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Chemicals Policies in Europe Set New Worldwide Standard Registration, Evaluation and Authorization of Chemicals (REACH):

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In late October, 2003, the European Union will finalize draft environmental legislation with worldwide significance. The new legislation will fundamentally restructure industrial chemicals regulation in the European Union and, in doing so, will likely significantly affect how these chemicals are managed on the world markets. The legislation will also have a profound impact on the U.S.'s \$20 billion chemical industry and other U.S. manufacturers, which will be required to meet the new standards if they want to sell their products in Europe.

The Problem: Increasing body burdens and impacts of toxic chemicals

Increasing scientific evidence indicates that exposure to toxic substances in food, water, air, and from everyday products, may play an important role in chronic disease in humans and wildlife. In particular, children are often more vulnerable to impacts caused by toxic substances due to their immature and rapidly growing physiologic systems and greater exposures. It is quite likely that toxic substances play a role in the increasing rates of childhood cancer, asthma, and learning and neurobehavioral disabilities. Of particular concern are chemicals that persist in the environment for long periods of time and build up in human tissues (called persistent and bioaccumulative chemicals). Although some of these persistent and bioaccumulative chemicals, such as polychlorinated biphenyls (PCBs), were banned some 25 years ago, they are still found at levels of concern in cord blood of newborns and adult blood and breast milk.

Despite this evidence, during the past half-century, thousands of chemical substances have been developed and placed into commerce, including many everyday products, often with little information or consideration about their environmental or health implications. Studies conducted by government authorities in both Europe and the United States have found *that the vast majority of high production volume chemicals (those used over one million lbs. per year) lack basic toxicity and exposure information.*

Modern chemicals legislation passed in the late 1970s in Europe and the U.S. instituted rigorous data and review requirements for substances placed on the market after 1980, but those chemicals on the market prior to that time were ‘grandfathered’ with few regulatory requirements. *These chemicals, representing more than 99% by volume of chemicals on the market today, were presumed by law as safe until proven dangerous.* Because of this government officials must demonstrate on a chemical-by-chemical basis that a substance is dangerous before moving to regulate it. They do this through a process called Quantitative Risk Assessment, which has resulted in a slow, expensive and resource intensive process, during which the substance is considered safe and exposure continues.

By the time we know fully the toxicity of certain chemicals, these chemicals may already be pervasive in our environment and our bodies. For example, human body levels of polybrominated diphenyl ethers (PBDEs), which are used as flame retardants in foams and plastics, are doubling in the U.S. population every 5 years. We know as much about the toxicity of these substances now as when PCBs were banned in 1976, yet only California has made a move to ban them.

The Solution: An integrated government approach to chemicals control

The impetus in Europe for a broad new chemicals policy comes from several of its Member States – particularly Sweden, Denmark, the Netherlands, the United Kingdom and Germany – which, over the past decade, have developed their own policy initiatives in response to concerns over the impacts of toxic substances on human health and marine ecosystems and the lack of information on most chemicals in commerce.

The new European Union draft legislation entitled REACH (Registration, Evaluation and Authorization of Chemicals) builds on these efforts over the past decade and has the following components, which apply to both domestic European manufacturers and those that import chemicals into the European Union:

Registration: Chemical producers will be required to provide authorities, the public, and customers along the supply chain with basic toxicity and exposure information for *all* chemicals used over one metric ton per year within a limited time period (up to eleven years). *Absent such information, the chemicals will not be allowed on the market.* Certain chemicals, such as most intermediates, polymers, and research and development chemicals will be exempted from these requirements. Companies will be encouraged to share the burden of chemical testing and registration. Information on chemical toxicity will be compiled into a European database managed by a new European chemicals agency. The type of information required for registration for most chemicals is basic toxicity and chemical property information that should already be available to firms. For higher production chemicals, substantial new testing may be required. Chemical firms will need to understand the downstream uses of their chemicals and much of this information has not been readily collected to date.

Evaluation: Data submitted by manufacturers for chemicals used in large quantities or those of high concern will be evaluated by government authorities to avoid duplicative testing and determine whether additional data or restrictions are necessary.

Authorization: *Chemicals of very high concern (those that are carcinogens, mutagens, reproductive-toxicants, persistent or bioaccumulative chemicals, and others, such as endocrine disrupting chemicals and sensitizers) will be considered problematic unless shown otherwise.* Companies seeking to use these substances will be required to seek permission for their continued use, demonstrating that there are no alternatives; that they can be used safely; or that there is a compelling socio-economic need for their use. The goal of the authorization process is that problem chemicals should be substituted with safer alternatives wherever feasible.

New chemicals of concern. In addition, REACH establishes an expedited decision-making process to ensure that health protective measures for newly identified chemicals of concern can be instituted in a much shorter time period (eighteen months as compared to years in the past).

The European Parliament and Council of Ministers will begin to debate the draft legislation in spring 2004 and it is likely to be enacted by 2006.

Conclusion

The REACH proposal responds to growing concerns about the impacts of toxic substances on health and the environment, and the failures of the existing chemicals regulatory framework which has allowed thousands of chemicals to be considered safe until proven harmful with little information about their health impacts. The REACH proposal requires that chemical manufacturers provide basic information on all chemicals in commerce and institutes a presumption that certain chemicals because of their inherent hazards are potentially dangerous and should be substituted unless it is shown that they are necessary or can be used safely. It also allows government authorities to respond more rapidly to emerging chemical threats. The REACH proposal provides a unique opportunity to explore the strengths and limitations of chemicals policies in the United States and to engage a broad public debate on problem chemicals.