ATC

A SECTOR GROUP OF cefic

ATC POSITION on REACH

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ATC Position on REACH

PREAMBLE

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Following the publication of the proposed legislation for new Chemicals Regulations in Europe (REACH), the Additives Technical Committee (ATC) wishes to publicise it views regarding the overall impact of this programme. While several of our Member Companies are also members of CEFIC, the ATC Sector Group has developed specific views which highlight the more profound long term effects anticipated for our particular market sector.

REACH represents an aggressive forward-looking programme to manage all chemical substances equally on the European Market. Nonetheless, many of these same chemicals only circulate in commerce as integral parts of more complex and highly competitive chemical preparations, or formulations. What distinguishes one formulation from another competitive offering are the performance claims made (and proven) in the market. Details of the intrinsic chemical identities and proportions of those mixed substances are carefully guarded as they give away proprietary compositional information, but generally do not contribute to hazard characterisation or risk management.

Collectively, our membership represents those businesses that produce the vast majority of lubricant and fuel additive substances and concentrated preparations placed on the market in Europe today. In most cases, the substances present in these formulations are not by themselves placed upon the market today. This manufacturing/importer paradigm is extremely unlikely to change in the future due to the very proprietary nature of the lubricants industry in general.

Our very complex and extremely competitive chemical formulations are supplied to downstream users everywhere who prepare and market the finished lubricants and fuels that everyone must use on a daily basis. Our “stock in trade” rests with the continuing promise to deliver unique performance to the lubricants industry at large. Each supplier, in its own proprietary fashion, creates the formulations that fulfil this promise. The following position paper describes the specific problems facing the lubricant/fuel additive suppliers of Europe.

Emerging EU Chemicals Control Legislation (the "White Paper" & REACH)

ATC Position

Executive Summary

European manufacturers of lubricant and fuel additives design and develop highly specialised, proprietary additives that typically enter the market within complex chemical formulations targeting specific automotive, industrial, and heavy duty lubricating oil applications. Many of these products are deliberately designed to reduce the environmental impact of these finished lubricants and fuels. The creation, testing, and production of these chemical constituents require both a high level of applied research, technical skill and considerable investment capital. In the absence of industry's long-term ability to protect these internal resources, the apparatus of our modern society would stop.

Most petroleum additive companies are either small or medium sized enterprises (SMEs) or reflect the operational dynamics of SMEs on a slightly larger scale. On the basis of sheer volume, the Additives Technical Committee (ATC) represents those Petroleum Additives Producers in Europe who currently satisfy virtually the entire lubricant concentrate needs of the European market (and all non-EU lubricants markets as well). The ATC believes that the proposed REACH legislation will have its greatest impact on SMEs, especially those whose livelihoods depend upon the speciality chemicals industry sector. Therefore, petroleum additive producers and distributors will be amongst those most significantly and disproportionately affected by the proposed legislation.

The ATC supports the overarching aims and principles of REACH. However, we have a number of significant and continuing concerns about the details as the discussion draws down to draft EU regulation(s). Those implications of potential REACH legislation which are of greatest concern to petroleum additive manufacturers include:

- Loss of competitiveness resulting from the current and unnecessary disclosure of highly valued Intellectual Property and the anticipated further erosion of Intellectual Property Rights (IPR)
- Increasing and significantly disproportionate cost burdens on the SME-like additive companies who market formulations
- The potential loss of ability to formulate with many highly specialised and functionally essential additives because they are no longer cost effective
- The potential negative impact on existing downstream efforts to ensure a cleaner and healthier environment, which improved additives help to ensure
- The potential loss of additive industry skills, jobs and investment as companies are forced to either move outside the EU or transfer leading formulation technologies to more favourable market place environments.

ATC believes that a workable REACH programme and its sensible implementation is still achievable; however, the legislation must be more precisely tuned to ameliorate its potentially disproportionate impact on SME-like additive suppliers of formulations. ATC considers that the principal adverse consequences anticipated for the petroleum additives industry can be minimised by taking the following considerations into full

account:

- Ensuring that our commercially sensitive capital intensive Intellectual Property is not directly or inadvertently forfeit by disclosure e.g. in SDSs and labelscontaining
- Restricting information demands to only those which are truly essential for a proper hazard and risk assessment and subsequent development of meaningful risk managements practices
- Enabling maximum use of all existing data and other available information on individual chemicals and chemical groups, applying globally accepted principals of “read-across” in the process
- Encouraging the voluntary formation of consortia to maximise the value of existing data while minimising testing costs; developing a related voluntary pre-registration scheme as per the CEFIC Thought Starter
- Granting qualified exemptions for site limited intermediates that are essential to lubricant and fuel additive design and manufacture
- Delaying or derogating testing on substances of intrinsically low concern using a negotiated risk-based tiered testing design approaches
- Confining the authorisation process to CMRs, POPs and PBTs (whose harmful properties have been demonstrated, not alleged), excluding endocrine modulators and sensitisers
- Confirming that mandated additive substitution be based upon risk, as opposed to hazard, taking full measure of the socio-economic impact of such an action over the entire additive supply chain

Detailed ATC Position on REACH

1. The Petroleum Additives Business

The Petroleum Additives business is a fast-moving business supplying a wide range of both lubricant and fuel additive formulations meeting the full spectrum lubricating and power generating needs of our highly mechanised society. These complex preparations deliver both economic and performance benefits to users as well as more broad reaching benefits to man and the environment via documented improvements in fuel economy, lower fuel combustion emissions, and extended equipment life.

In Europe, the Petroleum Additives Producers are represented by the Additives Technical Committee, (ATC). The ATC was established in 1974 as a forum for member companies to discuss issues and trends of a technical and statutory nature that concerned the industry as a whole. In 1979, ATC became an affiliated Sector Group of CEFIC, the European Chemical Industry Council. Membership in ATC remains open to any EU additive company responsible for chemical processes for the supply, manufacture and/or distribution of lubricant and fuel additives and other chemicals stuffs in Europe, or manages regional performance testing facilities to support the businesses represented.

Several of our member companies in particular collectively represent lubricant additive manufacturers and suppliers that currently enjoy more than 99% of the European lubricant additives market. In that respect, we are fortunate to have been able to developed and share an industry specific and comprehensive assessment of the impact of new and emerging EU chemicals Directives and Regulations. Our industry sector in particular markets over 4000 unique formulations using approximately 1500 substances of which 10% are HPV designated chemicals (see Table 1). Of these formulating building blocks, roughly 500 substances are considered polymers by EU definition, and 225 are manufactured using substances currently considered site limited intermediates. In all, approximately 95% of all lubricant formulations on the EU Market today consist of “existing” chemical substances (the remainder being “notified” chemicals registered on ELINCS).

Table 1

	Total	HPV	Non-HPV	Existing	Notified	Polymers
Intermediates	225	175, est	50, est	Exempt	Exempt	175, est
Components	1500	150	1350	1425	75	500
Formulations	4000	3000, est	1000, est	Excluded	Excluded	NA

2. Development of Chemical Regulations in the EU

Since 1967, the legislative control of chemicals in the European Union has been defined by the Dangerous Substances Directive (Commission Directive 67/548, and its subsequent Amendments and ATPs[1]). This collection of Directives has evolved, spawning a number of daughter Directives, including the Dangerous Preparations Directive (Commission Directive 88/379), the Safety Data Sheets Directive (Commission Directive 91/155) and their subsequent Amendments and ATPs. In 2001, the European Commission published White Paper COM(2001) 88 final - Strategy for a future Chemicals Policy - which was envisaged as the basis for chemicals control legislation into the new millennium, replacing all currently adopted Directives in this area. On 29 October 2003, after a short Internet consultation process, the Commission published its final, formalised proposals for the REACH programme.

The Commission has reiterated several reasons for the publication of this radical plan, some of which can be understood from the original White Paper.

- The "burden of history": "The lack of knowledge about the impact of many chemicals on human health and the environment is a cause for concern… legislative action takes too long before yielding a result[2]."
- Uneven playing field between notified and existing chemicals: One of the key principals of the new strategy was that the historical distinction between "notified" and "existing" chemicals would disappear, and that all chemicals would be regulated under one system only.
- A new system of registration and evaluation of chemicals, REACH (Registration, Evaluation and Authorisation of CHemicals) will be implemented. This would be a sequential process, based on risk evaluation at each stage, requiring that all marketed substances be subject to an initial registration. A tiered evaluation process would then follow, and, for substances of demonstrated high concern (e.g. PBTs), an authorisation scheme linked to risk management measures would result.

3. Environmental Benefits

Petroleum additives, used in both lubricants and fuels, continue to offer a wide range of undisputed benefits to the users, as well as to man and the environment in more general terms. These include:

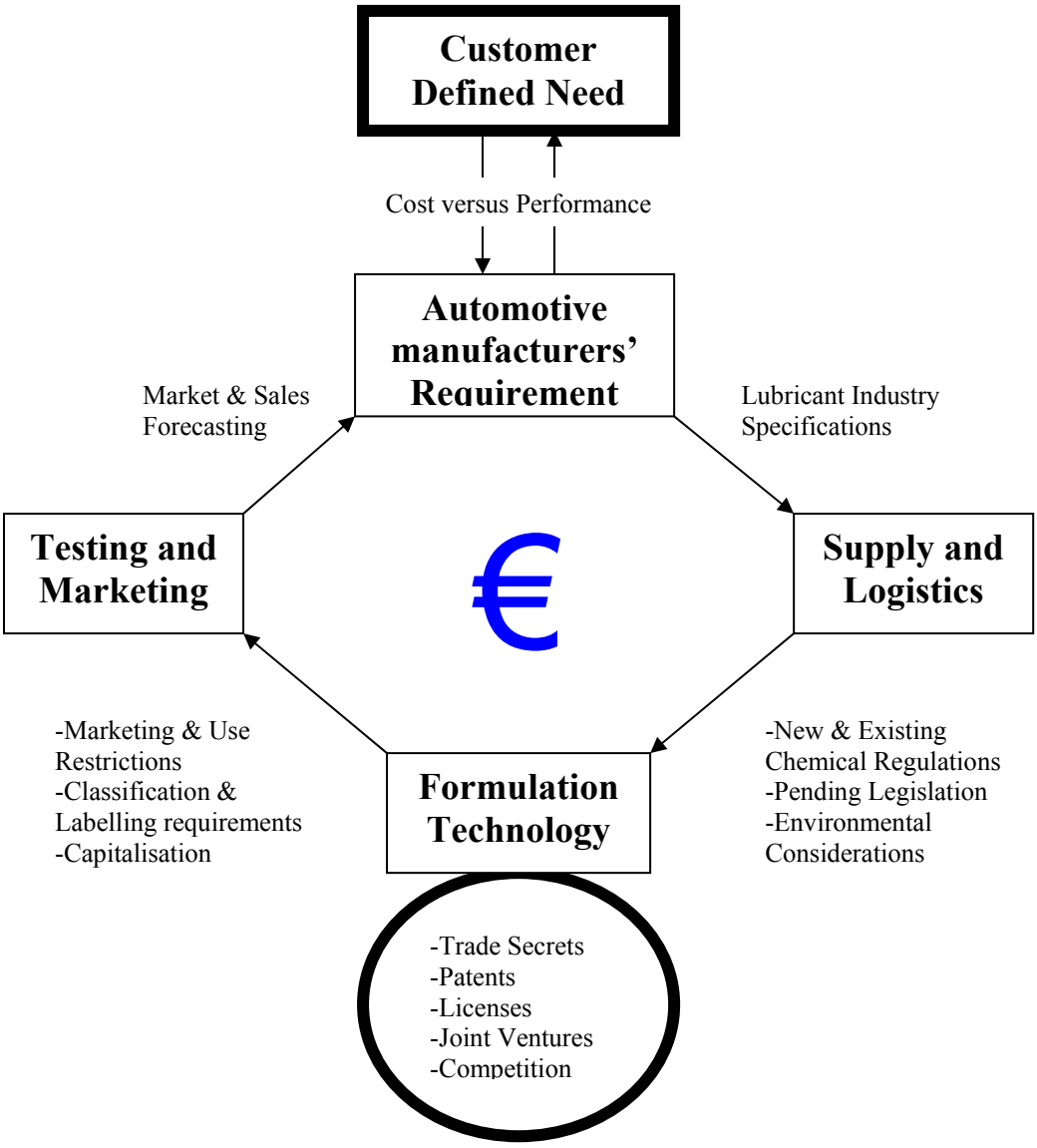
- Improved oil drain intervals which result in both reduced bulk oil consumption and waste oil volumes management
- Improved fuel economy and engine performance, resulting in
  - Lower fossil fuel consumption
  - Lower emissions (particulates, oxide of nitrogen and sulphur, and Green House gases)
  - Improved catalytic converter efficiencies and catalyst system longevity
- Improved durability of mechanical equipment (e.g. automotive engine parts) resulting in extended vehicle life

Figure 1 below illustrates how these benefits are delivered and the various agents and agencies that impact the life cycle of a typical lubricant technology.

[1] Adaptations to Technical Progress
[2] Text extracted from the White Paper

Figure 1

Benefits Delivery Scheme



4. Petroleum Additives Issues

4.1 General

While the ATC generally supports the wider principles of REACH, our anticipation of the impact of REACH remains dependent on the practicalities of the operation of the finalised legislation. Our view is that this Regulation(s) will bring forward serious adverse consequences affecting the overall Petroleum Additives business, as well as the chemical industry in general. We foresee significant cost burdens levied upon our formulations industry in particular that will result in the marginalisation of many existing lubricant products and their core substance building blocks. These economically motivated reassessments will stimulate a longer-term drift of existing beneficial lubricant technologies and leading edge research away from this region. In short, EU manufacturers will be unable to justify continuing financial support for many substances now on the market if they are rendered less cost effective under REACH.

ATC welcomes the changes made as a result of the Internet consultation, in particular:

- The decision to defer assessment of polymers, which are considered a low-risk category of substances
- The reduction in demands of the chemical safety reports (CSRs)

However, these changes do not go anywhere near far enough to soften the blow to industry. We envisage that the direct and indirect costs will comprise additional unnecessary chemicals testing, significant reversals in existing marketing planning and development, and increasing Automotive manufacturers' resistance to changing formulations technologies which are not specifically linked to Automotive manufacturers' performance specifications and emerging lubricant applications. We also strongly suspect that there will be significant additional Member States' Competent Authority management costs – which will ultimately carry forward to industry – thus placing an additional burden upon SMEs[3].

We appreciate that the administrative burden associated with managing the volumes of additional data generated at the national level is not our immediate responsibility or concern. Examples of the many activities that would add costs to industry include: REACH fees, testing, consortia participation, dossier/CSR preparation, SDS amendment, re-formulation (including performance testing) and obtaining info from suppliers and customers. However, we consider that this aspect resource alone could easily exceed even the most optimistic projections for developing such additional capacity within each Member State. The consequences of failure in this regard would be devastating to the overall success of REACH and the implementation of specific principals that we continue to support.

4.1.1 The Business of Formulating Lubricant Preparations

Our industry sector develops and markets lubricant preparations, which are incredibly complex collections of synthetic chemicals that are best defined individually by virtue of the raw materials employed and the chemical processing techniques brought to bear. These formulations most often contain highly refined lubricant base oils necessary to facilitate the blending of finished lubricants designed to deliver an agreed and consistent end use performance. The types of lubricant additives substances selected for formulation will vary widely depending upon the performance targets indicated by a finished lubricant application and those industry organisations that codify the standards and specifications necessary to assure industry wide consistency in performance.

Current automotive and industrial finished oils derive their performance attributes from the many lubricant additive concentrates or packages used to compound these products. The major lubricant blenders purchase these chemical concentrates from the lubricant additive manufacturers, thus formulating finished oils capable of providing all the performance characteristics desired to satisfy a particular lubrication application need.

The additive preparations (or concentrates) we market are sold to lubricant blenders and comprise a diverse mixture of chemical substance classes or types that we commonly refer to as components. When combined in the proper proportions, these individual components perform distinctive and quantifiable functions in bulk finished lubricants. Among these, we typically focus upon

[3] Small and Medium-sized Enterprises

detergency (deposit control), dispersancy (passive control of insolubles agglomeration of combustion residue such as soot, fragments of highly oxidised organic resins, etc.), oxidation inhibition, anti-wear, and rust and corrosion inhibition. Detergents also help to neutralise inorganic acids that form during the combustion of fuels that may contain sulphur-bearing contaminants (e.g. heavy diesel fuel). For each of these unique performance functions, there is a multitude of formulating approaches, each mandating a different slate of additive components or different intrinsic proportions of components designed to assure the necessary performance claims associated with the finished lubricant.

Specific issues affecting Petroleum Additives Formulators, which would be impacted by REACH, can be summarised as follows:

- Substances are selected by formulators primarily on the bases of demonstrated reliable performance, regulatory sanctions, ready availability, logistics, and overall cost, and future competitiveness in the industry.
- Newer (i.e. typically notified) chemicals are fewer in number, often more expensive to commercialise, and usually necessitate significantly extended market research and development cycles.
- Increases in the costs to "maintain" existing chemicals will severely reduce number of selectable substances and therefore the diversity of formulating options necessary to sustain a healthy business.
- The ratio of existing substances to new chemicals is uniformly high. Therefore, the economic impact of REACH upon existing chemicals will outweigh present environmental considerations in the product selection process.
- Testing costs for lower volume substances will be disproportionately high (see Table 2) relative to the respective business opportunities they may attract based on any projected performance merits.

Table 2

Volumes sold/year	**Add-on Testing costs per one year's sales**
1 – <10 t/a	5 – 50 €/kg
10 – <100 t/a	1.4 – 14 €/kg
100 – <1000 t/a	0.37 – 4.1 €/kg
>/= 1000 t/a	0.65 – 0.74 €/kg
>/=10,000 t/a	0.065 – 0.074 €/kg

For the lubricant formulation Industry, evaluation of these several aspects of REACH may be summarised by the following relationship:

$$\text{Environmental benefit} \propto \frac{\text{Number of chemicals available}}{\text{Regulatory burden}}$$

4.2 The Considered ATC Position on REACH

4.2.1 Key Issues for ATC

ATC supports the following attributes of the new programme.

i. Implementation of REACH must be achieved in a measured and balanced way taking into account the continuing need to:

- Protect man and the environment;
- Maintain or enhance the competitiveness of EU business while preserving Intellectual Property Rights as granted by the Treaty;
- Avoid unnecessary testing of chemicals on vertebrate animals.

These aims are implicitly or explicitly highlighted within the White Paper. However, the REACH legislation published in October 2003 appears to conflict with some or all of these stated objectives in many ways. Avoiding these discrepancies in practice will bear heavily upon the longer-term success (or failure) of the new programme.

ii. Consistent with the stated aims of (i) above, it is critical that unnecessary animal testing scenarios be avoided. This can be achieved by:

- Making maximum use of historical toxicological data, including pre- and non-GLP studies conducted using the best accepted scientific practices of the day;
- Making maximum use of QSAR[4] data, "read across" analogies, and prior evaluations of hazard and exposure for rational chemical groups;
- Delaying or derogating testing on *all* substances of low concern (not just polymers) and prioritising evaluations based upon risk criteria rather than tonnage bands;
- Proportionate testing at lower volumes. This is particularly important as studies have shown that the speciality/fine chemical business (representing about 20% of the EU chemicals market by value) would carry about 80% of the testing burden. This is because, although REACH test requirements are volume-driven, the higher volume substances are already more extensively tested under a number of both voluntary and mandatory schemes (US HPV, EU Existing Substances Regulation etc. Additionally, many of the higher volume substances are, in reality very high volume, and would therefore carry the costs of REACH compliance more easily, as a proportion of unit cost.
- Derogating of tests for substances for which the additional test data required would not change the risk management practices for the substance (e.g. missing sensitisation testing of a substance already known to be CMRs);
- Derogating of tests which are technically impossible or very difficult, or where meaningless test data would be generated (e.g. determining log P_{OW} on an ambiphilic polymer).

[4] **Q**uantitative **S**tructural **A**ctivity **R**elationship(s)

- Acceptance of data obtained on preparations that could be used for hazard assessment of component substances, where there are data gaps for the substance. This is particularly important where substances are marketed only in preparations, and where data have been developed consistent with the requirements of the Dangerous Preparations Directive (88/379/EC), and where development of addition data for component substances would add nothing to hazard management of the products actually sold.

4.2.2 Test Data

4.2.2.1 Data Sharing

ATC supports the concept of data sharing to reduce the overall number of animals used for chemical testing. However, ATC is opposed to mandatory formation of consortia and compulsory pre-registration for this purpose. We prefer a voluntary programme approach for the following reasons:

- Encouraging the voluntary formation of consortia (SIEFs[5], etc.) will minimise replicate testing on the same (or similar) chemicals if promoted in conjunction with a voluntary pre-registration scheme for substances. This natural synergy would quickly highlight substances of common interest to more than one manufacturer/importer, allowing sufficient time for coordinated development and execution of robust peer reviewed data summaries and test plans.
- A study by the German Chemical Manufacturers' Trade Association (VCI[6]) showed that mandatory pre-registration as per the "building blocks" could add €20 million to the costs of chemical manufacturers in Germany alone.
- However, formation of consortia is not appropriate in all situations. For example, potential legal conflicts may very well spawn anti-trust law violations both within and outside of the EU. There are market situations in which a manufacturer/importer would prefer to carry all of the required test costs to avoid such a potential outcome. There is also the matter of "free-riders" gaining additional market advantage because of forced consortia building activities. In simple terms, long-range business disadvantages could significantly outweigh any anticipated short-term benefits associated with attempts to form consortia by regulation.
- The incremental costs associated with running consortia for low volume substances is especially likely to exceed any anticipated test cost savings.

ATC supports the creation of *positive incentives* to encourage formation of consortia (e.g. discounted registration fees), while at the same time discouraging unnecessary replication of *in vivo* vertebrate animal testing. We could further envisage specific options such as:

- A bona fide duty on manufacturers/importers to enquire about the existence of animal test data before commissioning tests;
- Development of a mandatory register of available animal test data for substances that does not publicly expose the identity of the registrants for those substances.

5 SIEF: Substance Information Exchange Forum
6 Verband der Chemischen Industrie

- "Post-registration" of animal testing (e.g. at the time of registration of a substance, the manufacturer/importer advises the Competent Authority that an animal test is planned. The Competent Authority would then research whether such data exist, or whether tests are planned by another company to obtain the same data. Where appropriate, the Competent Authority would put the two companies in touch with one another only after independent consultation on a "no-names" basis followed by agreement between the parties involved to formally engage). To summarise, the avoidance of unnecessary duplicate animal testing would, in the absence of a consortium, be controlled by the central agency.

4.2.2.2 Data Waiving

The issue of data waiving has been extensively discussed, and the European Commission has indicated that it will look at all possibilities in framing the legislation where data requested is unnecessary, impractical, or impossible to obtain. ATC wishes to see risk based, as opposed to hazard based, criteria for making all decisions about data waiving.

4.2.2.3 Burden of Cost

It is important to always bear in mind the resource burdens to industry in conjunction with setting realistic goals for registration and evaluation, allowing costs and other limitations to be apportioned over a reasonable period. The timetable envisaged in the legislation is unrealistic and unachievable by any rational predictive metric and should be extended upon reasonable justification. If implemented as currently anticipated, REACH will fail owing to these principal factors:

a. Costs to industry, particularly SMEs

b. Lack of laboratory capacity

c. Inadequate Member States' infrastructure and/or capacity of the new Central Agency to manage the massive data gathering, the evaluations required, and the consistency in outcome expected by all stakeholders.

These factors present a serious risk for non-compliance by many SMEs. To encourage greater future compliance, ATC maintains that registration and testing should be completed according to a timetable that allows:

- Spreading test programmes for all substances over a period of up to 20 years (one generation);
- Prioritising evaluations based on risk, logically expanding beyond the simpler scope of volumes manufactured or imported on an annual basis.
- Making test concessions to low volume suppliers of high volume substances. This would help avoid the circumstance wherein SMEs are forced to disproportionately participate in specific substance test SIEF programmes that their business turnovers cannot possibly justify.
- A requirement to have data ***on*** rather than ***before*** reaching a tonnage threshold, as in the draft legislation.

4.2.2.4 Risk Based Testing

The development and conformation of **risk-based**, tiered testing protocol in REACH is critical. This will have a positive and reasonable impact on the issue of data waiving (q.v.). It is essential that data be generated for substances that clearly relate to exposure scenarios that could, in practice, occur. Examples include missing inhalation tests for non-volatile substances, or passing over chronic environmental testing of substances having a short environmental half-life, exceptionally poor water solubility, etc. While data sets could have to be framed initially on volumes manufactured or imported, agreed final test plans should not be required which reflect the mere "box-ticking" of hazardous concerns. Rather, necessary and appropriate tests based on **risk**, which consider foreseeable exposures, should be conducted. Risk-based testing programmes must be carefully designed and assessed, but they provide the only economically sensible means for ensuring the short and longer-term health of man and the environment.

ATC envisions some difficulty in gathering sufficient information from downstream users to enable adequate exposure scenarios to be developed,, especially where low-tech industries are involved which may not themselves manufacture chemical. Some of these manufacturers will produce articles that contain hazardous chemical substances and preparations presenting no risk when used as intended. This process will be further complicated as and when the final user of the substance is not the immediate customer of the original supplier, but a "customer of a customer…". In very real terms, a downstream customer is unlikely to reveal the identity of his customers further downstream. Also, there needs to be adequate time to conduct *targeted* risk assessments taking into account the identification and use of *product groups* for this purpose. Some guidelines must be provided as to how to involve downstream users who may be unwilling to provide the necessary data.

4.2.3 Intellectual Property Rights (IPR)

The amended Safety Data Sheets and Dangerous Preparations Directives have already resulted in a substantial additional erosion of these rights by seriously curtailing the means by which marketers can continue to protect their formulating technologies from competitive eyes. It is vital to our industry that these rights are not further suppressed by REACH. Our companies have invested significant capital in developing formulation expertise and EU formulators will by severely disadvantaged if their Intellectual Property is further devalued by additional public and thereby inappropriate business information disclosures. The classification and labelling database proposed as part of REACH will lead to significant erosion of the ability of Petroleum Additives manufacturing companies to protect legitimate intellectual property rights. Specifically, the following regulatory considerations with respect to IPR are paramount to the Petroleum Additives Formulation business:

- No disclosure of CAS or EINECS numbers on Safety Data Sheets or labels should be required, except where this information is fundamental to hazard assessment (e.g. with sensitisers). Generally, these have no intrinsic value for hazard assessment or risk management planning,

and are simply revealing proprietary business information related to our current formulating technologies and potential future approaches.

- Any disclosure of compositional information for preparations should be restricted to that which is required by the current Dangerous Preparations Directive, except where this is instrumental to the development of an improved hazard assessment. The information on the Safety Data Sheets and labels in particular should be limited to that which is necessary for downstream hazard assessments and risk management planning for the product at issue.
- Structural details of substances, not germane to their hazard assessment, should not be required. Such disclosures could severely reduce and possibly eliminate the longer-term commercial viability of the products in question.
- The REACH legislation needs to guard against "free riders" that are only motivated to bring a competing like-product into the market after another company has borne all the costs of registration, evaluation etc., and has been forced to reveal their technology in the mean time.

Failure to adequately protect the legitimate Intellectual Property Rights of formulators will result in:

- Erosion of the competitiveness due to competitors being able to reverse engineer products without the associated risks and costs of R&D;
- Increasing recurring costs for businesses that must reformulate products whose technologies were inappropriately "surrendered" to the public. This is a necessary defensive response for any business wishing to maintain a unique market claim and long term competitive advantage;
- Diminishing incentive to innovate due to inability to adequately protect investments in new formulation technology and future product revenues.
- Increasing reluctance of global market suppliers to deploy their latest and most advanced formulation technologies in the EU.

Thus it is clear that the Intellectual Property Rights of "first notifiers" are in jeopardy. Patent protection alone is inadequate in this regard since it is well understood that patents do not intrinsically allow their holders to practice the arts. They rather restrict others from doing so. If subsequent notifiers under the old scheme become openly aware of the marketing activity of the first party, they may chose to enter market sectors previously unexplored with little or no investment exposure and risk.

4.2.4 GHS (Globally Harmonised System)

The White Paper stated that: "The current negotiations on the elaboration of a Globally Harmonised System (GHS) provides an opportunity to fundamentally review existing labelling provisions, to consider simplification and to improve comprehensibility of the labels." Moving towards a global hazard communication system is paramount, and the GHS, now adopted by the UN, provides an excellent opportunity to discard outdated systems that have acted as non-tariff trade barriers for many years. ATC supports the

implementation of GHS , but recognises that the timing of this has to be coordinated with other groups implementing GHS. ATC also requires that any downstream legislation impacted by classification and labelling is decoupled or amended to reflect the new hazard criteria introduced by GHS.

4.2.5 Registration/pre-registration

ATC supports the idea of pre-registration and see considerable merit in a phased pre-registration program at this time to further facilitate the (later) registration) process. However, there is inadequate protection from disclosure for the first registrant over subsequent registrants.

4.2.6 Information supplied to users

The need to register for all 'identified' uses is unrealistic and burdensome. ATC would like to see the regulation require registration of major uses, and/or uses potentially resulting in significant exposure to man and/or the environment.

4.2.7 Authorisation

It is ATC's view that the authorisation process should be confined to CMRs[7], POPs, and proven (not assumed) PBTs leaving open for now the question of inclusion of endocrine modulators and sensitisers. ATC is generally opposed to their inclusion for the following reasons:

a. There are too many sensitisers on the market to immediately and automatically include all of them in the authorisation process. To do so would simply clog up the administration, further diluting the support necessary for their proper risk management at the customer/supplier interface. These substances are unique, critical to the performance of many lubricant preparations, typically well studied because of existing risk assessment policy, and clearly indicated and labelled according to the criteria established by the DPD (1999/45/EEC). Subjecting these chemicals to authorisation is highly unlikely to remove them from the market place as originally anticipated by some legislators.

b. The subject of endocrine modulation is, at present, poorly understood. ATC would support inclusion of these in the authorisation process, as and when validated testing and categorisation criteria are in place. Until such time, it is our view that they are best left outside of the process.

ATC also believes that authorisations should not be time limited. To limit the longevity of an authorisation would be harmful to the processes for innovation. It would be nearly impossible for manufacturers to gauge, with any reasonable assurance, the rate of return on investment in new substances that may be prematurely or arbitrarily captured within the authority of this scheme.

4.2.8 Polymers

ATC welcomes the decision to defer the evaluation of substances of lower concern (e.g. polymers).

4.2.9 Intermediates

[7] CMRs – Carcinogens, Mutagens and Reproductive Toxins

The status of intermediates was the subject of debate following the publication of the original White Paper. Such chemicals are often not listed on EINECS, wherein the requirement was originally based on **marketing activities** rather than **manufacture,** as is now required under REACH. ATC advocates that intermediates be considered in the context of the 4 types (a. – d.) defined in Table 3, and that controls be applied according to the following regulatory remarks.

Table 3

	Type	Regulatory controls
a.	Non-isolated	Excluded from REACH
b.	Isolated - stored and used on site	Exempted from REACH
c.	Isolated - transported between sites of one legal entity or supplied to a limited number of sites under strict contractual control (including toll or contract manufacture)	Included in REACH, but with a reduced data set requirements based on risk
d.	Isolated - supplied other than within strict contractual controls between the original supplier and a third party recipient.	Included in REACH

4.2.10 Substitution

There are a number of inherent risks in the implementation of REACH, which could work *against* its stated objectives. One of particular importance is the principle of product substitution. The desire of the European Commission is that products of high environmental concern (i.e. those that impact the environment adversely, particularly long-term) would be phased out in favour of those with lower environmental impact. The problem is that REACH is very likely to force industry to remove products from the market based upon *economic* rationalisation rather than environmental concerns. This could result in products, and the chemicals they contain, being substituted with those that manifest a relatively higher overall hazard potential.

4.2.11 Central Agency

The planned Central Agency is envisaged with a very limited and, in ATC's opinion confused role under REACH. This role should be expanded and clarified. There is a serious danger, if this is not done, that the Central Agency will simply be a mailbox, adding to the administrative costs of implementing REACH, but bringing no added value to the process. This is viewed as particularly important given the new EU accession states, which will have no history of EU membership, and there may be a risk of an uneven playing field, where new Member States interpret REACH more conservatively than other states. Any MS involved in the detailed Evaluation of substances must act transparently and in a manner that clearly affirms our expectations for a balanced and consistent Agency oversight in these matters.

Another concern exists regarding the role of the Central Agency; there is a provision for a board of appeal, which will address registrants concerns, but the board of appeal is to be appointed by the Central Agency! There is a danger that the Central Agency would become judge, jury, police, executioner, and the villain in this process. ATC would prefer to see an independent appeal board, appointed jointly by all stakeholders.

Also, there appears to be no mechanism for seeking clarifications/rulings ahead of REACH implementation.

4.2.12 Other issues

4.2.12.1 Phase in substances

REACH envisages a 10-year rule for phase-in substances; we can see no logic in this, and believe it should be either dropped or provide for the option of justifiable extension on a case by case basis.

4.2.12.2 Dangerous Preparations Directive anomaly

ATC notes that he anomaly in the Dangerous Preparations Directive (1999/45/EEC), in that substances classified as dangerous for the environment but not otherwise hazardous are ineligible for confidentiality submissions, whereas substances classified as dangerous for the environment with either irritant or harmful ***are*** eligible. The publication of REACH gave an opportunity to correct this anomaly, which has unfortunately been missed. ATC appreciates the intended repeal of the new SDS Directive (2001/58/ECC), however, the root cause of our concerns lay in Article 15 of the DPD. ATC would like to see this anomaly corrected by either amendment, the issuance of rectifying technical guidance, or by direct repeal (as already proposed vis-à-vis Article 14 of the same Directive).

4.2.12.3 Articles

ATC is concerned about the requirements in REACH relating to substances in articles. Whilst recognising that this is a particularly problematical area, ACT considers the current proposals in REACh to be poorly thought out and unworkable, and would like to see the Commission give further consideration to this issue.

5. Conclusions

ATC recognises the need to overhaul chemicals control legislation for substances on the European Union Market. However, many elements of the current proposal, conceived albeit with good intent, are poorly fitted to the needs of the European Petroleum Additives Industry in particular. Our historical business strength and long term financial health derives from the development and downstream deployment of complex chemical preparations. We market lubricant performance technologies whose life cycles depend fully upon the range and diversity of chemical tools we can chose from to guarantee that performance. There are several issues that are of major concern to the Petroleum Additives industry, summarised below:

- The continued erosion of Intellectual Property Rights;
- The added short-term management burden and timetable of the tiered testing proposed;
- The overall deleterious economic effect on several of our SME members including a multitude of our downstream customers;
- The “rationalisation” of existing and emerging high performance products that will be re-cast as economically unattractive opportunities should REACH be implemented in a manner according to the plan now before us;

- The unfortunate implementation an Authorisation scheme designed to force the untimely substitution of hazardous chemicals with less hazardous substances on grounds other than the clear and precise assessment of the socio-economic consequences associated with such an action.

CEFIC commissioned its own business impact study, and meanwhile several others have been organised at the behest of the Commission. Each in its own fashion has highlighted significant business consequences for the European Union if these issues and others are not properly addressed prior to the implementation of REACH. ATC Member Companies that market chemical formulations will have to bear significant additional, and presently unaccounted for adverse economic impact extending far beyond the scope of concern already expressed by most bulk chemical producers.