ORGALIME POSITION[1]

On

REACH Consultation Documents

Brussels, 9 July 2003

1. Introduction

Orgalime speaks for 32 trade federations representing some 130,000 companies in the mechanical, electrical, electronic and metalworking industries of 21 European countries. These industries employ some 7.3 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. Our industry is also one of the main downstream users of chemicals, accounting for an estimated 9% of chemicals used.

European engineering industries are committed to the **proper management of environment, health and safety aspects** when performing business. Therefore, Orgalime shares the general objective of the future chemical policy to ensure the safe and environmentally sound handling of chemical substances by closing information gaps on chemical substances and improving the level of communication in the supply chain.

At the same time, our manufacturers have to answer to the needs of the market and therefore bear in mind the fitness for purpose and functionality of their products in a rapidly evolving market place. In addition, our industries have to comply with the considerable number of specific health and safety requirements and provisions stemming from internal market directives (machinery directive, low voltage directive, pressure equipment directive, EMC directive, etc.) or consumer legislation (such as general product safety directive, consumer guarantees directive, product liability directive, etc.).

2. Consultation of all stakeholders, a key to Better Regulation

Given the complexity and far reaching consequences of the envisaged REACH system in particular on downstream users, Orgalime believes that it is vital **to consult *all* stakeholders thoroughly and in a co-ordinated way prior to advancing with this ambitious legislative initiative**. While we appreciate the possibility to comment on the draft REACH consultation documents during the eight weeks internet consultation process, we question if such a process is adequate to seriously analyse the considerable impacts of REACH on European industry, and downstream users in particular, according to the better regulation principles. To underline this concern we wish to cite that the **2003 RPA study on the benefits of REACH** commissioned by DG Environment has been made available only during the advanced stage of this consultation process, which under the given time scale makes precise analysis for downstream users almost impossible. At first sight, we already question the comparability of this study with the previous cost assessments of the Commission as the time spans on which assumptions are based in these

[1] This position is supported by **EECA-ESIA** representing the European Semiconductor Industry and by **CECED** representing the household appliance manufacturers.

two studies differ considerably (benefits assessment: 30 years; cost assessment: over a period to 2020).
Notwithstanding the fact that the recently published **RPA Business Impact Assessment on the "Availability of Low Value Products and Product Rationalisation"** attempts to address one or other downstream user issue, we believe that a considerable gap of understanding concerning the far-reaching consequences of REACH on downstream users does exist.

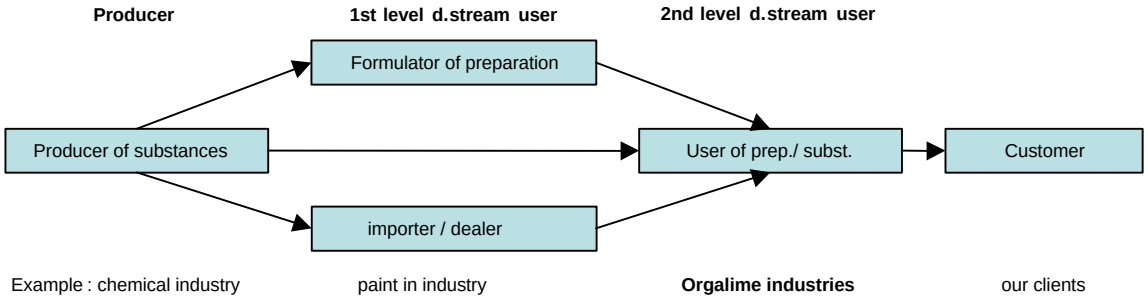
In this context, Orgalime would like to pose two questions to the European Commission:

- *How will the comments that the Commission will receive during the stakeholder process be analysed in order to ensure their proper reflection in the future chemical proposal?*
- *How will specific downstream user concerns be taken into consideration when advancing with the proposal?*

Orgalime urges the Commission to undertake **an appropriate downstream user consultation** in order to arrive at **a well-balanced proposal,** which would be **based on the risk of a substance instead of its potential danger**. We believe that the risk of a substance, once it is scientifically proven, should be **addressed as early as possible in the supply chain** in order to **avoid multiplication of unnecessary registrations and further creation of general burden for all users** of the valuable products that chemicals are.

3. Orgalime key messages given the expected main impacts of REACH on European engineering industries

Orgalime industries represent "**second level downstream users**" to be understood as users of substances or of preparations according to the intended use determined by the "first level downstream user" or the producer of the substance.
The **second level downstream user can only be expected to guarantee competent and reliable knowledge concerning the safe handling of the substance or of the preparation. This must be distinguished from the knowledge concerning intrinsic properties of a substance or of a preparation**. The latter can only lie with producers and first level downstream users.
The Commission's draft proposal does not contain this distinction, which to our mind is essential.



After a preliminary consultation with our industry, we are seriously concerned about the following **impacts** that we expect on our industry if the draft regulation were adopted as it stands:

1. We are seriously concerned about the estimated –and apparently for the Commission acceptable- **loss of substances produced in smaller quantities**, which according to different studies rank from 8-12% up to 20-40%. As Orgalime industries use a number of substances or of preparations which are essential in our manufacturing processes, even if used in small quantities, the innovation capacity of our industry risks to be substantially hampered. We stress that such a withdrawal of specialities would occur, not because of risk of certain

substances for health or environment reasons, but simply because of economic considerations of chemical suppliers.

*Orgalime is of the opinion that EU chemical policy should aim **at ensuring the availability of the broad range of often indispensable chemical substances and preparations on the market**, rather than accepting de-selection in the variety of useful and necessary substances and preparations independently from their risk.*

*Example: **Coronary artery stents in the treatment of various forms of heart diseases**:*
*Such stents are normally manufactured from stainless steel mesh and the manufacturing process produces small burrs that make the stent unusable. Only by applying electro-polishing techniques, are these burrs removed and the stents then safe for use. The **electro polishing process uses some speciality chemicals** that we understand may well no longer be produced if the REACH system is introduced as proposed.*

2. Even if substances produced in smaller quantities are not completely withdrawn from the market by their producers, we expect a **considerable price increase** in such substances resulting from the additional registration and/or authorisation costs.
In some cases, these economic considerations might even result in a **shift of the responsibility for carrying out risk assessments down the supply chain**.

*Therefore, Orgalime believes it is essential that **the level of duties of the various actors under REACH appropriately reflect their individual role in the supply chain**. This means that producers and first level downstream users should be responsible for the detailed chemical properties of a substance or of a preparation, **whereas second level downstream users can only be expected to guarantee the safe handling of the substance or of the preparation**. Orgalime cannot accept a concept, which would widen duties or shift responsibilities to the whole production and processing chain.*

3. REACH as it stands today would, to our mind, results in an extremely time consuming procedure, which could hamper the innovation and in particular the competitiveness of our industries, especially in those areas with fast evolving technologies, many of which are essential to keeping the lead that Europe has achieved in certain areas or is seeking to attain in certain areas.
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.

*Orgalime therefore calls upon the Commission to ensure that **innovation capacities of industry are safeguarded** in order to prevent delays in the development and introduction of new technologies.*

For example, in the semi-conductor industry, a six months time delay to accomplish REACH formalities for a new use of a chemical would already correspond to a loss of a total chip generation.

4. We expect an unacceptable **competitive disadvantage for European manufacturers** in comparison to our Non-EU-competitors, who would not have to follow the REACH procedures in production facilities located outside the EU. It must be clear that any legislation, which so thoroughly impacts the manufacturing processes of only those

industries, which are based in the EU, creates a severe handicap for EU manufacturers in the face of their overseas competitors. Consequently, EU manufacturers would have to face an **increase of imports of finished goods from outside the EU**.

An inclusion of substances in such finished articles in the REACH system, would, to our mind, not serve to solve the problem, as it would be impossible to guarantee efficient and effective market surveillance.

Furthermore, **exports from the EU** - and we wish to recall that our industries represent one third of the total exports of manufactured goods of the EU - will be at a disadvantage, since additional costs resulting from the REACH obligations would lead to a situation that all EU manufactured goods would only be available for higher and consequently **less competitive prices**.

*Consequently, Orgalime urges the Commission **to ensure that REACH does NOT undermine the role of European engineering industries in international trade**. **The compatibility of the EU chemical policy with WTO rules** is also to our mind vital to ensuring the competitiveness of our industries.*

5. Finally, if a manufacturer cannot meet the REACH requirements/restrictions within his European production facility, we have received strong feedback from Orgalime members pointing out that that in many such cases it will be easier to **re-locate the whole manufacturing process to a Non-EU-country rather than complying with REACH obligations**. As a result, not only skilled employment, but also the potential for innovation and technological know-how within Europe would be lost even more quickly.

*In the light of the Commission's Communication on Industrial Policy in an Enlarged Europe, Orgalime expects that the Commission will seek **to encourage manufacturing to continue in Europe on a competitive basis**.*

4. Orgalime proposed improvements for REACH to work in practice

In view of the key messages specified above, Orgalime gives hereafter recommendations for improvements in the draft REACH regulation. We stress that these are preliminary proposals which we hope to develop as our industry continues analysing in more detail the almost 1200 pages of draft legislation.

- To our mind, the **definition of "downstream user"** needs further clarification and specification, as there are different categories of downstream users of chemical substances, which we believe should be called upon to meet different forms of responsibility.

  Orgalime suggests that **a distinction between first level and second level downstream users should be introduced (in particular, point 2/11 and 16; point 3; point 4; title VI; annex XI of the draft REACH regulation)**. A "first level downstream user" would have to be understood as the importer or user of substances to formulate preparations. A "second level downstream user" however would be only *using* preparations or substances for his industrial or professional activities manufactured by the chemical producer or first level downstream user.

- Therefore, we believe that in particular **annex XI should apply to first level downstream users only**. Second level downstream users however would depend on the proper communication of the results of the chemical safety report established by the producer or the first level downstream user in order to fulfil our obligations to ensure the safe handling of the preparation or of the substance.

- Moreover, the second level downstream user would use the already established **Safety Data Sheets**, which would include the results of the chemical safety report of the producer or of the first level downstream user, as a core instrument for ensuring the safe handling of the substance or of the preparation they use. This would in particular help SMEs to fulfil their obligations in a workable and reasonable manner. Otherwise REACH would just result in a multiplication of needless and burdensome bureaucracy for all actors in the supply chain. It is of utmost concern to us that the Commission should seemingly to be unaware of the threat that the ever growing weight of bureaucracy required for operating in the EU has on companies and particularly SMEs which do not have the structures, capacities or resources required for operating under such conditions.

- Orgalime takes the view that **substances in article, such as in electronic consumer appliances, should not be included in the scope of REACH.** This would impose unacceptable and unnecessary burden in terms of an extended duty of care on our industries. Once again, those areas where "speed to market" is decisive for a company's success, would feel the strongest impact. The exclusion of substances in articles from the scope of REACH would also avoid creating incoherent and overlapping regulation in sectors where other specific environmental legislation, such as the WEEE and RoHS directives, already exist. **Therefore, we suggest deleting title X and all related cross-references to substances in articles in the draft REACH proposal.**

- We believe that an appropriate configuration of **"intended use**" is essential to address the risk of a substance as early as possible in the supply chain. The present registration and evaluation procedures are too burdensome in terms of data collection and reporting obligations and would have negative results on the innovation of our industry. Therefore, we encourage the Commission to look for **alternative solutions under annex I** of the draft REACH regulation, which would reduce bureaucratic and administrative tasks. A possible way forward may be to **consider the integration of "exposure categories" under annex I of the draft REACH regulation**. Industry proposals presented in the course of the preparation of this legislative initiative, such as the Matrix of the German chemical industry and the Ökoinstitut Freiburg, may serve as a starting point in this direction. It could enable second level downstream users to practice an efficient assessment on the basis of the information provided from the upper supply chain. A classification as proposed in the EU-Technical Guidance Document (TGD), which differs between 16 industrial uses or even 55 categories of functional uses, however, is highly complex and would certainly fail to work in practice within our industries, which overwhelmingly comprises small and medium sized enterprises.

- Subject to Directive 76/769/EEC, we believe that substances or preparations must further on be available without limitation.
  During the period of registration of a substance, downstream users must be allowed to continue using the substance or the preparation. Otherwise, whole production chains would break down from one day to the other.
  In particular, the provisions concerning the registration or authorization should not lead to the limitation of substances and preparations, which are already in use. Therefore, we take the view that especially **during the testing and inspection of possible substitutes or alternatives, manufacturers must be allowed to continue the use of the original**

substance without hindrance. Respective paragraphs should be introduced into the draft REACH proposal (e.g. under title VI on "downstream users").

- **We suggest introducing a priority system into the draft proposal** that would concentrate on substances with the highest negative impact on human health and the environment first and address those, which are of lower impact and volume only at a later stage. This would also help improving the practical workability of REACH, as it would contribute to prevent the system from being overburdened from the very beginning.

- Developing substitutes without compromising the safety, the functionality or performance of final manufactured goods, requires time. Therefore, if a specific substance is going to disappear, manufacturers need **sufficient time frames 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 innovation where "**time to market**" may be the deciding factor for the economic, environmental and social performance of a company.

- In order to fulfil the obligation of proper and appropriate **up-stream communication**, Orgalime feels that practical tools and new concepts, which are not only time consuming but also cost intensive, still have to be developed for second level downstream users. As a possible example for the development of such new tools, we could cite a publicly supported communication project[2] undertaken in the Netherlands, which aims at coordinating and improving the communication and cooperation with respect to health, safety and environment in the product chain chemicals-paint-metalworking.

- In order to be able to fulfil their own obligations, a second level downstream user must be guaranteed **access to information** which provided by the supply chain would of course be as clear and understandable as possible.

- Overall, we believe that the REACH system must ensure **the highest possible level of protection of sensitive and proprietary data**. A decision of our (EU or Non-EU) chemical supplier NOT to market a substance due to the risk of disclosure of such data, would seriously affect us.

  Therefore, Orgalime doubts that the mandate given to the central agency in **point 102/2** of the draft regulation to decide upon the confidentiality of submitted information would provide the vital certainty for companies. We believe that a **centralised system with one single focal point** instead of shared competences between the agency and member states authorities could better ensure that sensitive business information is kept confidential.

- Orgalime prefers **the application of as harmonised rules as possible throughout the European Union**. Consequently, Orgalime favours a **centralised system** rather than splitting competences between the central agency and a growing number of EU member states. We believe that only a harmonised and therefore centralised approach may serve to prevent different standards for testing requirements in (a growing number of) EU Member States and, therefore, the distortion of competition within the internal market.
  In this context, Orgalime believes that the reference to **article 95 of the EC Treaty** is vital in the draft REACH regulation.

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Naar een effectieve communicatie en samenwerking op milieugebied in de productketen Chemie, Verf, Metalektro. 21 maart 2002

Conclusions

Orgalime understands the intention of the Commission to address the current lack of information and knowledge about the extremely broad variety of different chemical substances for environmental, health and safety reasons.
However, we believe that the draft REACH proposal calls for in depth revision particularly along the following principles:

- Downstream user concerns must be assessed by undertaking a specific downstream user impact assessment in line with the better regulation principles.
- Market reality of companies that are acting in rapidly evolving market places where time to market is essential for business success must be taken into account.
- The definition of "downstream user" needs to be revised in order to address the risk of a substance as early as possible in the supply chain.
- The availability of substances must be ensured and sufficient time frames for finding substitutes for any substance that is called upon to be withdrawn must be provided.
- The multiplication of administrative work in the supply chain, in particular for SMEs, must absolutely be avoided. Simplicity is a must.
- Any future system should follow a priority system tackling substances with highest negative impacts on human health or the environment first and addressing the uses of concern based on risk rather than hazard.
- The disclosure of proprietary and confidential business data and internal company know how must be prevented.

Orgalime urges the Commission to seriously consider the impact of the proposed draft REACH regulation on all dimensions of sustainable development, i.e. environmental, social and economic, before advancing further with this proposal.