
# COMMENTS ON PROPOSAL CONCERNING THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTIONS OF CHEMICALS (REACH)

**JULY 10, 2003**

## Introduction

This document summarizes the comments of five trade associations regarding the European Union's Proposed Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH) System. These trade associations represent key members of the electrical and electronics industries – AeA (formerly the American Electronics Association), the Electronic Industries Alliance (EIA), the Information Technology Industry Council (ITI), the National Electrical Manufacturers Association (NEMA), and the Semiconductor Industry Association (SIA) (See Appendix 1 for a description of each of the associations). The member companies of these trade associations have a significant presence in the European Union, with sales in excess of 100 billion Euro and numerous facilities employing hundreds of thousands of Europeans.

Our associations appreciate the opportunity provided by the Internet Consultation to present the comments of the electrical and electronic industries on this very important proposal. High tech industries are characterized by rapid innovation and short product lifecycles. This innovation, which has accelerated over time, has yielded significant benefits to the world's consumers in the form of better products at lower prices. We are concerned that the broad scope of the proposed REACH system, the regulatory burdens it will impose, and its potential application to chemicals embedded in our products will inhibit technical innovation, delay or prevent introduction of new products to the EU market, raise the price of new products, and reduce economic growth in the EU. We believe that a new chemical regulatory system can be designed to address critical chemical risks without harming innovation.

We are encouraged by the provision of this Internet Consultation period. Due to the broad-ranging impact of the proposed REACH system and its potential impact on virtually all products sold in the EU, it is critical that the Commission hear from all potentially affected stakeholders regarding the proposal's potential impact. This consultation represents a significant step towards ensuring that all stakeholders potentially impacted by the proposed REACH system will have a meaningful opportunity to comment on the proposal. We commend the Commission for providing the Internet Consultation period and we look forward to working with the Commission to ensure that the most workable scheme emerges. It is critical that the Commission carefully consider

and respond to the comments and suggestions from all stakeholders before formally adopting the Regulation.

Our members share with the European Commission a concern for reducing the environmental impacts of chemical production and use. The electrical and electronics industries are leaders in environmental stewardship. Our members strive to reduce the use of chemicals of concern when feasible and promote the responsible procurement, use, and end-of-life management of chemicals to the greatest extent possible. Our members are leaders in product "design for the environment" efforts and ensure that their production processes minimize negative health and environmental impacts.

We recognize that deficiencies have been identified in the EU's current chemical regulatory framework. We support the development of a new approach to the regulation of chemicals that better protects human health and the environment; however, any new system must apply the scientific principles of risk management in a transparent manner so that important uses are not jeopardized through application of arbitrary or scientifically indefensible regulatory requirements.

Our comments on the REACH proposal reflect our members' roles as "downstream users" of chemicals and as manufacturers of products that may be affected by the REACH proposal. We are aware of concerns that have been raised regarding the potential international trade impacts of the REACH proposal; however, we will restrict our comments to concerns regarding the workability and implementation aspects of the proposed REACH system. We hope these comments will greatly improve the practicability and workability of the REACH system.

**Summary of US High Tech Industry's Comments on the REACH Proposal**

As "downstream users" of chemicals that will be covered by the REACH proposal, we have specific concerns and recommendations regarding the following four issues:

(1) The coverage of the REACH Proposal is overbroad and will regulate chemicals and articles that pose little if any environmental or worker safety risk. Its scope should be narrowed by providing exemptions for articles, polymers, intermediates, and "highly controlled" process chemicals. These exemptions will improve the workability of the REACH system without diminishing environmental or worker safety protections.

(2) The REACH proposal's definition of "use" is ambiguous and requires clarification. Because of the ambiguity regarding the term "use," we are concerned that chemical manufacturers will restrict the types of "uses" covered by their authorizations, placing a burden on downstream users to register additional uses. A defined list of potential exposure categories for which chemical manufacturers are responsible would help clarify this ambiguity.

(3) The REACH proposal would require that chemical producers prepare detailed, complex, and lengthy Chemical Safety Reports (CSR) for all registered chemicals. Currently, companies and their customers use Material Safety Data Sheets (MSDSs) to communicate information on chemicals. We recommend that the REACH proposal be amended to allow MSDSs to be the vehicle of

communicating chemical information along the supply chain in order to minimize paperwork requirements on downstream users.

(4) The REACH proposal currently provides insufficient protection for Confidential Business Information (CBI). Expanded CBI coverage and a means of judicial redress are essential to adequately protect highly sensitive CBI.

These general comments have been inserted into the comment template and are explained in more detail below.

## REACH REGULATION
## PUBLIC INTERNET CONSULTATION

### A - Contact details
(Please enter your contact details)

**Name: AeA, EIA, ITI, NEMA, SIA**
**Organisation : US-Based High Tech Trade Associations**
**Address : Various**
**Post/zip code : Various**
**City/Town: Washington, DC and vicinity**
**Country : USA**
**Telephone : Contact Holly Evans: (EIA) 703-907-7576**
**Fax : Contact Holly Evans (EIA): 703-907-7501**
**E-mail: Contact Holly Evans (EIA): hevans@eia.org**

### B - Confidentiality

☐ **I would like my identity to be kept confidential**
(please leave this box blank if you agree that your name and organisation will be identified on the Commission's website for public access)

### C - SME

☐ **Are you a small or medium sized enterprise?** (EC legal definition)
please specify the number of members:

### D - Description of your primary activities
(please select only one of the following)

**Industry**

☐ **Manufacturer**
☐ **Importer**
☐ **Downstream user**

☐ **Distributor**
**X** **Trade association**
☐ **Other**

**NGO**

☐ **Environmental group**
☐ **Animal welfare group**
☐ **Trade union**
☐ **Consumer organisation**
☐ **Other**

**Public authorities**

☐ **EU Member State government**
☐ **Other national government**
☐ **International organisation**
☐ **National or regional authority**

**Other**

☐ **Academic or technical institute**
☐ **Worker in chemicals or downstream industry**
☐ **EU citizen**
☐ **Other**

## E - Topics :

1. Duty of care
2. **Chemical safety assessment**
3. Information flow
4. Registration procedure
5. Polymers
6. Intermediates
7. Data requirements
8. Data sharing/consortia formation
9. Procedures for downstream users
10. Evaluation procedure
11. Authorisation procedure
12. Restrictions procedure
13. The Agency
14. Other

The proposed REACH system would require chemical manufacturers to produce detailed Chemical Safety Reports (CSR) for all registered chemicals. Annex I defines the amount of information that must be generated for the CSR, which will be extremely voluminous and complex. The proposed regulation would require that downstream users review the CSR to make sure that their uses are covered by manufacturer risk assessments. If the downstream use is not covered or the downstream user elects to use a different risk management method than specified in the CSR, then it will need to prepare its own CSR.

Our members currently do not employ toxicologists or highly specialized risk assessment experts at their facilities. Therefore, the proposed requirement that downstream users must assess CSRs to determine their coverage of downstream uses would be extremely burdensome and costly. To remain competitive in the marketplace, high-tech downstream users need to make decisions quickly and efficiently. Therefore, we need to receive chemical information in a format that is clear, simple, and understandable.

For this reason, we strongly believe the material safety data sheet is the most appropriate tool for communicating risk and risk management techniques to the

downstream user community. From a downstream user perspective, we need to understand the physical properties of the material we are using (corrosive, reactive, explosive, etc) and the health and environmental impacts from using the material. The material safety data sheet has adequately fulfilled this role for many decades.

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The high tech industry commends the Commission for recognizing the importance of exempting certain applications of chemicals to the overall workability of the system. However, we are concerned that certain exemptions are too limited. Without effective exemptions, the REACH regulation will pose significant burdens on government and industry without advancing the Commission's stated goals. A number of additional exemptions are absolutely critical to make REACH workable. **These exemptions include articles, polymers, intermediates, and chemicals used in highly-controlled processes. Allowing for these specific exemptions will make REACH more workable and not diminish its ability to protect human health or the environment.**

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Polymers should also be exempted from the proposed REACH system because there is currently no evidence that their use poses health, safety, or environmental risk. Due to their inherent properties that prevent the release of the monomers of which they are comprised, polymers should be exempted from the registration, evaluation, and authorization requirements.

Environmental and worker safety concerns about the chemical monomers or which polymers are made will be addressed under the REACH system when the monomers are registered and evaluated. In the event that a monomer is a chemical of concern, the risk management process will provide any additional needed protection. This exemption would also conform to international requirements and understandings regarding the minimal risks posed by chemical polymers.

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Chemicals for intermediate uses should also be exempted from REACH registration requirements. Since intermediates are "solely manufactured for and consumed in or...transformed into another substance," they do not present the same environmental or health risks as other chemical substances. In addition, we are concerned that the current proposal appears to place burdens on imported uses of intermediates that do not apply to those produced in the EU. This disparate treatment of intermediates from inside and outside the EU is unnecessary and may violate WTO requirements.

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One of our most significant concerns with the REACH proposal is its proposed treatment of Confidential Business Information (CBI). The proposed regulation would obligate manufacturers and downstream users to provide an extensive list of information that would not be considered confidential. The high tech industry relies on a highly specialized use of chemicals that are essential to the functioning and manufacture of high tech products. As such, it is important that strict safeguards are established in order to prevent the disclosure of trade secrets and the disruption of the competitive marketplace.

In the manufacture of photo resists and other materials for the semiconductor industry, for example, the exact way in which chemicals are used (the manufacturing technology) and the identity of the chemicals themselves are extremely commercially sensitive. The use of consortia has been proposed to facilitate the exchange of information among downstream users. Although that might appear as a practical solution to mitigating costs, confidentiality issues will make chemicals suppliers highly unwilling to share data and information on specific substances, thereby posing a very big problem to the formation of such consortia. It is critical, therefore, that the REACH system ensure that all information submitted at all phases of REACH system implementation is eligible for a claim of business confidentiality.

Moreover, the proposal does not include any procedural safeguards to prevent the release of CBI or punitive measures for officials who fail to comply with CBI obligations. In addition, there is no appeal mechanism if the Agency or Member State disagrees with a CBI claim. Instead, the proposal presumes that information that is not granted CBI protection will be released to the public without an opportunity for the claimant to protest or obtain court protection of its CBI and without ensuring that the dispute is decided by a neutral party in a timely fashion. It is essential, therefore, for the REACH system to include a credible, accountable, and transparent mechanism for ensuring that CBI claims are adjudicated fairly and in a manner that does not jeopardize trade secrets.

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|---|---|
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As discussed in more detail, supra, the imposition of extensive reporting and data generation requirements on downstream users is extremely burdensome and unnecessary. In addition, a number of additional exemptions are critical for the downstream user community. These exemptions include articles, polymers, intermediates, and chemicals used in highly controlled processes. Allowing for these additional exemptions will make the REACH system more workable and not diminish its ability to protect human health or the environment. The rationale for exempting articles and highly controlled processes is presented below. The rationale for polymers and intermediates is contained in their respective section of the template (see above).

**Articles:**

An exemption for articles is of high importance to the high tech industry. As currently written, an importer or producer of articles may need to register any chemical substance contained in an article in quantities totaling over 1 ton per year if "during normal and reasonably foreseeable conditions of use and disposal, the substance may be released in sufficiently high amounts and in such a way as to adversely affect human health or the environment." While we support the rationale for exempting smaller quantities of chemicals used in chemicals, we believe this reasoning should apply to all articles.

Under the proposed requirements, chemical manufacturers will already be required to provide risk assessment information for chemicals used in articles. Imposing duplicative registration requirements on article manufacturers will achieve no additional environmental or worker safety protection yet impose significant burdens on such downstream users. Many international chemical regulatory schemes have recognized the potential for this duplication and exempt "articles" for this reason (see the United States Toxic Substances and Control Act, 19 CFR 12.120(a)).

The REACH proposal also would require an assessment of potential exposures caused by the disposal of articles. This requirement is also unnecessary since in the case of most articles, disposal concerns are covered under existing EU Directives. In the case of electrical and electronic equipment, specific concerns have already been addressed through the Waste from Electrical and Electronic Equipment (Directive 2002/96/EC) and its companion Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (2002/95/EC) Directives.

The Commission should expand the current exemption to apply to all articles so as not to overburden the REACH system with duplicative requirements and to promote consistency with other international chemical regulatory regimes.

**Highly Controlled Process Exemption:**

The draft legislation also fails to recognize that some uses of chemical substances present little or no risk to workers, the public, or the environment because they are used in highly-controlled processes that, by their nature, reduce to the maximum extent technically possible the potential for exposure. The Commission should recognize the minimal risk posed by the use of such processes and exempt them from the proposed requirements. Such an exemption would prevent companies from being discouraged from using highly controlled processes that are a safe and effective way of managing the risks associated with the use of chemical substances. Any decisions on which chemicals are eligible for this "highly controlled process" exemption should be made by a central authority so that competitiveness issues, which could result from disparate Member State treatment, are avoided for users of such chemicals.

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The REACH proposal would require a special authorization process for chemicals of "high concern." If a chemical falls within this authorization category, explicit permission must be given for each "use" of the chemical. Downstream users of chemicals are responsible for obtaining specific permission for "uses" of authorized chemicals that are not covered by manufacturer authorizations. We share the chemical industry's concern with the entire authorization approach and the difficulties associated with the proposed definition of "use." The REACH program proposes to define "use" broadly to capture most activities in the entire commercial chain, but it does not clarify how the "use" definition will be used for purposes of registration and authorization.

As downstream users of chemicals, we are concerned that manufacturers may narrowly define chemical "uses," tying them to specific product categories or certain formulations. In such cases, downstream users would be left with the burden of authorizing chemical uses that are not covered by manufacturers. Downstream users typically do not have the resources or expertise to conduct detailed toxicological analyses. As manufacturers of articles, we rely heavily on the material safety data sheets provided by chemical manufacturers to provide us with clear, simple and direct information that we need to

make decisions regarding material selection and to meet our occupational health and safety and environmental obligations.

Based on its long experience in dealing with risk assessment, we believe that the chemical industry is in the best position to conduct risk assessments for all foreseeable uses. The main purpose for putting a burden on downstream users is to make sure that the exposure aspects of risk assessment are appropriately addressed. Accordingly, we believe the real question is not: How is the chemical being used? Rather, the question should be: What are the exposure scenarios that a chemical manufacturer should reasonably evaluate, anticipate and communicate to downstream users in a manner they can understand and rely upon? Assuming a downstream user's activities fall within reasonably anticipated exposure scenarios from foreseeable uses, no further testing or analysis should be required.

Manufacturers should be required to develop the risk assessment for all potential human exposure pathways (for example, dermal contact, ingestion, inhalation, etc), and a standard set of environmental pathways, unless they can demonstrate that the exposure pathway is unreasonable given the nature of the chemical. If this approach is adopted, only very unusual and unforeseen uses, with actual exposure pathways that fall outside of these categories, will require additional downstream user risk assessment.

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We agree with the chemical industry that the entire REACH system should be administered by a central agency.

## Conclusion

We appreciate this opportunity to provide the comments of the electrical and electronic industries on the proposed REACH system. This proposal will have significant impacts on our members' ability to procure, use, and manage their chemical inventories. Most importantly, this proposal could impede the ability of our member companies to innovate and produce products that provide significant benefits to the world's consumers in the form of better products at lower prices. We sincerely hope that you consider our comments when working to improve the workability of the proposed REACH system.

# APPENDIX 1

# DESCRIPTION OF ASSOCIATIONS

**AeA** (formerly the American Electronics Association) is the nation's largest high-tech trade group, representing more than 3,500 U.S.-based technology companies. Membership spans the industry product and service spectrum, from semiconductors and software to computers, Internet and telecommunications systems and services. With 18 regional U.S. councils and offices in Brussels and Beijing, AeA offers a unique global policy grassroots capability and a wide portfolio of valuable business services and products for the high-tech industry. For 58 years, AeA has been the accepted voice of the U.S. technology community.

The **Electronics Industries Alliance** (EIA) is a federation of associations and sectors operating in one of the most competitive and innovative industries in the world. We are committed to promoting business opportunities for our industries. Comprised of over 2,100 members, EIA represents 80% of the $550 billion U.S. electronics industry. Our member and sector associations represent telecommunications, consumer electronics, components, government electronics, semiconductor standards, as well as other vital areas of the U.S. electronics industry.

The **Information Technology Industry Council** (ITI) represents the top U.S. providers of information technology (IT) products and services. ITI is the voice of the high tech community, advocating policies that: advance U.S. leadership in technology and innovation; open access to new and emerging markets; support e-commerce expansion; protect consumer choice; and enhance the global competitiveness of its member companies. ITI promotes the understanding of the digital world by educating lawmakers, opinion leaders, the media and consumers about the issues and policies that impact the high tech industry. Our mission is to foster innovation, expand global market access, and advance the competitiveness of U.S. IT companies while meeting the growing demand and expectations of consumers worldwide.

The **National Electrical Manufacturers Association** (NEMA) is the largest trade association representing the interests of U.S. electrical industry manufacturers. Its mission is to improve the competitiveness of member companies by providing high quality services that impact positively on standards, government regulation and market economics. NEMA's 400 member companies manufacture products used in the generation, transmission, distribution, control, and use of electricity. These products, by and large unregulated, are used in utility, industrial, commercial, institutional and residential installations. The Association's Medical Products Division represents manufacturers of medial diagnostic imaging equipment including MRI, CT, x-ray, ultrasound and nuclear products. Member companies' worldwide annual sales of electrical products exceed $120 billion.

The **Semiconductor Industry Association** (SIA) is the leading trade association representing the computer chip industry. The mission of the SIA is to provide leadership for U.S. chip manufacturers on the critical issues of trade, technology, environmental protection and worker safety and health. With the assistance of our members, we strive

to achieve free and open markets worldwide, U.S. leadership in technology, and state-of-the-art programs to protect the environment and provide safe working conditions.