

## WHITE PAPER

### EU REACH and U.S. Regulation of Chemicals and Chemical Users

#### National Electrical Manufacturers Association (NEMA)

##### **I. Introduction and Summary**

The European Union (EU) recently overhauled its chemical regulatory system by enacting its new Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH") regulation. Some parties in the United States already are advocating that the REACH regulation should serve as a model for reforming the U.S. chemical management system.

However, the National Electrical Manufacturers Association (NEMA) is convinced that there is no need to significantly modify the current U.S. chemical regulatory program, since the U.S. Environmental Protection Agency (EPA) already possesses ample authority to regulate chemical substances and protect human health and the environment. Alternative approaches to chemical regulation such as the EU REACH regulation offer few advantages and instead would create many substantial problems and unwarranted regulatory burdens. In fact, REACH is not an effective model for reform in the U.S. due to its enormous financial costs, harmful effects on innovation, imposition of serious barriers to trade, and distortion of global competition.

This White Paper provides a brief analysis of the EU's REACH, the existing U.S. chemical management system and why it is currently effective, and the substantial ramifications if a new regulatory approach such as REACH were to be adopted. Based on this analysis, NEMA urges that Congress and state legislatures reject REACH-based approaches for reforming chemical regulatory authorities. NEMA further requests that legislation be adopted that would federally preempt state and local governments from adopting REACH-like programs or related chemical content and labeling requirements in order to ensure that a consistent, uniform and effective chemical regulation system remains in place in the U.S.

##### **II. What Is REACH?**

The basic elements of REACH are the "Registration" (by industry), "Evaluation" (by a new European Chemical Agency), and "Authorization" (and possible Restriction) of "Chemicals." The extent of the obligations placed on industry sectors will vary depending on the quantity of each chemical substance manufactured in, or exported to, or incorporated into finished products exported to Europe by each affected company, and on the hazard properties of the particular chemical substance. REACH's requirements apply to

*NEMA is the trade association of choice for the electrical manufacturing industry. Founded in 1926 and headquartered near Washington, D.C., its approximately 450 member companies manufacture products used in the generation, transmission and distribution, control, and end-use of electricity. These products are used in utility, medical imaging, industrial, commercial, institutional, and residential applications. Domestic production of electrical products sold worldwide exceeds \$120 billion. In addition to its headquarters in Rosslyn, Virginia, NEMA also has offices in Beijing, São Paulo, and Mexico City.*

individual chemical substances, as well as to chemical substances found in “articles” (i.e., manufactured goods) or in preparations (i.e., mixtures of two or more chemical substances).

REACH represents a major departure from the historical regulatory schemes employed in the EU and the United States. REACH specifically applies the “precautionary principle” to chemical regulation: No longer does the regulation presume the inherent safety of existing chemical substances that have been commonly used and marketed for many decades. Rather the manufacturers and importers of particular chemical substances to the EU must now effectively overcome a presumption that these substances are not safe, by developing detailed technical information for each substance to fulfill their "Registration" obligations. Thus, industry will be required to prepare comprehensive dossiers for affected chemical substances that provide specific data on the physical, chemical and toxicological properties of each substance, and information on its intended uses and potential human health hazards. Recent studies show that this effort will be extremely costly, leading to the expenditure of more than \$3 billion over the next eleven years to complete all of the new required testing, toxicological studies and related technical work.

The EU Commission has estimated the total REACH implementation costs to be incurred by industry (including downstream users) will range from about \$3.8 billion to \$7.0 billion. However, other studies have indicated that the total direct and indirect costs associated with REACH implementation could range from about \$10 billion to more than \$32 billion.

Moreover, REACH imposes a significant regulatory hurdle for many useful substances that could be designated as “substances of very high concern” (SVHCs) that will require prior Authorization by a new European Chemical Agency. While REACH does not expressly require the banning or phase-out of these, the extremely onerous regulatory process specified by REACH for such chemicals likely will lead to a "black-listing" effect that could essentially have the practical effect of an outright ban on any substance that is formally classified as an SVHC.

### **III. The Current U.S. Regulatory Scheme is Effective**

The current U.S. regulatory system for chemical substances is working well, so there is no need for a dramatic overhaul as embodied in REACH. In the U.S., the federal Toxic Substances Control Act ("TSCA") already gives EPA broad authority to regulate, and even ban, the manufacture, use and distribution of both new and existing chemicals. In addition, chemical producers already are required to track chemical health effects information and to immediately supply EPA with information about the substantial risks of particular chemical substances. Furthermore, EPA possesses significant authority to require manufacturers to provide additional chemical test data when necessary. In fact, through its current TSCA authorities EPA already has obtained chemical data covering more than 95% of all chemicals in commerce today by volume.

While giving EPA abundant regulatory authority, the U.S. TSCA program also has facilitated tremendous innovation by industry. Commentators have noted that more new chemical applications are filed in the U.S. than under any other chemical regulatory scheme in the world, including the EU's and Japan's. Moreover, it is estimated that approximately one-quarter of all new U.S. patent requests involve chemicals or chemical applications, and the U.S. chemical industry recently has spent at least \$23 billion a year on research and development.

The U.S. electroindustry takes part in and benefits from that research, development and innovation as it strives to continuously improve the safety, efficiency and environmental performance of its products. NEMA member companies develop, design and manufacture equipment used in the efficient generation, transmission, distribution, control, and end-use of electricity in the U.S. and around the globe.

#### **IV. Alternatives Such as REACH Are Not Appropriate**

Various parties have suggested – without sound regulatory basis – that alternative approaches to the current TSCA regulatory scheme are needed in the U.S. These alternatives have included REACH and a patchwork of mixed, burdensome state laws that have created significant administrative and regulatory confusion. As discussed above, REACH represents a major departure from the historical regulatory approach employed in both Europe and the United States.

A proliferation of REACH-like legislation at the state level within the U.S. could impair interstate commerce and impose unjust economic burdens on the manufacturers of affected products. Indeed, NEMA and its electroindustry members already have been confronting increasing numbers of state chemical initiatives, such as proposals to ban or restrict the use of lead, mercury or other chemicals in an array of electroindustry products. These efforts are hindering the efficient and cost-effective manufacture and delivery of many beneficial products.

Key problems of regulatory approaches such as REACH for the U.S. electroindustry are:

- REACH will stifle innovation and hinder the continued production of thousands of beneficial materials. In fact, it could result in the elimination of essential chemical products that are critical to the electroindustry;
- Studies suggest that the REACH regulation will cause up to ten (10) percent of the existing chemicals and chemical-containing products to be removed from the EU market;
- Imposition of REACH will impose significant regulatory compliance costs. Recent studies show that compliance with REACH will require the expenditure of many billions of dollars to complete the required toxicological studies and related technical work;
- REACH requires downstream users of chemicals to disclose their uses of each substance to their suppliers (and thus the sharing of what is often business

confidential information) or face the cost and administrative burden of registering their use directly with the EU authorities.

- REACH-like proposals can dramatically distort global trade and commerce in products that contain chemical substances; and
- REACH will substantially increase production costs for downstream users, including electroindustry manufacturers here in the U.S., as well as many chemical manufacturers and importers. A KPMG study suggests that REACH will produce a one-time six to twenty percent increase in production costs.

## V. Future Steps on Chemical Regulation

Given the enormous consequences of any REACH-like legislation, NEMA is urging the U.S. Congress to reject proposals to adopt REACH-type requirements or substantially reform TSCA. The U.S. chemical regulatory scheme already is working well and is fostering the continued introduction of innovative new products. In fact, manufacturers already are participating in several specific EPA-led programs that are generating important chemical data for those substances that have the highest use and exposure risks. These types of cooperative efforts between EPA and the regulated community should be encouraged, since they can better achieve the dual objectives of protecting human health and the environment, and encouraging the efficient production of safe and cost-effective products.

At the same time, NEMA urges Congress to adopt legislation that would federally preempt state and local requirements that are more stringent than TSCA, or that would conflict with its provisions. A uniform federal scheme would effectively preclude the states from developing a patchwork quilt of state-specific requirements that would impose substantial burdens on interstate commerce. By avoiding these burdens, the Congress would foster continued technological and industrial innovation for electrical and electronic equipment, increased public and private sector productivity, and the creation of new job opportunities, while still providing for the environmentally compatible production, use, and end of life disposition of such equipment.