REACH and its impact on base oils and lubricants markets

This article is based on a presentation that was made at the ICIS World Base Oils & Lubricants Conference, London, February 2010 by ATIEL.

REACH is the European Union regulation covering the Registration, Evaluation, Authorisation & restriction of Chemicals. REACH came into force on 1st June 2007 as Regulation EC1907/2006 contains over 840 pages, plus many guidance documents.

What is the intention of REACH?
REACH places the responsibility on the ‘chemical’ industry to demonstrate the safety of its products throughout the supply chain and it is designed to provide a high level of protection to human health and the environment. Base oils and lubricants are seen as part of the chemical industry under these regulations.

The REACH process will ensure that any data gaps between EINECS (existing chemicals) & ELINCS (new substances) are completed. REACH provides a single EU regulatory system with an efficient decision making process and clear timelines. REACH was designed to encourage innovation and there is some evidence that this is happening.

Where does REACH Apply?
The REACH regulation impacts all substances manufactured in or imported into REACH impacted countries, which are detailed below,* 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 and the 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). The 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 and all other lubricants) and the use of formulated products professionally by a ‘downstream user’.

Does REACH affect base oils & lubricants?
Yes, REACH impacts on both base oils and blended lubricants as they are substances and preparations respectively and their raw material components.

* Base oils are substances
  - includes base oils that are manufactured in the EU
  - includes base oils that are imported into the EU
* Blended lubricants are preparations
  - includes lubricants blended in the EU
  - includes lubricants imported into the EU
  - includes blended lubricants may be used in ‘articles’
    e.g. vehicle gearboxes

The REACH timeline

REACH challenges
Pre-registration phase closed on 1st December 2008 for all substances manufactured or imported at > 1 t / a

Suppliers and manufacturers who completed the pre-registration process could continue to manufacture and / or continue importation.

* Importantly 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) and required 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

For each registration there will be a Substance Information Exchange Forum (SIEF) activity this is to ensure there will be no duplication of testing and even stricter rules apply to animal testing, to ensure this is minimised.

The rules are simple: one substance = one registration

Each registration will have a base set hazard data, plus additional testing proposal for higher tonnage levels.

REACH statistics

- Original estimate expected 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

Importation into Europe

It is still 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, an 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 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 (ES)

REACH brings with it a new concept of exposure scenarios. 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 to be used. ES will be developed by manufacturer/importer for >10t classified substances (Hazardous or vPvB etc.).

EXPOSURE SCENARIO DEFINITION

These are a 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 Downstream User Association (DU). GESs can be set up as libraries for sector use.

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) needed for sufficiently protecting human health & the environment.

The exposure scenario considers

<table>
<thead>
<tr>
<th>Operational conditions</th>
<th>Substance properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk Management Measures</td>
<td>Formulation properties</td>
</tr>
</tbody>
</table>

Chemical Safety Assessment (CSA) is the process aimed at determining the risk posed by a substance and, as part of the exposure assessment, it develops exposure scenarios, including risk management measures to control the risks. REACH 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 a further step is triggered in the chemical safety assessment:

- Exposure assessment;
- Risk characterization - REACH Annex I.
### The Chemical Safety Report

#### Exposure Scenarios

- **Registration**
  - Inform ECNA of intent to register
  - SIEF and consortia formation for data sharing
  - Chemical Safety Report to ECHA
  - Testing proposals
  - Allocation of Competent Authority
  - Pay Registration Fee
- **Evaluation**
  - Dossier audit and/or evaluation
  - Risk management checks
  - Socio-economic analysis
  - Replacement plans
  - Time limited Authorisation
- **Authorization**

### Base Oils REACH process

**Step 1 – Use Identification & 'Table 1' mapping**
Identify the uses for lubricant base oils (Industrial / Professional / Consumer).
- Communication through CONCAWE member companies via Petroleum Product Management Group (PPMG)

**Complete 'Table 1' Mapping**
- List lifecycle key steps for each known use (contributing scenarios)
- Ensure each use/application is described in common terms using the standard REACH Use descriptor system i.e. PROCs and typical use conditions (Operational Conditions and Risk Management Measures)
- Confirm / discuss use mapping with Downstream Users Associations (DU) and revise mapping
- Extensive peer review within CONCAWE - PPMG – Uses / STF-29 Human Health / EG – Environment

**Step 2 – Complete '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).
2. Obtain relevant DNELS (dermal and inhalation) and undertake the CSA to derive the Risk Characterisation Ratios (RCR), for both dermal inhalation and for each contributing scenario.
3. 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.
4. Document the necessary risk management measures and operating conditions (to ensure the RCR <1) in a short narrative using standard phrase library.
5. 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.

**DNEL** - Derived No-effect Level - the level of exposure above which humans should not be exposed

**Step 3 – Complete the Generic Exposure Scenario (GES) Narrative**
- 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

**Issues**
- How to determine DNEL (derived no effect level)?
  - Substance definition
  - Additionally the analytical data requirements to support substance definition is currently in consultation

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**REACH & 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.

Base oils are UVCB substances.

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

(UVCB) Unknown or variable composition substances, 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.
**Current CONCAWE base oil product category use mapping**

![Base Oil REACH Process]

**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 REACH position paper available from www.atiel.org

**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.

**Features of the Sector**

- Lubricant additives are complex mixtures and frequently contain 20 – 30 substances
- There are numerous applications in most industry sectors: Automotive, industrial, greases
- There is a wide range of use types: Industrial / Professional / Consumer, totally closed to total loss and point use to widely dispersive
- There are a range of hazard profiles from non-classified to a range of hazard classifications and products generally have low volatility

**Overview of the Lubricants Supply Chain**

The stakeholders in the lubricant supply chain can be divided into three groups:

- Additive Manufacturer & Formulator (Industrial)
- EU Lubricant Formulator (Industrial)
- Lubricant Users (Industrial, Professional & Consumer)

The overview interactions are best shown in the next chart
Lube-Tech
PUBLISHED BY LUBE: THE EUROPEAN LUBRICANTS INDUSTRY MAGAZINE

Lubricant Uses
A matrix of lubricant uses and exposure determinants has been compiled and this identified over 200 separate uses identified (so far), including:-

<table>
<thead>
<tr>
<th>ATIEL Use group</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Formulation including greases</td>
</tr>
<tr>
<td>B</td>
<td>Closed uses</td>
</tr>
<tr>
<td>C</td>
<td>Open uses</td>
</tr>
<tr>
<td>D</td>
<td>Open high temperature processes</td>
</tr>
<tr>
<td>E</td>
<td>Soluble metalworking fluids</td>
</tr>
<tr>
<td>F</td>
<td>High energy open processes</td>
</tr>
</tbody>
</table>

ATIEL ATC Use mapping
Member companies surveyed for ‘uses’ and more than 200 users have been identified. These identified uses grouped according to their shared exposure patterns. This resulted in 6 general use groups labelled A to F.

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

ATIEL Use groups

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
- Streamlined 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 and a summary is available in all EU languages.

REACH Enforcement
Each Member state competent authorities is responsible for enforcement of REACH and numerous obligations are enforceable such as:-

- Articles 5 and 28; register, or to have pre-registered, phase-in substances manufactured or imported in the EU in quantities >= 1 t/a
- Articles 5, 24 and 26; register non phase-in substances before manufacturing or importing them in the EU in quantities >=1 t/a, after submitting an inquiry to ECHA
- Article 31 & 32; communicate information down the supply chain, in the form of a SDS, when required or requested but also other information down the chain for substances for which SDS do not apply

REACH-EN-FORCE launched by ECHA
A new REACH-EN-FORCE initiative enforcing the core principle of REACH has been launched by ECHA

"no data, no market" is their motto

Throughout the EU national inspectors are checking (pre)-registration and SDS provision and so far nearly 1,000 audits have taken place & shipments have been halted at ports. They mean business!

Finally...
- There has been a significant cost to industry for implementation of REACH
- The end of pre-registration was just the start of the process - now the real work begins for REACH and the lubricants industry!
- There is a requirement for ongoing data maintenance & reporting
- Communication is key to success!

Howard Hayes
Chairman of ATIEL REACH Special Task Force

LINK
www.atiel.eu
Federal Mogul’s Innovative IROX™ Bearing Shell Design Enables Fuel Consumption and CO₂ Reduction

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The Federal-Mogul Corporation has expanded the performance capabilities of engine bearings by developing an innovative polymer coated bearing shell that can reduce fuel consumption and CO₂ emissions by withstanding mechanical loads produced by heavily boosted engines. Called IROX™, the new technology addresses the lubrication challenges associated with frequent engine re-starts found in hybrid and other future stop-start systems by protecting both the crankshaft and the bearing shells from damage where metal-to-metal contact would otherwise occur. It is estimated that the IROX bearing overlay can help increase the life of crankshafts and bearing shells by more than five times in more extreme applications, such as direct-injected engines and engines with stop-start systems.

“The drive for increased engine efficiency is placing demands on crankshaft bearings that require new designs and materials applications,” said Michel Prefot, Federal-Mogul’s vice president, technology and innovation, bearings. “Satisfactory lubrication requires an adequate oil film between the bearing shell and the crankshaft to keep the surfaces apart. Efforts to reduce fuel consumption and CO₂ output is pushing engine design towards reducing oil film thickness and significantly increasing the number of starts, which is where bearings are most vulnerable. Federal-Mogul’s new IROX bearing overlay technology overcomes many of the most challenging wear-related issues that will be faced by a majority of new generation engines.”

As engines are downsized but maintain their output through turbo-charging, the specific loads on the bearings increase. When hybrids operate in electric mode or when drivetrains using stop-start strategies switch off the engine, the crankshaft speed drops to zero. Without rotation, the crankshaft settles into contact with the bearing shells and the oil pump stops providing lubrication, allowing metal-to-metal contact and causing wear when the engine restarts.

The lubrication conditions at start up are very different from those that exist during high-speed, high-load operation. While solid lubricants or dry bearing materials are effective at preventing metal-to-metal contact at low running speeds, these conventional solutions are not suited to higher speeds, which require journal bearings with a generous lubricant supply. Federal-Mogul’s new system combines the best features of both these established technologies by introducing a polymer coating for traditional metallic bearing shells, integrated with solid lubricants and wear inhibitors to produce a cost-effective, robust and production-ready solution. Extensive development has led to the identification and optimisation of a number of key parameters, such as layer thicknesses, substrate material specification, resin binder properties, curing conditions and functional additive specifications, and a number of patents on the technology.

The IROX bearings have an overlay that is a PAI (PolyAmideImide) polymer resin binder containing a number of additives dispersed throughout the matrix. These additives provide a variety of properties to the finished coating, such as wear resistance, mechanical strength, thermal conductivity and embeddability (the ability to safely envelop loose abrasive particles).

Test results have shown a dramatic improvement in life compared to both conventional shell materials and state-of-the-art competitors. “Typical bearings with aluminium overlays show significant wear after 100,000 stop-start cycles,” said Prefot. “However, the new generation of engine systems require 250,000 to 300,000 cycles, so the durability challenge has been raised. Bearings with the IROX overlay can meet the demands of repeated starting; in comparison tests where conventional aluminium overlays showed 100 microns of wear and lead-free bronze showed up to 50 microns, our shells still looked like new with a measurable wear of just a few microns.”

Another advantage of the new Federal-Mogul bearings is improved conformability, which has the effect of increasing the bearing surface area and hence increasing the load capacity. This means specific loading can be increased through the use of boosting, and low viscosity oils can be used by vehicle manufacturers (to improve fuel economy) without increasing risk of engine seizure, both important benefits in the development of low emission engines.

Because of superior IROX bearing overlay durability, vehicle manufacturers also can now consider utilising cost-effective nodular iron crankshafts, thus mitigating the need for an expensive, forged steel crank. This compatibility also eliminates the need for hardening of the pins and journals on the crankshafts. As vehicle manufacturers struggle to offset the cost burden of increasingly sophisticated engine systems such as turbocharging and direct injection, any reduction in base component specification is welcome.

IROX-overlay bearings are the latest addition to Federal-Mogul’s comprehensive portfolio of lead-free bearings products. “The IROX bearing overlay is an excellent example of how we’re continuing to strengthen our position as the world’s leading engine and transmission bearings manufacturer,” said Gerard Chochoy, senior vice president, Powertrain Sealing and Bearings. “We see excellent opportunities to displace conventional bearings in many automotive and other applications with the IROX overlay.”

“We believe our IROX overlay is a game-changing technology,” concluded Prefot. “Increasing fuel economy and reducing CO₂ emissions, while meeting the durability challenge of start-stop and hybrid applications supports the trend of highly-loaded downsized engines while enabling the use of more cost-effective crankshaft materials.” Pilot manufacture of the new shells has been underway since 2005, and full-scale production is scheduled for next year.