information

There are many web based sources of information and advice on REACH. Some of these but not all are listed below....

ATIEL

www.atiel.org

European Chemicals Agency

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>



REACH - further information

Consult the website of the European Chemicals Agency:

<http://echa.europa.eu>

This website contains:

- Navigator tool which will assist finding out your REACH obligations and how to fulfil them
 - "About REACH" which gives an overview of the legislation
 - Guidance documents
 - IT tools for REACH
 - FAQ - Frequently asked Questions
-
- Industry associations - ATIEL & CONCAWE
 - Suppliers can answer chemical specific questions.
 - REACH helpdesk in your country (contact details can be found on the ECHA website).



Thank you for listening