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 paper
Brussels, 6 September 2005

In view of your further proceedings with the REACH proposal, Orgalime[1] would like to request your support on the following issues of concern which we raise from our perspective of a downstream user and producer of final articles for both, professional and private consumers.

I. Substances in articles

What are Orgalime's concerns?

European engineering industries act in a highly complex globally sourcing supply chain and expect significant **trade implications** with the inclusion of provisions regarding substances in articles under REACH. European engineering companies depend heavily for their competitiveness on free trade of both inputs, such as components, and exports. The present provisions of article 6 regarding substances in articles would inevitably cause **significant disruptions in the timely flow of world wide sourced components and assemblies** entering into the articles that we manufacture in Europe. While the deletion of article 6 should provide a solution to our industry, amendments which propose to delete article 6 but also to modify article 5.1 by requiring the registration of all substances in articles would render the REACH system even more unworkable than it is today while at the same time contradicting WTO requirements.

Our industry is already subject to a considerable body of sector specific product related regulation (see annexed list of examples) covering the health and safety of users of our products and the impact of our products on the environment. Such product specific legislation applies on an equal basis to products manufactured within the EU and products produced outside the EU and therefore helps ensuring a level playing field for our industry.

The latest legislation, adopted by the European Parliament of 13 April 2005 and finally approved by the Council on 23 May 2005, is the directive on eco-design of energy using products (EuP):
The **EuP directive** establishes a **framework for the integration of all environmental aspects into the design of energy using products**. It regulates energy-using products from cradle to grave by considering all environment aspects as a whole, including for example energy efficiency besides substance use. It does so both for products manufactured in the EU and for imported products and would allow, where necessary, a more timely approach.
EuP includes in annex I specific provisions relating to the use of substances, their impact on environment and human health in the following areas:

- Raw material selection and use,
- Use of substances classified as hazardous to health and/or the environment,
- Emissions to air,
- Emissions to water,
- Emissions to soil.

Furthermore, the EP has introduced **strict requirements on producers concerning consumer information** in the EuP directive.

[1] Speaking for European engineering, Orgalime, represents **3 industrial branches** (metalworking, mechanical engineering and electrical engineering) that manufacture over **27% of total EU manufacturing output** (initial estimates set the industry's output at 1235 billion euro in 2004) and 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.

On 7 July 2005, the Commission has published call for tenders for 14 preparatory studies on eco design requirements for energy using products, including on boilers, water heaters, PCs, computer monitors, copiers, faxes, printers, scanners, television sets, battery chargers, office and street lighting, residential room-conditioning appliances, electric motors, refrigerators and freezers, dishwashers and washing machines.

For energy using products, REACH would therefore clearly lead to inconsistent and overlapping legislation, which would create confusion and legal uncertainty and therefore undermine enforcement and thereby the achievement of the environment and human health objectives.

Finally, the present provisions on substances in articles (article 6 REACH proposal) and the present definition of "article" (article 3 REACH proposal), introduce a **high degree of legal uncertainty**. They can therefore not ensure fair competition between European engineering industries and their Non-EU competitors.

What way forward?

- Besides full harmonisation in Europe, REACH should be **harmonised at global level** to guarantee a level playing field for our industry that acts globally. Article 95 of the EC Treaty should be the sole legal basis of REACH.
- **Applying sector specific legislation** to the products that we produce instead of overburdening REACH with the inclusion of provisions regarding substances in articles would in our view present a more coherent approach (For example: the recently adopted EuP directive regulates energy using products and provides a holistic approach to the impact of such products on the environment and human health from cradle to grave). Such an approach is reflected in a number of EP amendments and at the same time has been considered as an option in the previously issued Swedish proposal for substances in articles.
- The draft reports of the EP environment, industry and internal market committees all include amendments to at least **delete article 6.2-6.4 regarding unintentional release of substances in articles** given their unworkability and unenforceability. We support this.
- The present **definition of "article"** is misleading and requires clarification as provided in amendment 218 of the draft ENVI committee report.
- Introducing **concentration values into article 6.1 and deleting the reference "each article type to be considered separately" from article 6.1** would in our view improve the present text.
- However, the proposal for creating a "**European quality mark**" or establishing **additional labelling requirements of manufactured goods** would in our view clearly risk overlapping with the so-called "CE mark" that is to be placed on the vast majority of our products according to various product specific legislation applying to our products. Double marking would risk confusing consumers. In addition, sector specific legislation, such as the EuP directive, provides for particular information requirements.
- Also, an **inclusion of all substances in articles in the general registration requirements of article 5** would besides overburdening the REACH system, clearly contradict WTO requirements.

We therefore kindly request your <u>support</u> for:
Draft IMCO committee report amendments: 42 –45, 352, 353, 360-363, 365, 366, 368, 369, 373. Other improving amendments would be 354, 356, 358
Draft ITRE committee report amendments: 13, 14, 15, 192, 284-288, 290-292, 294, 295
Compromise amendments to draft ITRE committee report: 13, 15, 16, 19
Draft ENVI committee report amendments: 218, 431 (while at the same time rejecting 417 and 430), 436, 448, 451, 455, 458, 462
Draft ECON committee report amendments: 9 (while at the same time rejecting 8), 64, 131, 140, 141, 142, 144, 145, 148, 151

We consequently ask you to <u>reject</u>:
Draft IMCO committee report amendments: 283, 297
Draft ENVI committee report amendments: 15, 19, 110, 417, 430, 456, 739
Draft ECON committee report amendments: 8, 10, 147
Draft ITRE committee report amendment 118
Compromise amendments to draft ITRE committee report: 12, 14

II. Confidentiality

What are Orgalime's concerns?
We are particularly concerned to ensure that new legislation should not affect the ability of leading sectors of our industry, such as the semiconductor industry, to develop innovative products in the EU: while already producing to the highest safety standards, such industries are particularly sensitive to any threat to the confidentiality of their know how.

The present concept of "identified use" requires downstream users, such as our industries, to reveal individual uses and confidential business data, which would become available also to Non European competitors. This clearly puts European IPR at stake and risks damaging the competitiveness of European engineering industries. The identification of individual uses would also render communication in the supply chain extremely complex and be particularly burdensome for SMEs.

Finally, it remains uncertain whether "identified use" can be reliably defined.

If downstream users are obliged to communicate uses to their chemical supplier (in our view preferably in use/exposure categories only), the chemical supplier should not have the possibility to refuse the inclusion of this communicated use/exposure category in his registration file for economic reasons alone. Otherwise, responsibilities would be shifted down the supply chain on economic operators, whose primary competence does not lie on chemical substances and their intrinsic properties, and weaken the achievement of the objectives of REACH.

What way forward?
It is essential to replace the concept of "identified use" by **clear, broad and simple use and exposure categories**. To ensure legal certainty and a level playing field for companies, these use and exposure categories need to be established **in the legal text** of REACH rather than in implementation guidelines only.

We therefore kindly ask for your **full support** for **the draft IMCO committee report amendments** 26, 27, 34, 141-145, 196-198, 204-213, 251 and 267 as well as 5, 11, 12, 81, 135, 136, 278, and 285.
Also draft amendments 332 and 331 of the IMCO committee in our view could be supported.

The concept as such is also introduced in several **draft amendments of the ITRE committee** (e.g.: 198, 199, 331) and **draft amendments of the ECON committee** (e.g.: 97-100, 292, 300, 399, 404, 408, 409, 412, 413). Also, numerous **draft amendments of the environment committee** clearly improve REACH in its present form by also introducing use and exposure categories. We generally support these, however, amongst these, we consider draft ENVI committee amendments 1026, 1030 and 1039 particularly relevant and ask you for your support.

Besides, there are several understandings of "unsupported use" which are misleading and would in our mind weaken the achievement of the REACH objectives, such as **draft amendment 1023 of the draft environment committee report**. Such amendments should in our view be rejected.

III. Authorisation-substitution

What are Orgalime's concerns?

Orgalime is particularly concerned that while a risk-based approach, which we support, seems to gain acceptance for registration, some amendments aim at moving away from this principle when it comes to the use of substances. Our practical experience with restrictions on the use of only a limited number of substances (e.g. under the RoHS directive 2002/95/EC) underlines the difficulties and costs of re-engineering products and processes in highly complex supply-chains. "Substitution" is often not possible without compromising other important characteristics of a product, such as its safety. Multi-annual re-development and long-term retesting may be required. Moreover, "substitution" does not necessarily present the most advantageous option in terms of environmental and health benefits from a life-cycle perspective.

What way forward?
While our industry is committed to a responsible selection of substances used, our sector strongly opposes proposals to establish a mandatory "substitution principle" and rejects the proposed inflexible time limits. Instead, sound scientific and socio-economic considerations must be the prime factor for individual authorization / restriction decisions. The diversity of applications means that any time limits have to take into account application-specific lead-times and product cycles.

Our industry encourages you to <u>reject</u> those amendments that go against these principles, such as:
Draft ENVI committee report amendments 120, 121, 594, 595, 596, 597
Draft IMCO report amendments 269 and 649.
Draft ITRE committee report amendments 59, 60, 68, 69, 107
Draft ECON committee report amendment 1, 20

Please <u>support</u> draft ECON committee report amendments 403, 421 and 425 in order to take into account application specific lead times and product cycles in the authorisation phase.

IV. Other issues

Orgalime also appreciates the considerable efforts made by MEPs to ensure a workable REACH and give their full support to those amendments that provide for:

- the full exemption of R&D throughout the supply-chain,
- the full exemption of wastes for recycling and
- a clearer definition of "metallic alloy" and
- support measures for SMEs.

What way forward?
We would like to encourage you to support these amendments in your further proceedings:
Draft IMCO committee report amendments 37, 39, 199, 301, 302, 335
Draft ENVI committee report amendments 132, 193, 216, 231
Draft ITRE committee report amendments 90, 120, 132, 133, 183, 184, 185, 186, 188, 228
Draft ECON committee report amendments 3, 112, 118, and 470.

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Annex

Examples of existing legislation that applies to engineering products in Europe

- Directive 2005/32/EC for establishing a framework for the setting of eco design requirements for energy using products (EuP) of 23 May 2005
- 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 Mercury Directives 82/883/EEC and 84/156/EEC
- The End of Life Vehicles Directive 2000/53/EC (EOLV)
- The General Products Safety Directive 2001/95/EC
- 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/EC
- The Physical Agents Directives (noise 2003/10/EC, vibrations 2002/44/EC, electromagnetic fields 2004/40/EC) and proposal on optical radiation COM 92/449/D)
- Carcinogens directive 90/394/EEC