ATIEL Position Paper on REACH

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ATIEL Position Paper on Proposed REACH Regulation
Executive Summary

ATIEL represents Europe's leading lubricant manufacturers. This paper highlights ATIEL's position on the REACH regulation as presented in the European Commission's proposal of October 2003.

ATIEL supports the principles outlined in the REACH proposal**,** namely protection of human health and environment. We believe however 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 both up and down the supply chain. As the draft proposal progresses through the regulatory approval process, it is expected there will be many changes to the text, but the fundamental principles i.e. registration, evaluation and authorisation, together with a need for greater communication, are likely to remain. ATIEL believes however that, for a successful outcome, the current text needs to be simplified considerably. ATIEL has identified the following key areas of concern for the lubricant industry, which are summarized below and described in detail in the attachments:

- Protection of Intellectual Property / Confidential Business Information
  - REACH requires a significant amount of information to be communicated both up and down the supply chain, for substances as such and when present in preparations. Some of this information does not contribute to reducing the risk for those handling the substances but does disclose confidential business information (CBI). Therefore information disclosure requirements must be better balanced to only give relevant hazard and risk information to the user, whilst protecting CBI.
  - More of the information that has to be given to the Agency must be considered confidential and therefore must not be disclosed by the Agency to other parties.

- Maintaining 'level playing field' for Import and Export Business
  - Unregistered imports of small quantities (< 1t/y) of performance chemicals, i.e. in lube oil additives, and in fully formulated products, through several independent importers could bias the competitive situation. Clear enforcement actions, consolidated import quantities and declaration of production source on the SDS must be considered.
  - Chemicals produced for non EU-export only should be exempted from REACH. Existing workplace control legislation provides adequate protection during the production process.

- Increased administrative and cost burden for information management imposed by REACH
  - REACH information requirements should focus on availability and provision of appropriate risk related information through the supply chain.
  - Sufficient time needs to be allowed for information to cascade through complex supply chains from manufacturer to end user.
  - Continuous updating of documentation needs to be avoided by aligning update requirements with key regulatory dates e.g. at set intervals or within a set time limit.

- Loss of low hazard, low risk chemistry may lead to the use of higher risk, lower performance chemistry.
  - Economics for some chemicals may not be adequate to support registration and stewardship through REACH. Loss of these chemicals from the market would require costly replacement/re-engineering programmes with the possibility of replacement by higher risk or less effective alternatives.
  - Ecologically favorable chemistry might be withdrawn from Europe to maintain confidentiality for rest-of-world markets.

The implications of 'loss of chemistry' for the lubricants industry will be the subject of a separate briefing paper.

A well balanced REACH legislation should achieve the desired benefits for man and the environment without compromising the sustainability of the European lubricant industry.

ATIEL REACH Technical Committee

Proposed REACH Regulation - Issues of Technical Concern for the European Lubricants Industry

The European Commission adopted its formal proposal for the REACH Regulation in October 2003, which is now under discussion by the European Parliament and Council. This is an extremely ambitious proposal, which is likely to take some time to pass through the full regulatory approval process. Based on current information, it is not anticipated that the REACH regulation will adopted until at least 2007.

The draft Regulation is extremely complex and, as written, will have significant impact on all manufacturers, importers and users of chemicals within the EU. The 'supply chain' for Lubricants in Europe involves many individual companies in roles such as suppliers of chemicals and raw materials, formulators of performance additive packages and finished lubricants, distributors, industrial end-users and OEMs. REACH will impact significantly on all these 'actors in the supply chain'.

ATIEL supports the principles outlined in the draft REACH proposal**,** namely protection of human health and environment. We believe however that success for REACH will depend on close co-operation between chemical supplier and customer and that all participants need to recognise their responsibility to provide information both up and down the chemical supply chain. As the draft proposal progresses through the regulatory approval process, it is expected that there to be many changes to the detailed text. The fundamental principles ie. registration, evaluation, communication and authorisation are likely to remain however and ATIEL believes that, for a successful outcome, the text will need to be simplified considerably.

The complexity of the draft Regulation and the large number of organsiations involved in the lubricant supply chain, present a significant challenge when assessing the likely impact of REACH on the European Lubricants Business. The ATIEL REACH Technical Committee has been asked to identify key areas of concern for the industry and if possible make recommendations to improve the workability of the REACH Regulation. Three generic areas of concern have been identified as follows:

- Protection of Intellectual Property / Confidential Business Information.
- Import / Export - Potential Impact on Industry Competitiveness.
- Provision of information through the lubricant supply chain.

Each of these key issues is discussed in the attached papers and where appropriate suggestions are included for simplifying and improving the current REACH proposal.

Protection of Intellectual Property / Confidential Business Information

Issue of Concern

Release of Intellectual Property (IP) / Confidential Business Information (CBI) under proposed REACH Regulation.

Background

A key theme of the draft REACH proposal is the need for information to be communicated to users and other parties who may come into contact with chemicals. The registration process requires manufacturers and importers to report specified information to the Chemicals Agency and all 'actors in the supply chain' are required to provide information both up and down the supply chain, to their immediate supplier or downstream user.

Some of the specified information is considered to be Confidential Business Information (CBI) and hence part of a companies 'Intellectual Property'. Release of such commercially sensitive information therefore has the potential to cause significant financial harm to commercial enterprises.

In the Lubricant industry, a key part of a company's Intellectual Property is the ability to formulate products which meet specific technical requirements. This technical 'know-how' and the required technical approval testing, represent a significant financial investment which needs to be protected. Release of CBI also presents a threat to continued innovation and the long-term competitiveness of the European Lubricants Industry.

Relevant REACH Articles

Article 5, 6, 9 - Registration
Article 29, 30 - Communication to down stream users
Article 110, 111 - Classification and Labelling Inventory
Article 115 - Access to Information
Article 116 – Confidentiality
Annexes 1A and IV

Key Issues

- The REACH proposal requires manufacturers, importers and users of chemicals to provide specified information to the Central Agency and / or 'downstream' users.
- The Central Agency is required to make specified non-confidential information available on the Internet, and other non-confidential information available on demand, in accordance with Regulation (EC) No. 1049/2001.
- Chemical product suppliers are required to identify registration numbers for hazardous chemicals on SDSs, and provide registration numbers for all components to immediate downstream users.
- Article 116 does not afford confidentiality to some information which is considered CBI/IP.

Industry Position

The European Lubricants Industry support the principle objectives of REACH ie. protection of man and the environment. We accept the need for information on the health safety and environmental impacts of chemicals to be communicated down the supply chain, but only in circumstances where there is a clearly identified risk. We do not believe that it is necessary to communicate information throughout the supply chain for non-hazardous chemicals or where hazardous chemicals are present in amounts that do not present a risk to health or the environment. The current 'confidentiality' provisions in REACH (Article 116) are not sufficiently protective of Intellectual Property and hence present a significant threat to the financial well-being and long-term competitiveness of the lubricants industry.

Suggestions for Improvement

Specific 'Confidentiality' issues of concern to the European Lubricants Industry are detailed in the attached Table, together with suggestions for improvement and identification of benefits.

Issue of Concern	Suggestions for Improvement	Benefits
SDS section 3 declaration. We agree that the SDS should be the main vehicle for providing information to downstream users on hazardous chemicals and constituents of preparations. Existing provisions of the Safety Data Sheet Directive (2001/58/EC) are considered adequate in this respect. REACH (Annex 1A, section 3.5) proposes to extend the declaration of information on components to include the registration number of hazardous substances. The inclusion of registration numbers does not bring any health, safety or environmental benefit to downstream users. The addition of registration numbers adds complexity and cost to the SDS production and supply process. It also allows identification of the	Amend Annex 1A, section 3.5 as follows: **3.5. The name and the EINEC or ELINCS number of the above substances shall be given in accordance with Directive 67/548/EEC. The CAS number and IUPAC name (if available) may also be helpful. For substances listed by a generic name, according to Article 15 of Directive 1999/45/EC or the footnote to point 3.3 of this Annex, a precise chemical identifier is not necessary. ~~The registration number assigned under Article 18(1) of this Regulation shall also be given for each substance that is subjectto registration.~~**	Protection of IP (supplier identity). Avoids the need for declaring multiple registration numbers for interchangeable components in preparations. Avoids the need for multiple SDS updates as chemicals become registered.

supplier of the chemical, which is considered as IP.		
Declaration of REACH registration. Article 30 requires suppliers to provide downstream users (throughout the supply chain) with registration numbers for non-hazardous chemicals and constituents of preparations. This proposal does not align with the declaration requirements in SDSs (Annex 1A, section 3.5), which only requires identification of registration numbers for hazardous chemicals above specified amounts. Downstream users do not need to know the registration numbers, just confirmation that the chemicals they have been supplied with have been registered or are exempt.	The supplier of a chemical or preparation should be required to confirm to the immediate downstream user or distributor the REACH registration status of the chemical, or constituents of a preparation. This should be done in writing, preferably by inclusion of a 'positive' statement in the SDS eg "This chemical is (or the components of this product are) in compliance with the registration requirements of REACH" Each supplier in the chemical supply chain shall maintain appropriate records to show compliance and make these available to authorities on request. **Amend Article 30, part 1, as follows:** **1. All actors in the supply chain of a substance on its own or in a preparation who do not have to supply a safety data sheet in accordance with Article 29 shall communicate the following information down the supply chain to the immediate downstream user or distributor:** ~~**(a) the registration number(s) referred to in Article 18 (1), if available;**~~ **(a) confirmation that the substance is registered in accordance with the Regulation or is exempt from registration;** **(b) whether the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;** **(c) details of any restriction imposed under Title VIII;** **(d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied.**	Common requirement for hazardous and non-hazardous chemicals / preparations. Protection of IP (supplier identity). Avoids the need for declaring multiple registration numbers for interchangeable components (Intellectual Property). Clear supplier responsibility to provide 'positive' compliance statement.
Classification and Labelling Inventory. Articles 110/111 require chemical manufacturers and importers to provide specified information to the Chemical Agency for inclusion in a database. This includes manufacturer/importer identity and registration numbers. Non-confidential information is to be publicly accessible. Other information will be made available to other notifiers and registrants. Some of the information is considered as CBI or IP.	The manufacturer / importer identity and REACH registration number should be considered confidential and not be publicly accessible. **Amend Article 110, part 1,As follows:** **1. Any importer or manufacturer, or group of importers or manufacturers, who place on the market a substance within the scope of Article 109, shall notify to the Agency the following information in order for it to be included in the inventory in accordance with Article 111, unless submitted as part of the registration:** ~~**(a) the identity of the manufacturer or importer responsible for placing the substance(s) on the market;**~~	Protection of IP (supplier identity). Simplification of the C&L database. Allows public access to necessary information on hazardous chemicals.

	(b) the identity of the substance(s) as specified in part 2 of Annex IV; **(c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;** **(d) the resulting hazard label for the substance(s), resulting from application of Articles 23, 24 and 25 of Directive 67/548/EEC;** **(e) specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.** **Amend Article 116, part 1 and 2, as follows:** **1. The following information shall not be considered as confidential:** **~~(a) the trade name(s) of the substance;~~** **(b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;** **(c) if applicable, the name of the substance as given in Einecs;** **(d) physicochemical data concerning the substance and on pathways and environmental fate;** **(e) the result of each toxicological and ecotoxicological study;** **(f) any derived no-effect level (Dnel) or predicted no-effect concentration (Pnec) established in accordance with Annex I;** **(g) if essential to classification and labeling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;** **(h) the guidance on safe use provided in accordance with section 4 of Annex IV;** **(i) the information contained in the safety data sheet, except for the name of the company/undertaking or where the information is considered confidential by application of paragraph 2;** **(j) analytical methods if requested in accordance with Annex VII or VIII which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans;** **(k) the fact that testing on vertebrate animals has been carried out.** **2. The following information shall be considered as confidential, even if no declaration in accordance with Article 115(2) is made:** **(a) details of the full composition of**	

	a preparation; **(b) the precise use, function or application of a substance or preparation;** **(c) the precise tonnage of the substance or preparation manufactured or placed on the market;** **(d) links between a manufacturer or importer and his downstream users.** **(e) The Registration number.** **(f) The trade name of the substance** **(g) The identity of the manufacturer and importer.** **(h) Details of the manufacturing process** **In exceptional cases, where there are immediate risks to human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.**	
Confidentiality. Article 116 defines information that shall be considered as non-confidential and confidential under REACH. The list of confidential information is quite short. The non-confidential information listed, and all other information not specifically mentioned, shall be made available to 3rd parties on request, subject to a 30 day consultation (Article 115) with the information 'owner'. Information which is considered by the lubricants industry to be CBI or IP eg. registration numbers, manufacturer identity, is not designated confidential. In addition information considered to be 'sensitive' or of possible commercial value to 3rd parties eg toxicity study results, analytical methods is considered non-confidential. There is a conflict between the provisions of Article 115 and that of 111&116. The former, requires the Agency to consult with the information 'owner' whereas the latter two articles require the Agency to make the specified non-confidential information (Article 116 [1]) publicly accessible.	There is a need to clarify in Article 111 exactly what information will be publicly accessible in the C&L inventory. Information that constitutes IP /CBI, or is considered sensitive / of commercial value should not be publicly available on the database, such as identity of trade names, supplier and registration numbers. The conflicts between Articles 115 and 111/116 need to be resolved. Article 116 needs to be amended, to include designation of information considered to be IP /CBI, sensitive or of commercial value as confidential. This includes trade name, details of manufacturing process, manufacturer/importer identity, toxicity & ecotoxicity results, hazard summaries, analytical methods, vertebrate testing proposals and registration numbers.	Protection of IP / CBI Clarifies what can and cannot be disclosed to 3rd parties Allows public access to necessary information on hazardous chemicals

Import / Export - Potential Impact on Industry Competitiveness

Issue of Concern
A lack of "REACH compliance" controls on imported substances and preparations, together with a requirement for exported substances and preparations to comply fully with REACH is likely to result in significant negative impact on the competitiveness of the European Lubricants Industry.

Background
The draft REACH proposal requires identical information for imported substances/products to that required for EU manufactured substances/products. The amount of information required is based on the quantity of the substance imported/manufactured by each legal entity.

An importer, who is legally responsible for the registration of any chemical(s) imported into the EU, either on their own or when present in a mixture, is defined as "any natural or legal person established within the Community who is responsible for import". Imported quantities of chemicals and products (preparations / mixtures) can therefore be split across several legal entities ("Penny-Companies") to avoid registration completely, or avoid triggering the next level of REACH requirements. This can significantly reduce the cost competitiveness of EU-produced lubricant products and performance chemicals, such as additives that are used in lubricating oils.

The legal framework for enforcement of REACH requirements on imported substances and preparations, as well as articles is not yet outlined. Technically it can be very difficult to identify and quantify individual substances in complex preparations. A distortion of the market, based on cost competitiveness, is considered possible as a result of the lack of enforcement of REACH for imported chemicals, preparations and articles. Uncontrolled import of chemicals, that do not meet the standards required under REACH, has the potential for adverse impacts on health and environmental protection in the EU.

REACH requires manufacturers of chemicals, which are manufactured, either exclusively or partially, for non EU-export, to provide the specified information to the Central Agency. This adds significantly to production costs and reduces the competitiveness of EU based manufacturers in non-EU-markets.

Relevant REACH Articles
Article 1,5 - Registration
Article 19 - Manufacture and Import of Substances

Key Issues
- The REACH proposal requires manufacturers and importers of chemicals to provide specified information to the Central Agency based on quantity manufactured or imported annually.
- The REACH proposal does not prevent splitting imports across several legal entities, thus opening potential for avoidance or reducing registration requirements.
- A lack of specific enforcement provisions on imported chemicals and products in the current proposal has the potential for competitive advantage for imported quantities, particularly when spread across a number of legal entitities and countries.
- The REACH proposal requires manufacturers of chemicals produced for export only, or where a significant proportion is exported, to provide specified information to the Central Agency based on quantity, thus adding significant costs compared to non EU-competitors.

Industry Position
The European Lubricants Industry accepts the need of for provision of health, safety and environmental information to Authorities on chemicals and agrees that information requirements should be identical for all chemicals / products placed on the market in the EU (ie. imports and EU-manufactured). Adequate, uniform control measures to check REACH compliance on imported chemicals and products need to be developed to prevent distortion of the EU market in favour of non-European production. Equally export of chemicals and products manufactured within the EU must not be disadvantaged commercially due to increased costs of compliance. Hence reduced requirements for exported materials, in line with provisions for site limited intermediates should be developed, whilst maintaining adequate health and environmental protection during production.

Suggestions for Improvement

Suggestions for improvement, with associated benefits are shown below

Issue	Suggestions for Improvement	Justification
Import: Imports of chemicals and formulated preparations might be less strictly controlled than EU manufactured material.	Clearly assign the enforcement actions under REACH for control of imports to National custom authorities. Include provisions for National Customs authorities to share information on imported chemicals and products	Provides a 'level playing field' through adequate control checks on imported goods. Avoids multiple import points across EU.
	SDS, container label and customs documentation to clearly identify non-EU production source.	Facilitate easy identification of imported chemicals and products
	SDS – include a requirement for a 'positive' statement on REACH compliance. To be checked by custom authorities.	Transparency of information on compliance to authorities and end-users
	Require importer to consolidate and track imported quantities of chemicals across all EU Member States.	Avoids intentional "import volume split". Will be consistent with existing legal requirements for registration of new substances. Ensures total volume imported into EU is controlled.
	Registration of imported chemicals should be through single importing legal entity, based in the EU country of 1st import	Reduce potential for import through multiple legal entities. Consistent with existing legal requirements for registration of new substances. Ensures total volume imported into EU is controlled.
Export: Increased production costs for non-EU exported chemicals and products	Reduce REACH requirements for production volume destined for export, in line with reduced registration requirements for on-site isolated intermediates. Full REACH registration would only apply to EU manufactured volume placed on the EU market.	Avoids reduced cost competitiveness on non-Eu market. Reduces risk of transfer of current EU production capacity to non-EU Country.
	Existing workplace controls of hazardous substances eg CAD, would protect health and the environment during production.	Existing workplace health and environmental control legislation provides adequate protection.

Provision of Information Through the Lubricant Supply Chain.

Issue of Concern
Increased administrative and cost burden for information management and transmission, imposed on manufactures, importers and users of lubricants under proposed REACH Regulation.

Background
A key theme of the draft REACH proposal is the need for information to be communicated to users and other parties who may come into contact with chemicals. REACH provisions will require manufacturers and importers to report specific information to the Chemicals Agency, while all 'actors in the supply chain' are required to provide information both up and down the supply chain, to their immediate supplier or downstream user, and if necessary, act accordingly.

Relevant REACH Articles

Article 13 - Chemical safety report
Article 29, 30 - Communication to down stream users
Article 31 - Communication information up the supply chain
Article 34, 35, 36 - Downstream users obligations

Key Issues

- The REACH proposal requires manufacturers, importers and downstream users of chemicals to provide specified information to the Central Agency and throughout the supply chain.
- Information on risks from chemicals and risk reduction measures (not simply hazards) has to be supplied to Central Agency.
- A significant amount of supplementary information has to be provided to downstream users, directly and/or upon request. Other information may have to travel from downstream users 'up the supply chain' in a formal way.
- Requirements for SDSs are expanded and subject to more onerous updating requirements.
- Data on information exchanges have to be kept for a prolonged period.

Industry Position
The European Lubricants Industry supports the principle objectives of REACH, i.e. protection of man and the environment. Whilst increasing the amount of information that must be collected and shared between the actors in the supply chain will have a beneficial effect, there is a complementary need to improve the efficiency of this process, and focus on relevant information and issues to avoid an unnecessary burden on all parties.

In the registration phase, the issue of consortia formation and sharing of costs/responsibilities will result in increased complexity. The basic registration process could also easily develop from an onerous, but straightforward, "data collection / gap filling" exercise into a series of repeated loops, with additional information being added at various timepoints along the way (eg. constant addition of new identified uses proposed by downstream users) and repeated submission of updates for acceptance by the authorities. All these information exchanges will need to be documented, with a significant record keeping burden for industry and authorities.

The requirement for documented Chemical safety reports / Chemical Safety Assessments to satisfy proposed REACH requirements will be a significant new cost and administrative burden for industry. It is likely to require a disproportionate amount of time and effort, in relation to health or environmental benefit, particularly for preparations. The time lag for exchange of information between all interested parties in the supply chain is likely to result in significant time-to-market delays for new products or applications.

There is an obvious need for information on the health, safety and environmental impacts of chemicals to be communicated down the supply chain, but this is already achieved through the provisions of the SDS directive. It has been suggested that the level and quality of information provided by "average" SDS's is not adequate for the intended purpose. This problem would be better addressed through increased attention on training requirements and awareness among interested parties, rather than increasing the amount of information required.

There is a trend in REACH towards requiring the inclusion of information in SDSs on highly technical issues that will require the reader to have a high level of specialised knowledge. This will increase the length and complexity of the SDS, with a corresponding decrease in readability and understanding, without giving any real added value to the user.

In addition, REACH SDS requirements include the need to provide advice on HSE risks during downstream use, which are outside of the direct control of the chemical supplier. Downstream user organisations have an existing legal

obligation under other Community legislative provisions to undertake health and environmental risk assessments, which necessitates access to specialised expertise (eg industrial hygienist or safety engineer). The obligation on suppliers to identify risk reduction measures for downstream uses in the SDS does not remove the legal responsibility on downsteam user organisations to protect the health of their workers and the environment.

Suggestions for Improvement

Issue	Suggestions for Improvement	Justification
Update of registration information Article 20 requires an **immediate** report to the Agency if the information contained in the registration dossiers changes, with respect to the specified cases.	For those cases listed in article 20, points (d) - new use of a substance) and (g) - updates of CSR), an immediate report should be required, **only** if the new information obtained by the Manufacturer/Importer has a **relevant** impact on recommended risk management practices. Otherwise, updating of registration dossiers should be made at **fixed time points** (like HEDSET/IUCLID)	Minimising updating and transmission of documents.
Safety data sheets Article 29, point 8) lists circumstances which require an update of SDSs. Some instances are now linked to REACH milestones, rather than to update information on safety.	Point Bullet (a) - (new information,) should be amended in order to require update of SDSs only in cases where new **relevant** information results in **different** risk reduction measures (i.e. new exposure scenarios with clearly increased risk) Point Bullet (b) - (registration of substance,) should not be considered as a reason for **"immediate"** update of SDS. Update of SDSs for this reason should be deferred to a date within six months of the relevant registration deadline, with an additional six months allowed for including the information on SDSs of preparations containing the substance.	Avoiding constant document processing and transmission in non relevant cases. Would allow sufficient time for information to flow through the supply chain and avoid the problems encountered during the implementation of the Dangerous Preparations Directive
Information for non-hazardous substances/preparations Article 30 point 2). Same consideration as the preceding point [Note: some member States expressly require that information for non-hazardous substances and preparations **must** be supplied in the **same** 16-section format of normal SDS]	Same consideration as the preceding point	Same consideration as the preceding point