



ORGALIME

Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent organic pollutants

ORGALIME POSITION

Brussels, 10 May 2005

ORGALIME speaks for 35 trade federations representing some 130,000 companies, the vast majority of which are SMEs in the mechanical, electrical, electronic and metalworking industries of 24 European countries. These industries employ some 7 million people and account for 1200 billion Euro of annual output, which is over a quarter of the EU's output of manufactured products and a third of the manufactured exports of the European Union.

EXECUTIVE SUMMARY

1. ORGALIME's role in the supply chain

The engineering industries which ORGALIME represents account for some 9% of the total substances. As second level downstream users, we are major clients of the chemical industry. We are also the supplier of capital goods to all other industries, to the health, environmental and social sectors of the economy and of final products to consumers.

2. Principles for EU chemical policy

ORGALIME is committed to the objectives of REACH. The following principles are in our view vital for a workable REACH:

- The EU's chemicals policy must safeguard the innovation capacities and competitiveness of European engineering industries, by especially
 - opting for a harmonised approach at global level and cross Europe,
 - keeping as broad as possible a portfolio of chemical substances available across Europe,
 - ensuring the protection of European IPR,
 - avoiding delays in the development and introduction of new technologies, particularly in areas where time to market is the crucial factor for business success.
- The EU's chemicals legislation should be consistent with other existing legislation, such as product specific or occupational health and safety legislation.
- Clear and justified responsibilities in the supply chain should mirror the individual role and competence of the economic actor in the chain.
- Proper information of the supply chain is a prerequisite for a workable REACH.

3. Key recommendations to shape the REACH proposal

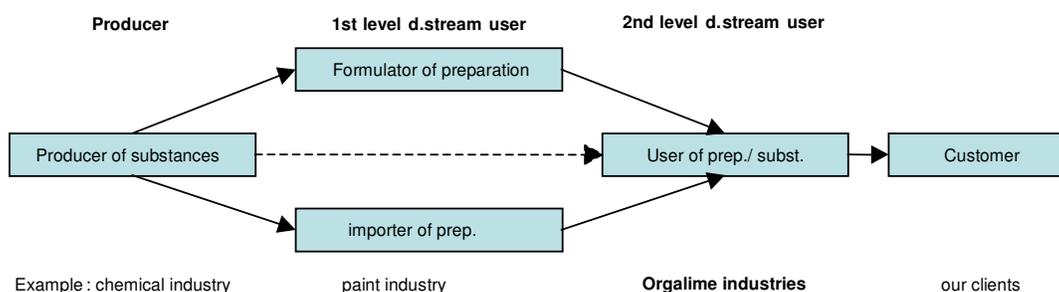
- Clear, broad, simple and standardised **exposure and application categories** should replace the concept of "identified use" to avoid yet more unnecessary administration and superfluous paperwork, to protect European IPR and to reduce the time spent by skilled people, such as engineers, on administrative tasks.
- **There must be sufficient time frames for finding alternative solutions** if a substance can no longer be made available.
- The **information** passed on in the supply chain needs to be harmonised, simple, straightforward and operational so as to ensure the REACH objectives of effective protection of human beings and the environment.
- **Substances in articles** should be out of the scope of REACH given WTO obligations and existing specific product related legislation for engineering products.
- Neither **waste** nor **basic raw materials** for the metal industry should fall under the scope of REACH.
- REACH should **not overlap with other legislation**, such as occupational health and safety or specific environmental legislation.
- REACH should not follow a tonnage based, but establish a **risk based priority system** following the explicit criteria of intrinsic toxicity and exposure.

I. ORGALIME'S ROLE IN THE SUPPLY CHAIN

As supplier of investment goods to all other industries and final products to consumers, we play a major role in the economy, both in the internal market and on global markets. We also are a major client of the chemical industry, using a variety of substances and preparations, such as paints, sealants, cleaning products, galvanic fluids, hydraulic fluids, lubricants or solvents, in our day-to-day business. Our industry is one of the main downstream users of chemicals, accounting for an estimated 9% of chemicals used as a simple substance or as a substance in a preparation.

More precisely, our industries represent "second level downstream users".

Second level downstream users such as those in our industry have specific competence in the way substances are used, but little possibility to influence the production of substances. The second level downstream users are there in apposition to guarantee competent and reliable knowledge concerning the safe handling of the substance or of the preparation when using them in their own manufacturing processes subject to receiving on reliable and satisfactory information passed on to him by the supplier of the substance or preparation. His role therefore needs to be clearly distinguished from the competence of those economic operators in the supply chain who own the knowledge concerning intrinsic properties of a chemical substance or of a preparation. The latter can only lie with producers of chemical substances and first level downstream users.



ORGALIME is committed to the REACH objectives of protecting human health and the environment.

II. PRINCIPLES FOR A CHEMICALS POLICY OF THE EUROPEAN UNION

We believe in the following principles of a EU-wide chemicals policy to be effective, efficient and workable:

a) The EU's Chemicals Policy must safeguard the innovation capacities and competitiveness of European engineering industries

Orgalime believes that a harmonised approach at global level is necessary to prevent European companies from being at a competitive disadvantage both, at home and export markets, when faced with engineering products manufactured outside the EU.

We also support a harmonised approach at European level in order to ensure a level playing field.

REACH, in its present form, is not an exclusive issue of the chemical industry, but burdens the whole supply chain, and in particular on (ill-defined) downstream-users.

Engineering industries depend on a number of factors to keep their business competitive. Among the most obvious needs is **easy availability of materials inputs**. Raw materials represent 10-70% of manufacturing costs in our industry. Among these, chemical substances, mostly in preparations, have an important role to play. While it is clearly difficult to obtain detailed information today about substances that will be withdrawn, if only for commercial reasons, the present REACH proposal is expected to reduce the number of substances

available, particularly those produced in small quantities. The withdrawal of substances, especially for economic reasons only, would steadily erode our supply base in the EU.

Limiting or even prohibiting the menu of chemicals for use while no appropriate substitutes are available would further undermine our industrial base in Europe. The success of engineering industries on rapidly evolving markets depends to a large extent on a broad and flexible choice of substances to be used.

Furthermore, our industries do not produce in a “closed economy”. We are competing on all markets, national, European and global: thus, any restriction in the availability of chemicals in Europe will result in negative economic effects for our industries. The present REACH proposal would clearly lead to a situation where our foreign competitors will have a competitive advantage as they will not face any restriction in the availability of chemicals and are able to make free use of substances in their production processes.

Business success depends to a large extent on **know how**. A chemicals policy that would require company internal data of various applications being made public, including to EU and foreign competitors, will further impact our capacity to operate and innovate in Europe.

Many of the products that our industries produce are characterised by short innovation cycles. In such areas of technology, the **time to market aspect** is vital and, more often than not, the decisive factor for the success of the companies that we represent. Too time consuming and bureaucratic procedures, as currently foreseen in the REACH proposal, bear the risk of introducing delays in the development and introduction of new technologies. This would inevitably hamper the innovation potential and in particular the competitiveness of our industries.

b) Consistency of EU chemicals legislation with other EU legislation

Companies need legal certainty to operate successfully.

Overlapping and inconsistent chemical and product legislation will not only lead to legal uncertainties, but also confusion and failures to achieve the human health and environment objectives pursued by REACH.

For our industries, REACH will overlap with already existing product specific legislation, especially:

- Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)
- 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 (EOLV).

Furthermore, REACH will overlap with the future eco design of energy using products directive (EUP), which aims at providing a framework for the integration of environmental aspects (including substance related aspects) into the design of the products that our industry produces.

Finally, REACH would add on to already existing occupational health and safety legislation that applies on the products that we produce, such as:

- The General Products Safety Directive 2001/95/EEC
- The Machinery Directive and ongoing revision of Machinery directive 95/16/EC
- The Low Voltage Directive 73/23/EEC
- The EMC Directive 89/336/EEC recently updated by Directive 2004/108/EEC
- The Physical Agents Directives 98/24/EC (noise, vibrations, electromagnetic fields) and proposal on optical radiation)
- Carcinogens directive 90/394/EEC

c) EU chemical policy should establish clear and justified responsibilities in the supply chain: the level of duties of the various actors under REACH should mirror their individual role and competences in the supply chain

The Commission's REACH proposal mixes up actors and their roles and consequently abilities to contribute to the realisation of its objectives in a fair and realistic manner.

While we recognise the Commission's attempt to find better solutions for downstream users, this was only done at very last minute and consequently led to incoherent and partly even more bureaucratic requirements, thereby not optimising the pursued objectives of protection of the environment and human health.

d) Information through the supply chain

Communication in the supply chain will be at the core, if REACH is to develop added value for the environment and human health by increasing the safety of input. Though this is not an easy task as multiple aspects, such as confidentiality of data or different levels of expertise or different roles of the individual players in the supply chain, are involved.

It is of importance to achieve a balance between the confidentiality of certain business information and the need of information to take cost effective measures to protect human beings and the environment.

Second level downstream users depend on sufficient and reliable information passed on to them in the supply chain in order to foresee the most effective protection measures when manufacturing. It is important that information about chemical substances is passed on in a comprehensive, complete and at the same time easily understandable and practicable format to those who are obliged to ensure the safe handling.

Being obliged to communicate individual uses (identified uses) to manufacturers of substances or preparations, in our opinion provides no added benefit, but jeopardises the confidentiality of our manufacturers' intellectual property.

e) The EU's chemicals policy should keep the administrative burden at a minimum level

The EU chemicals policy must not result in drowning companies, and especially SMEs, in superfluous paper work, which would not benefit the environment or human health. Unnecessary bureaucracy should be avoided to reduce the time spent by skilled people, such as engineers, on administrative tasks.

III. ORGALIME RECOMMENDATIONS FOR SHAPING REACH

While we recognize the Commission's will to address the specific situation of downstream users and certain improvements that have been introduced late in the process of preparation of REACH after the internet stakeholders' consultation, Orgalime believes that further substantial modifications are necessary to make REACH work in practice without compromising the functionality, performance or competitive edge of engineering products manufactured in the EU.

We urge the European Parliament and the Council to improve the Commission's proposal particularly in the following areas:

a) Exposure and application categories should replace the concept of "identified use"

The risk of a substance/preparation should be addressed as early as possible in the supply chain. The present concept of identified use and the registration and evaluation procedures are too burdensome in terms of data collection and reporting obligations and would have negative results on the innovation capacities of downstream user industries.

Moreover European IPR would be at stake when individual companies would be required to tell each individual user of a substance/preparation in their production process and skilled personnel would have to spend too much time for fulfilling purely administrative tasks.

We therefore encourage the European institutions to replace the concept of “identified use” by the introduction of clear, broad, simple and standardised exposure and application categories, such as the basic proposal of the German Ökoinstitut Freiburg.

Any attempt to define these exposure and application categories should not lead to a situation where downstream users are overburdened with responsibilities which by nature lie upstream in the supply chain.

b) Sufficient time frames for finding alternative solutions

As indicated above, the availability of substances in terms of keeping a maximum variety of chemical substances constitutes a key factor for the business success of engineering companies. We therefore do not support the introduction of a general substitution principle. Decisions on limiting the use of a certain substance or preparation should be fully based on scientific evidence.

Developing alternative solutions without compromising the safety, the functionality or performance of final manufactured goods, requires time.

Therefore, if a specific substance is called upon to disappear, manufacturers should be granted sufficient time to research and develop alternative solutions.

In addition, such changes, which might even result in a change in technology, must not lead to a delay of the marketing of a product. This particularly applies in the case of innovative products where “**time to market**” may be the deciding factor for the economic, environmental and social performance of a company.

We recommend that during the period of looking for alternative solutions, the substance in question should remain available on the market.

Moreover, as only those substances that have been registered can be used, it is important that all uses that have been communicated by a downstream user to his supplier are indeed included in the registration of the chemical supplier. We encourage regulators to clarify the introduced “right of downstream users” in the present REACH proposal in this direction.

c) Information and communication in the supply chain

In order to be able to fulfil their own obligations, a second level downstream user must be guaranteed **access to clear and understandable information**.

Orgalime suggests that an appropriate, detailed and standardised Safety Data Sheet should be used as the exclusive communication instrument.

Besides this, special training courses for second level downstream users would be a useful means to facilitate the necessary translation of passed on information of the supplier into cost-effective measures to be applied on a day-to-day basis by the second level downstream user in the interest of the environment and human health.

d) Substances in articles

As specified above, for our industries, specific product-related substance legislation and product safety legislation exists, which already addresses the human health and environmental concerns related to these products. Such product legislation has the advantage that it can be applied to EU and non-EU manufacturers in compliance with WTO requirements and at the same time it is better targeted to meet the environmental objectives pursued. For our industries, REACH would therefore only duplicate substance and product safety legislation besides causing WTO compatibility problems.

Also, we cannot see for what reason substances in articles that appear in closed systems (e.g.: substance in hydraulic assembly) should fall under REACH. There is no risk, which would not already be addressed by the existing occupational and safety legislation.

In particular, at present the requirements on substances in articles are:

- Not workable in practice (What is an article? How should one define “likely to be released”, “intended to be released”? What threshold values for minimum concentrations?) .
- Overlapping and/or inconsistent with existing sector specific legislation
- Overlapping and/or inconsistent with existing occupational health and safety legislation.
- Not enforceable.
- Not protecting EU producers of articles from unfair competition from foreign competitors that produce the same articles.
- Critical from a WTO perspective.

Therefore, Orgalime believes that article 6 should be deleted and that the possible inclusion of substances in articles in REACH should be discussed once the concept is fully established. At present, the provisions are foreseen to enter into force only 11 years and 3 months after the entry into force of REACH. The inclusion of article 6 at the present time would nevertheless carry the risk of establishing unworkable and unenforceable requirements.

While Orgalime clearly prefers the above option, as an alternative, article 6 should in our view at least be restricted to the case where a substance is intentionally released. Other cases have to be dealt with in product-specific legislation or when the concept is fully developed (in accordance with Directive 2001/95/EC). It is assumed that waste is excluded from REACH.

e) **To our mind, the SCOPE OF REACH is far beyond what can be managed by both, companies and authorities:**

- In particular, we believe that the inclusion of **waste** under REACH will unnecessarily overburden the system and will be a serious handicap for the recycling of materials. Wastes are already controlled and managed under EU waste legislation (e.g. Directive 2002/96/EC on waste electrical and electronic goods). To include waste within the scope of REACH would therefore mean that a double system would be applied, which is against the principles of 'better regulation'. The obligation of a registration of wastes intended for recycling or recovery could represent a serious handicap to the recycling and recovery sector and even result in less recycling and recovery. This is in conflict with the environmental objectives of other directives and with the Commission's commitment to sustainable development and the best use of all resources.

Therefore we suggest amending the paragraph 1 of article 2 by adding that waste is excluded from the scope of REACH.

- In the present proposal of REACH the **basic raw materials of the metal industry**, such as **minerals, ores and concentrates** are included in the scope of REACH. In addition to their high tonnage production volumes, many minerals, ores and concentrates are highly complex materials whose composition can vary widely depending on their source. Therefore, multiple registrations for each and every resource and the high number of minerals, ores and concentrates would become necessary if REACH stays in its present form. This would clearly overwhelm the presently proposed system during the phase of registration, which follows a tonnage-based approach. This burden can even have an influence on the availability of these raw materials on the European market.

In addition, the registration of all these raw materials will have very limited benefit for environment or man's health. The potential risks to the environment arising from minerals and ores are already addressed under the IPPC Directive and the potential health risks under workplace legislation.

Metals and alloys in massive form exist in very large numbers (around 30 000 in commercial production), though pose only limited risk to man and environment.

In the interest of workability, Orgalime suggests that the basic raw materials for the metal industry would be exempted from the obligation to register, by analogy with the basic raw materials for the organic chemicals sector (natural gas, crude oil, coal). The regulatory burden on metals and alloys in massive form should be in proportion to their potential risk to man and environment and ensure their availability for indispensable applications.

- We support the **exclusion of polymers and intermediates**.

f) The EU Chemicals Agency

Orgalime points out that the application of harmonised rules on chemicals throughout the European Union is essential for the functioning of the internal market and for fair competition within EU. It is furthermore vital for the competitiveness of the European industry that the system is non-bureaucratic and fast acting. Consequently, Orgalime favours a **centralised system** rather than splitting competences between the Central Agency and -for the time being - 25 EU member states.

In the context of harmonised rules, Orgalime believes that the reference to article 95 of the EC Treaty is absolutely necessary as a basis for the REACH regulation.

The administrative procedures foreseen in REACH are very complex. The interplay between the Commission, the Chemicals Agency and member states authorities' is still unnecessarily complex. *Orgalime proposes developing the Chemicals Agency into a strong, central decision-making authority with responsibility also for the evaluation process.*

g) Risk based prioritisation of REACH

REACH should consider a risk-based approach. The fact that a substance is produced in high volumes does not automatically lead to the conclusion that the substance is hazardous. Also, the fact that a substance is hazardous must not lead to the conclusion that its safe use cannot be guaranteed.

Orgalime believes that only if the hazard properties of a substance is coupled with a concrete exposure scenario, should action be considered. Otherwise, we do not see what direct risk would justify the extended burdens of the REACH system.

IV. CONCLUSIONS

Notwithstanding the improvements that have been made since the Internet consultation document, Orgalime is still concerned by the bureaucratic burden and likely negative consequences that the REACH proposal, if finally adopted in its present form, would impose on our industries.

We particularly believe that the general structure of REACH should follow a risk based priority system.

REACH would need substantial revision in order to arrive at a sustainable proposal, which would balance its social, economic and environmental dimension:

- For our industries, REACH should not result in a cut off of our supply base, thus, undermining innovation capacities in a rapidly evolving market place.
- We believe that REACH should not aim at substituting chemical substances, but ensure as wide and as multiple a variety of chemical products being available.

- Neither waste, nor basic raw materials for the metal industry should fall under the scope of REACH.
- Substances in articles should be out of the scope of REACH given WTO obligations and existing specific product related legislation for engineering products.
- Where alternative solutions need to be found, sufficient time to do so is essential.
- The introduction of exposure categories should replace the concept of “identified use”.
- We support the establishment of a strong chemicals agency including the evaluation phase.
- To enable companies, and SMEs in particular, to comply with this ambitious legislation, the necessary information for the safe handling of a chemical substance should be provided in a standardized manner.