ORGALIME

# POSITION PAPER

## REACH First Reading Results

### Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants

**Brussels, 29 June 2006**

*Orgalime as the European Engineering Industries Association represents 3 industrial branches (metal-working, mechanical engineering and electrical engineering) that manufacture over 27% of total EU manufacturing output (initial estimates set the industry's output at 1598 billion euro in 2005). Orgalime has 35 member trade federations in 24 European countries. The industry not only represents more than one quarter of the output but also a third of the exports of the EU's manufacturing industries. It is the largest manufacturing sector in Europe. It is also the largest industrial employer in the EU25, providing some 10 million jobs.*

In the context of REACH, Orgalime represents a major EU downstream user industry, as well as EU producers of final articles including many of their parts for both, professional customers and consumers: we are clients of the chemical industry and supplier of capital goods to all other industry sectors, including the automotive, aerospace, chemical, food or textile industries as well as to the health and environment sectors.

In view of the further proceedings of the European institutions on the REACH proposal, Orgalime would like to request the support of regulators for our comments and proposals following the results achieved by the institutions in first reading.


## Summary: Orgalime key comments and requests

**Registration**: We welcome that further to the introduction of use and exposure categories as a means of communication along the supply chain by the European Parliament, the Council has taken up and completed this proposal in the relevant downstream user chapter. We request the European Parliament to support the Council's approach to the benefit of the workability of REACH, especially for SMEs, and in the interest of the protection of European Intellectual Property Rights (IPR).

**Authorisation**: Innovating and manufacturing in Europe requires a wide substance portfolio and therefore, as flexible as possible provisions regarding authorisation. Authorisation in our view needs to be based on the principle of "adequately controlled" following sound scientific assessment. If Europe's engineering industry is supposed to remain competitive on global markets and to innovate and manufacture within the EU, authorisation must not establish a mandatory principle of substitution nor foresee time limits, which would cause significant legal and planning uncertainty, a negative investment climate as well as disruption in our whole supply



**ORGALIME** THE EUROPEAN ENGINEERING INDUSTRIES ASSOCIATION
Bd A. Reyers 80 - Diamant Building - B-1030 - Brussels – Ass. Intern. A.R. 12.7.74 - VAT BE 0414341438
Tel. 32 2 706 82 35 - Fax 32 2 706 82 50 - secretariat@orgalime.org - www.orgalime.org

chain. The authorisation chapter, as established in the Council's common position, in our view represents a strong compromise and definitely the maximum feasible for our industry. Going beyond the Council text would be unmanageable, disproportionate and at the expense of the competitiveness of European engineering industries. We call upon the European Parliament to accept the Council's common position as a compromise solution in the light of the jobs and growth agenda.

**Substances in articles**: One outstanding issue for the engineering industry remains article 7 of the common position, which imposes registration/notification requirements on substances released from final goods. We are concerned with the potential overlaps of these provisions with existing sector specific legislation applying to our products, and the trade implications linked with them. The Council in its common position has considerably shifted forward compliance dates for "substances in articles" provisions, which in our view put EU article manufacturers, the majority of which being SMEs, at a competitive disadvantage. We encourage the European Parliament to re-introduce the transition period of 11 years for the entry into force of article 7 in order to avoid a shift of responsibility in the supply chain.

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## 1. Registration/use and exposure categories

We thank the European Parliament for having been instrumental in first reading to the introduction of use and exposure categories into REACH. This will help meeting both, an efficient communication through the supply chain and downstream user business confidentiality requirements. Timely access to and availability of information is essential for downstream users. We therefore find it important that information regarding not only pre-registered substances but also regarding covered uses/use and exposure categories is made available and accessible to downstream users as early as possible in the REACH process.

We welcome that the Council has taken up the European Parliament's proposal regarding use and exposure categories and more particularly completed Title V on downstream users (article 36 and ff) in its common position, especially in Article 36(2) which reads:

> Any downstream user shall have the right to make a use, **as a minimum the brief general description of use**, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a preparation with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate **a use and exposure category**, for his use in the manufacturer, importer or downstream user's chemical safety assessment.
> Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.

*We would welcome that the European Parliament supports these further improvements brought by the Council in the interest of both, the workability of REACH, especially for SMEs, and the protection of European IPR.*

## 2. Authorisation

We believe that the Council's common position has arrived at what we perceive a strong approach towards authorisation, which is the utmost feasible for our industry. In particular, the Council text requires applicants to issue an analysis of alternatives and foresees a review of granted authorisations on a case-by-case basis.

Going beyond the provisions of the common position would to our mind be unmanageable and disproportionate, especially if the principle of mandatory substitution or time limits were to be re-introduced:

- Mandatory substitution would create a negative investment climate in the EU since it causes legal and planning uncertainties. It would hamper the innovation capacities and consequently the competitiveness of companies operating in the EU and would be an incentive for driving business and know how out of Europe.
- Mandatory substitution would force the clients of the chemical industry to re-engineer highly complex products, often to the detriment of other important factors, such as safety, functionality, fitness for purpose or even the environmental performance.
- Substitution does not necessarily present the most advantageous option in terms of environmental and health benefits from a life-cycle perspective and is not always feasible. This has been accepted by regulators in existing directives affecting manufacturers, that even when they restrict the use of certain substances, do provide for specific exemptions.
- Substance legislation for downstream users means product- and process legislation: we rely on a wide portfolio and flexible use of substances to offer safe, high-quality and high-performance products on highly competitive world markets. Mandatory substitution would continuously reduce the number of substances available for operating in the EU, even if the risks involved were adequately controlled.
- Time limits disregard the reality of our product and investment cycles. Having to re-engineer highly complex products mid-cycle or adapt product lines every few years would result in preventing companies from recovering high investment costs. This would significantly hamper the competitiveness of EU industry and force certain European industry to delocalise.

Orgalime therefore takes the view that an authorisation must be granted if the risks involved are adequately controlled in order to secure valuable technologies, know how, skills and jobs available in Europe, such as the following:

- *Complex electronic components such as semi conductors for example may need for their production minute quantities of classified CMR substances. Those substances are used in closed and tightly controlled processes, in terms of both environment and health and safety, and are not present in the final product. It is of course clear that if Europe is unable to pursue production of semi conductors in the EU, one of the essential links in the high technology chain which is essential to the future competitiveness of all industry sectors will be broken.*
- *Manufacturing processes require certain specific results, for example highly finished polishing of medical cardiac stents. Such stents are normally manufactured from stainless steel mesh and the manufacturing process produces small burrs that make the stent unusable without further treatment. Only by applying electro-polishing techniques, are these burrs removed and the stents then safe for use. The chemicals required for achieving this result are used in an absolutely controlled working environment and not present in the final product.*

We also believe that in the interest of legal and planning certainty for companies sound scientific assessment must be the basis for decisions on whether or not to restrict the use of a certain substance.

*We therefore request the European Parliament to accept the provisions of the Council's common position on authorisation as a compromise solution, which, we insist, is the maximum feasible for our industry. Compromising further on the authorisation chapter bears the risks of this being done to the detriment of the competitiveness of downstream users.*

## 3. Substances in articles (article 7)

While we acknowledge the commitment of the European Parliament and Member States to find a workable and enforceable solution regarding the complex issue of substances in articles, our industry remains concerned about the workability of article 7 which in our view offers little legal certainty and is open to interpretation to an extent which it will be difficult to resolve in the Technical Guidance Documents. We would particularly wish to highlight the following:

- Firstly, the engineering industry is a highly regulated industry in both the environmental and health and safety field (see annex on examples of EU safety and environment legislation that applies to engineering products). We are therefore very concerned about the multiple overlap of REACH, and article 7 in particular, with sector specific legislation applying on our products. For example, the recently adopted Energy Using Products Directive (EUP) 2005/32/EC establishes a framework to incorporate environmental aspects from a life cycle perspective into the design of our products. It applies to both, products manufactured in the EU and products imported to the EU and, after many years of piecemeal and often conflicting regulation, establishes the basis for a more coherent approach. We believe that Article 7 provisions will just undermine the proper application of the EuP directive.

- Secondly, we would like to draw your attention to the potential trade implications linked with the provisions on registration and notification of substances released from final goods as established in the Council's common position. Our companies today work to extremely tight time schedules. Regulating articles in a way which would impact the "just in time" flow of hundreds of millions of components and parts used in our products risks causing major disruptions in the supply chain, which would entail losses of competitiveness and simply make the EU a less attractive manufacturing and investment location.

The Council has considerably shifted forward article 7 compliance dates. This would to our mind result in an unjustified shift of responsibilities down the supply chain, therefore to downstream users. Our companies, 95% of which are SMEs, may experience difficulties in being compliant under these tightened deadlines. This would also lead to a significant limitation of the use of the valuable instrument established in article 7(6), namely that no registration/notification by article manufacturers would be necessary if a substance has already been registered for that use. It however remains unclear to us how downstream users would know that such a registration has already been carried out.

*We therefore strongly encourage the European Parliament to re-introduce the differentiated entry into force of article 7 (11 year transition period) which, by granting our industries extra time to fulfil their new obligations under REACH, will leave them the possibility to fully explore earlier registrations, thereby avoiding a transfer of obligations from the producer of the substance to his client, the downstream user.*

## 4. Conclusions

Orgalime is fully committed to the realisation of the objectives of REACH in an efficient and effective manner.

Our industries, as downstream users and manufacturers of articles which are the clients of the chemicals producers welcome that the Council has followed the route traced by the European Parliament and introduced **use and exposure categories** as a means of communication in the supply chain, to simplify the administrative burden of the regulation while helping to protect IPR without undermining environment and health objectives of REACH.

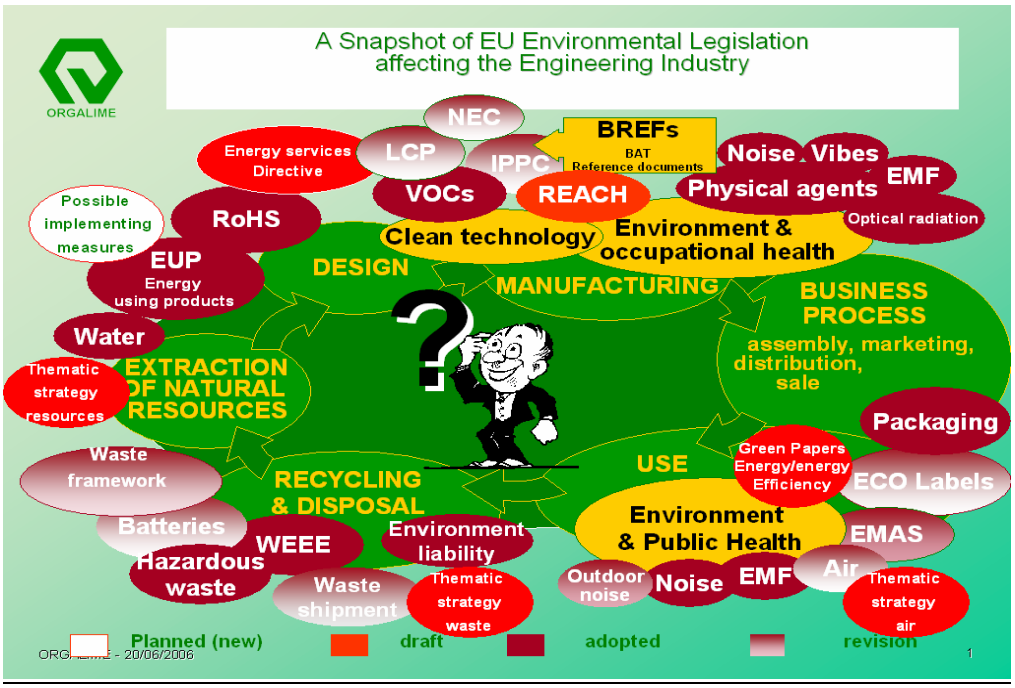
We ask the European Parliament to support the Council's approach to **authorisation** in its upcoming second reading, which we feel has achieved a delicate balance between the position of the EP and that of member states. We nevertheless consider it the maximum feasible for our industry. Any further compromise would significantly hamper the competitiveness of Orgalime industries manufacturing in the EU.

We are however still concerned with the **compliance dates for substances in articles** which the Council has considerably shifted forward and appeal to the Parliament to ensure that downstream users/article manufacturers are allocated enough time to fulfil their new obligations under article 7. We therefore strongly encourage regulators to re-introduce the differentiated entry into force of article 7 (11 year transition period) to ensure that, as a client industry, we are not unduly penalised by a shift of responsibility down the supply chain, and so as not to unnecessarily undermine the competitiveness of the EU as a manufacturing base for our industry, which, while increasingly global, employs some ten million people in the EU.

**Annex:**
**Examples of existing EU legislation that applies to engineering products**

In the environmental field (from a life cycle perspective):

- Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)
- Directive 2005/32/EC on Energy Using Products (EUP)
- Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)
- The Construction Products Directive 89/106/EEC (CPD)
- The Batteries and Accumulators Directive 91/157/EEC (and ongoing revision)
- The Cadmium Directive 91/338/EEC
- The Mercury Directives 82/883/EEC and 84/156/EEC, or
- The End of Life Vehicles Directive 2000/53/EC (ELV)




In the health and safety field:

- The General Products Safety Directive 2001/95/EEC
- The Machinery Directive recently updated by Directive 2006/42/EC
- The Low Voltage Directive 73/23/EEC
- The Electromagnetic Compatibility Directive 89/336/EEC updated by Directive 2004/108/EEC
- The Directive on the Protection of the Health and Safety of Workers from the Risks related to Chemical Agents at Work 98/24/EC (noise 2003/10/EC, vibrations 2002/44/EC, electromagnetic fields 2004/40/EC and optical radiation 2006/25/EC)
- Carcinogens Directive 90/394/EEC