REACH: The new European Chemicals Policy

Position Paper of the American Chamber of Commerce in Germany e.V.

In October 2003, the European Commission published the proposal for a REACH regulation (Registration, Evaluation, and Authorization of Chemicals), a major overhaul of the current European chemicals policy. Its purpose is to introduce a single, coherent regulatory framework for chemical substances in the EU. Using a "reversed burden of proof" principle, the legislation proposes that the industry proves substances are safe to use. The three elements of REACH are:

Registration requires companies that produce or import more than a ton of a given substance annually to submit information on that substance in a central registration dossier.

Evaluation to be carried out by competent authorities in Member States. This will take two forms: dossier evaluation and substance evaluation. Dossier evaluation ensures that unnecessary animal testing is avoided in the registration phase. Authorities may also evaluate registration dossiers for compliance with the registration requirements. Substance evaluation is performed when authorities have reasons to require information which exceed the regular information requirements of the registration step of REACH.

Authorization is reserved for substances that are deemed to be of very high concern on the basis of specific hazard properties e.g. carcinogenicity. Authorization applies to particular uses and will be granted if it is demonstrated that the risks associated with the use are controlled. If risks can not be controlled then authorization for use may still be granted if the socio-economic benefits of using the substance are shown to outweigh the risks.

The REACH regulation must be implemented in all Member States if adopted by the Council and the European Parliament. At the Member State level, the Competitiveness Council has been given the lead. An ad hoc working group consisting of representatives from both Industry and Environmental Ministries is reviewing the proposal. It is also under discussion in the European Parliament (with the Environment Committee in the lead and the Industry and Legal Affairs Committees to give an opinion.) The first reading should finish in late 2005 or early 2006. The second reading then takes 6-8 months, with an official adoption of REACH forecasted for the second half of 2006.

Business Impact

While AmCham Germany supports REACH´s three goals—increased environmental and human health protection, a consistent and coherent EU chemical policy, and increased industry competitiveness—we find the proposal does not balance these goals. Making the proposal clear, transparent and workable is critical, so that companies understand compliance standards and processes and are not burdened by unreasonable documentation costs. Both companies of US and German origin in Europe are concerned that the proposal will lead to substantially higher costs while delivering only marginal health and environmental benefits. European competitiveness as a whole could suffer.

1. Trade and the Economy are Unnecessarily Disrupted

Many countries and organizations have filed objections against REACH with the WTO. Whether REACH violates WTO rules or not, the REACH regulation will unnecessarily impact trade, creating a costly burden without reaping the desired benefits. Also, a significant number of substances could be phased out for economic reasons only, due to complicated and costly registration requirements. The phasing out of substances for economic reasons only generates no environmental protection or human health benefits. Between 20-40% of chemicals produced in quantities as small as 100 tons per year are potentially at risk. This could upset entire supply chains, leading to reduced availability and/or higher prices for users.

2. Inefficient Bureaucratic Process Lead to Unnecessary Expense and Confusion

The registration, evaluation, and authorization processes are currently foreseen to be supervised by multiple regulatory and registration checkpoints, each of which could be time-consuming. There is significant potential for inconsistent and contradictory regulatory decision making by the different authorities involved, which a strong central European chemicals agency would help to avoid. This is particularly the case in the Evaluation step of REACH.

AmCham Germany urges the implementation of a more centralized and transparent approach and also advocates for more opportunities for independent review and appeal. AmCham Germany supports mandatory sharing of vertebrate animal testing data and joint registration on a voluntary basis. Although, information and cost sharing needs to be managed carefully to avoid disclosure of sensitive proprietary information, the potential efficiency gains make this effort worthwhile. Finally, AmCham Germany would like to note that the current REACH proposal runs counter to the objective of the 2000 Lisbon strategy to make Europe the most competitive economic zone in the world.

3. Reasonable Exemptions Need to be Included

The REACH proposal creates burdensome and repetitive requirements for chemical regulation. The results of the current impact assessments should be evaluated carefully to determine where and for what substances the costs of testing, processing and registration outweigh potential environmental and health benefits. An exclusively volume-based approach to chemical regulation ignores the realities of chemical risk management, potentially leading to overlapping and burdensome processes. AmCham Germany supports the consideration of risk-levels to determine the timing as well as the information requirements of registration. Further, certain exemptions should be allowed for chemicals, agents, or products that are not harmful to the environment or human health (e.g. exemptions for polymer and certain finished articles.) Manufacturers of complex products (articles) need sufficient time to adjust to substitution. In the case of the car industry, all necessary processes, functional and consumer tests, must be satisfactorily completed, and this could take several years. As well, substitutions should be available on the market before the original substances are removed.

4. Confidential Business Information should be Protected

Protection of property right as well as the protection of confidential business information should be improved. For instance the period after which proprietary information may be made available freely should be extended to at least 15 years. Concerning confidential business information registrants should have extended rights to claim confidentiality and prevent disclosure of such confidential information.

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The American Chamber of Commerce in Germany (AmCham Germany) is a private, non-profit organization. With over 3,000 members, it is the largest bilateral economic organization in Europe and represents the largest group of foreign investors in Germany. The goals of AmCham Germany include the promotion of German-American trade relationships and investment in Germany.

This paper is partly based on information from AmCham EU, the American Chamber of Commerce to the EU. For more information, visit www.amchameu.be.

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