

Letter to our Readers

September 2007

Dear Colleague,

What is REACH?

By Pertti (Bert) Hakkinen, Ph.D.

This comprehensive program of chemical assessment and management will impact all manufacturers and importers into and throughout the EU.

Registration, Evaluation, Authorization (and Restriction) of Chemicals (REACH) is the European Union's (EU's) new legislation on chemicals (called "substances" under REACH) that became effective on June 1, 2007. It affects all manufacturers and all importers of products made or imported into the EU and requires consideration of potential exposures in all 27 EU member states. Thus, companies importing into the EU any products that contain substances over certain

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tonnage limits must comply with REACH in order to continue to sell their products there. REACH replaces a large set of directives and regulations, including ones for "existing" (marketed before 1981) and "new" substances. Before REACH, risk assessments for new and existing chemicals were performed by the European Commission

(EC) and EU member state regulatory agencies, which was a very slow process. Now, REACH places the responsibility on industry to develop risk assessments.

Two important goals of REACH are to improve protection of human health and the environment, and to maintain EU industry competitiveness. REACH requires companies to submit health and safety information and assessments that interpret it. EU government authorities will review the information and assessments to judge if the human and environmental exposures are adequately controlled and safe. By requiring these assessments, REACH is expected to lead to lower-risk alternatives as replacements for chemicals with a high level of health or environmental concerns. Another goal is to increase public access to chemical information, including the potential sources of exposure to a substance and how the exposures can be safely managed.

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In this issue of *Trends*, we take a first look at how REACH – the EU's new, comprehensive chemicals legislation – will affect industries in the U.S., from the almost overwhelming administrative and technical resources needed for the submission of required materials, to the legal ramifications of reporting information now considered proprietary. While you may already be aware of REACH, you may not know that it takes the place of over 40 individual pieces of legislation, over 800 pages of legal text, and thousands of additional pages of technical instructions and requirements. We hope this issue will provide insight into the efforts that will be needed to proceed through the pre-registration and registration process.

Contributors to this issue include Dr. Pertti (Bert) Hakkinen, leader of Gradient's REACH practice and one of the developers of REACH-related guidance and tools in his previous position with the European Commission, and Sunessa Schettler and Rosemary Mattuck, Gradient specialists in exposure assessment and REACH compliance. Joining *Trends* with our guest editorial is Kathleen N. Strickland, a partner specializing in environmental law with Ropers, Majeski, Kohn & Bentley, who shares her perspective on the legal implications of the REACH legislation.

If you would like more information about REACH, please visit our Web site at <http://www.gradientcorp.com/reach/> or email us to receive our "REACH in Hand" booklet.

Yours truly,



Neil Shifrin, Ph.D.
 President and Founder

Trends is a free publication of Gradient Corporation, a national leader in risk assessment and negotiation of risk-based remediation. If you have a colleague who would benefit from this publication, please contact Elizabeth Allen at (617) 395-5000 or email us at trends@gradientcorp.com.



What is REACH?

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The European Chemicals Agency (ECHA) has been established in Helsinki, Finland to provide technical expertise, to coordinate the overall efforts, and to maintain the information technology infrastructure of REACH. The ECHA Web site (<http://echa.europa.eu>) provides REACH information, guidance documents, and software tools, as well as answers to frequently asked questions.

Some substances are exempted from REACH (*e.g.*, radioactive substances, non-isolated intermediates, wastes, and substances under customs supervision) but are covered by other legislation. Minerals, ores, natural gas, hydrogen, oxygen, certain elemental substances, foods, medicines, and polymers are also exempted. All non-exempted chemicals made in or exported into the EU in volumes of one metric ton or more per year need to be registered. The annual volume of a chemical made in or exported into the EU will determine the types of data to be submitted.

REACH includes a pre-registration phase, followed by a full registration period. Prioritization of the registration process (see figure) is based on tonnage and the properties of the substance. Manufacturers or importers of existing substances should try to pre-register their substances between June 1 and December 1, 2008. The ECHA will then develop a list of all pre-registered substances and their associated companies. This will allow companies to form Substance Information Exchange Forums (SIEFs) to share information and develop the registrations. The registrations can include Chemical Safety Assessments (CSAs), and the more detailed exposure scenario-

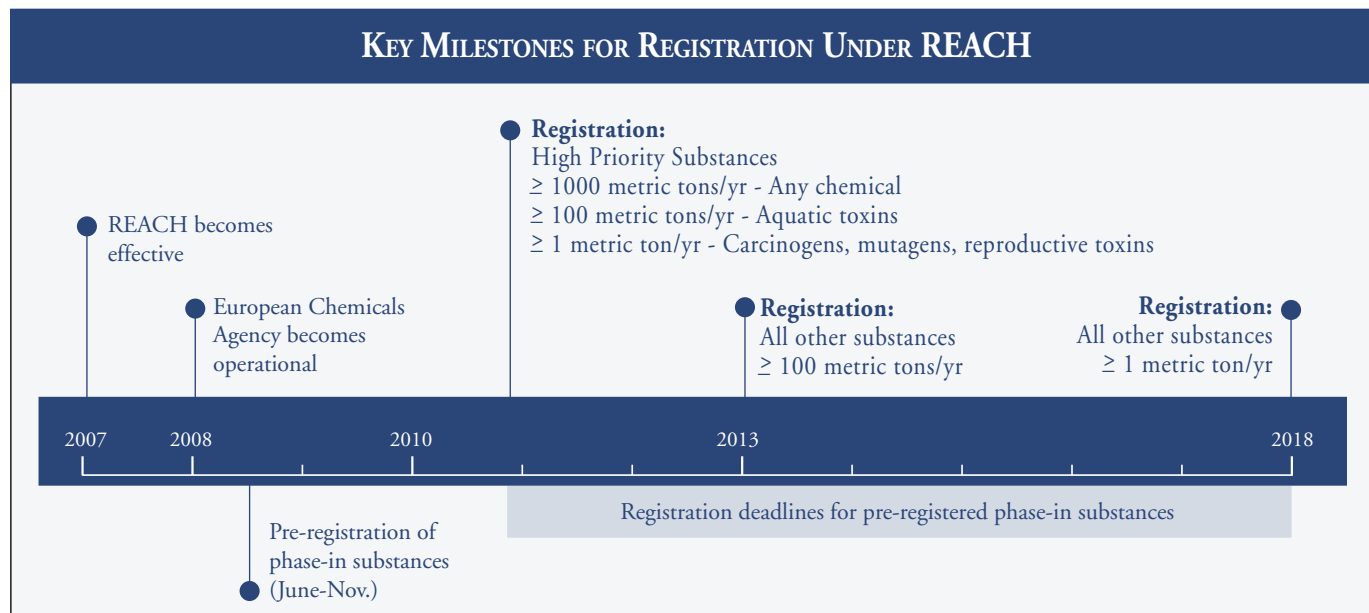
based Chemical Safety Reports (CSRs) that include operational conditions and risk management measures demonstrating how a chemical can be used safely. CSRs will be required for substances in volumes at or above 10 metric tons per year.

Communication up and down the supply chain will be very important, and each registration must cover all identified uses. Downstream users (DUs) are companies using chemicals to produce other chemicals, to make mixtures (“preparations”), and to make articles (*e.g.*, toys, household electronic devices, and clothing). A chemical used in an article must be registered if it is intended to be released under normal or reasonably foreseeable conditions of use. DUs can have suppliers include their identified use(s) in the CSR, or DUs may decide to protect their information and submit it directly and confidentially to the ECHA for review. REACH is also expected to improve the content of Safety Data Sheets (SDS) since more information will be available.

The ECHA will produce a candidate list of substances of very high concern, *e.g.*, substances that are highly carcinogenic, mutagenic, or toxic to reproduction and those that are very persistent or bioaccumulative. These substances will be subject to REACH authorization for each of their uses. Each request for authorization will need to consider including an analysis of possible alternative substances, and the availability of a suitable substitute could lead to an authorization being amended or withdrawn.

If your company does business as a manufacturer in, importer to, distributor of, or downstream user of substances in the EU, you need to understand how REACH might impact your business. It is essential to prepare for REACH now.

The author can be reached at bhakkinen@gradientcorp.com.



How Do Companies Prepare for REACH?

By Sunessa Schettler, MPH

A conscious and deliberate effort to understand the scope and impact of REACH will be critical to effective compliance.

As word of REACH and its requirements for information technology spreads, chemical industries and consumer products companies are realizing that they need a compliance plan. Companies understand that risking their EU market by being late on REACH compliance would be costly, and that early planning for REACH compliance makes good business sense.

There are three key areas in which to gather information: a company's role in compliance, availability of company resources

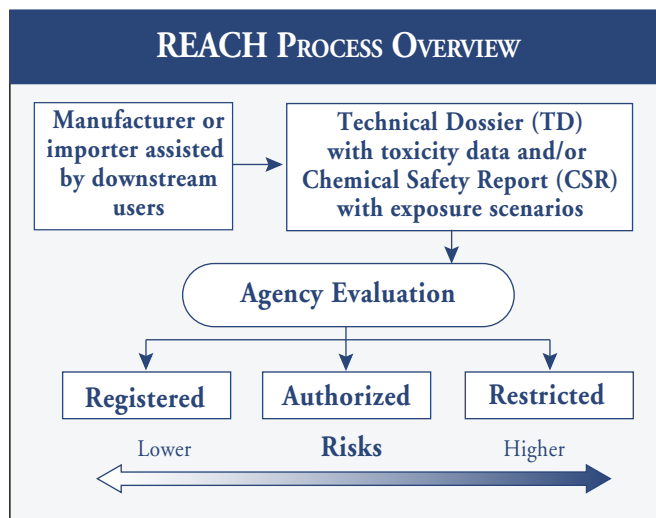
Companies understand that risking their EU market by being late on REACH compliance would be costly, and that early planning for REACH compliance makes good business sense.

for REACH compliance, and annual production information for REACH-relevant substances. First, identify whether the company is a manufacturer, importer, or downstream user of substances. This determines the company's responsibilities to register

substances for sale in Europe, or to simply communicate the general uses of substances in products to be sold in Europe. For example, the chemical manufacturer or importer of REACH-relevant substances must register each of their substances within one year of entry to market and ideally pre-register for extended registration deadlines. In contrast, a consumer product company that is a downstream user must only ensure that the uses of REACH-relevant substances in their products are registered by the substance manufacturers. Failure to do this means a loss of market because "no registration, no market" holds true under REACH.

The next step is to identify in-house resources and the need for outside assistance to accomplish REACH compliance tasks. Finding and tasking people to organize data and communicate with the supply chain is critical. Starting on June 1, 2008, manufacturers and importers will have only six months to pre-register their REACH-relevant substances in order to benefit from extended registration deadlines. Consumer product companies will need to prepare their suppliers to register or pre-register their uses in consumer products sold in the EU. Regardless of a company's role under REACH, organized and capable staff must be trained or hired now for the greatest benefit.

The final step of this simplified preparedness plan is to list annual production quantities of substances manufactured in or imported to Europe. This is the most data-intensive step in REACH preparedness and must be done by all companies,



regardless of whether the substances are sold as pure products or in consumer products. All companies doing business in Europe should list their substances and quantities now with an eye towards determining pre-registration needs prior to mid-2008.

Following these steps will facilitate the organization of people and data for REACH pre-registration and registration, allowing for the continued sale of substances and/or products in the EU. Complications will no doubt arise if REACH obligations are overlooked, roles and responsibilities are poorly understood, and registrations are delayed, incomplete, or missing altogether. Companies need to remember that they have only one year to register, unless their substances are pre-registered. Therefore, communication between downstream users and suppliers must be proactive, effective, and clear to achieve the benefit of REACH pre-registration in 2008. Companies who identify their roles, resources, and responsibilities now will be on track to meet their REACH obligations in a timely and effective manner.

The author can be reached at sschettler@gradientcorp.com.

REACH PREPAREDNESS QUESTIONS

- Does REACH apply to your company, and if yes, do you have a REACH strategy?
- Is your company ready for REACH's multi-disciplinary tasks?
- Are your suppliers ready for REACH?
- Are you able to communicate with the suppliers and buyers of your chemicals and/or products?
- Are you able to list the tonnage of each chemical that you manufacture or use?
- Are you able to effectively train your staff to gather, use, and submit REACH information?
- Do you have the needed technical resources?

Exposure Scenarios Drive REACH Analyses

By Rosemary Mattuck, M.S.

Exposure scenarios form the foundation of subsequent chemical safety assessments and chemical safety reports under REACH.

The development of an exposure scenario is a key element of REACH compliance. Exposure scenarios are the conditions of use, including risk management measures (RMMs) and operational conditions, which, when implemented, ensure safe handling and use of a substance. Exposure scenarios must account for consumer and occupational exposures, including industrial and professional exposures, as well as exposures in the environment after the product is disposed. The end result is a scenario demonstrating that risks from a substance are adequately controlled.

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Exposure scenarios form a key part of the required chemical safety assessment (CSA), and are documented in the chemical safety report (CSR). The CSR must include all reasonably foreseeable uses of the product (including intended, unintended, and accidental), associated exposure scenarios, and RMMs. Exposure scenarios will be incorporated into the Safety Data Sheet (SDS), which will follow the product down the supply chain. Inspectors will be able to check whether the use of a product is covered by one of the exposure scenarios listed in the SDS, and whether the RMMs that accompany that scenario are being implemented properly. Suppliers need to solicit input from their downstream users on how their products are being used, to ensure that these identified uses are incorporated into the SDS and CSR for the substance. Thus, communication with downstream users is essential, as they will be most familiar with how the product is being used.

RMMs form a key element of the exposure scenario. Unlike the traditional U.S. site-specific baseline human health risk assessment, which does not account for any planned remediation, exposure scenarios under REACH must document the RMMs that allow the product or substance to be used safely. RMMs fall into three categories: consumer, product-integrated, and administrative. Consumer RMMs include items such as the use of protective clothing (gloves and goggles), labeling, and instructions on proper storage, use, and disposal. Product-integrated RMMs include items such as product composition (use of a bittering agent), product packaging (child-

proof caps), and physical characteristics (gel instead of liquid). Administrative RMMs may include marketing restrictions, where a product may only be sold to industrial users. RMMs also include the waste management measures employed to reduce exposure of humans and the environment to the substance during waste disposal and recycling. An exposure scenario must also quantify the impact of the applied RMMs, *e.g.*, the reduction in exposure from wearing gloves or opening a window for ventilation.

A key technical need for REACH is the planned future development of a Web-based exposure scenario generator addressing exposures to a substance over its occupational, consumer, and environmental lifecycle. Although tools and approaches exist for assessing individual parts of this complex lifecycle, no single tool currently does it all. ConsExpo, which was developed by the Dutch Institute for Public Health and the Environment, contains a number of scenarios designed to model consumer exposures to common products like paint, cleaning products, and disinfectants. However, ConsExpo is applicable to a limited range of products and cannot be used to model occupational or environmental exposures. Given the importance of exposure scenarios in REACH compliance, new tools will need to be developed to standardize the evaluation of exposures to many types of products in different settings.

The author can be reached at rmattuck@gradientcorp.com.

For Additional Information:

De Bruin, Y.B., P. Hakkinen, M. Lahaniatis, D. Papameletiou, C. Del Pozo, V. Reina, J. Van Engelen, G. Heinemeyer, A.C. Viso, C. Rodriguez, and M. Jantunen. 2007. Risk management measures for chemicals in consumer products: documentation, assessment, and communication across the supply chain. *J. Exposure Sci. Environm. Epidemiol.* <http://www.nature.com/jes/journal/vaop/ncurrent/abs/7500587a.html>.

BY THE WAY...

The European Union is the world's largest chemical producer. The industry is Europe's third largest in manufacturing, and the EU is the main exporter in the world and the second biggest importer.

Source: European Union. 2007. "Key facts and figures about Europe and the Europeans: Trade and the economy." Accessed at http://europa.eu/abc/keyfigures/tradeandeconomy/index_en.htm.

What's New at Gradient

Recent Appointments

Julie E. Goodman has been elected secretary-treasurer of the Risk Assessment Specialty Section of the Society of Toxicology.

Perti J. Hakkinen was appointed to the Society of Toxicology's World Wide Web Advisory Committee, reappointed as Vice-Chair of the Mickey Leland National Urban Air Toxics Research Center's Scientific Advisory Panel, and reappointed to the U.S. EPA's Core Panel of experts for 2007 for the Voluntary Children's Chemical Evaluation Program.

Recent Awards

Eric J. Wannamaker and Eric Adams won the 2007 Harold Jan Schoemaker Award, given by the International Association of Hydraulic Engineering and Research, for their paper "Modeling descending carbon dioxide injections in the ocean."

Lorenz Rhomberg and **Tom Lewandowski's** "Methods for identifying a default cross-species scaling factor" has been named as the Human Health Risk Assessment Paper of the Year for 2006 by Human and Environmental Risk Assessment.

Recent Articles

De Bruin, Y.B., **P. Hakkinen**, M. Lahaniatis, D. Papatzioti, C. Del Pozo, V. Reina, J. Van Engelen, G. Heinemeyer, A.C. Viso, C. Rodriguez, and M. Jantunen. 2007. Risk management measures for chemicals in consumer products: documentation, assessment, and communication across the supply chain. *J. Exposure Sci. Environment. Epidemiol.* <http://www.nature.com/jes/journal/vaop/ncurrent/abs/7500587a.html>.

Kephalopoulos, S., Y.B. De Bruin, A. Arvanitis, **P. Hakkinen**, and M. Jantunen. 2007. Issues in consumer exposure modeling: Towards harmonization on a global scale. *J. Exposure Sci. Environment. Epidemiol.* Advance online publication doi: 10.1038/sj.jes.7500605.

Sax, S.N., P. Koutrakis, P.A. Ruiz Rudolph, F. Cereceda-Balic, E. Gramsch, and P. Oyola. 2007. Trends in the elemental composition of fine particulate matter in Santiago, Chile, from 1998 to 2003. *J. Air & Waste Manage. Assoc.* 57:845-855.

Wait, A.D. 2007. The measurement process. In Introduction to Environmental Forensics (Second Edition). (Eds.: Murphy, B.L., and R.D. Morrison), Elsevier Academic Press, p83-128.

Upcoming Presentations

New York, NY. September 24, 2007. Barbara Beck. Day Pitney LLP. "Nanotechnology: An Overview of Key Issues Affecting Industry."

Durham, NC. October 14-18, 2007. International Society of Exposure Analysis:

- **Christopher M. Long, Perti J. Hakkinen, and Peter A. Valberg.** "Do We Know Enough to Apply the 'No Exposure, No Risk' Paradigm in Safety Assessments of Nanotechnology-Based Consumer Products?"
- **Christopher M. Long and Peter J. Drivas.** "Characterizing Airborne Hydrogen Sulfide Exposure Levels Near a Midwestern Concentrated Animal Feeding Operation Using Both Measurement Data and Air Dispersion Modeling."
- **Sunessa Schettler and Perti J. Hakkinen.** "Incorporating REACH-Relevant U.S. Consumer Exposure Information into Europe's EIS-ChemRisks Toolbox."

Washington, DC. October 17-19, 2007. A. Dallas Wait. IntertechPira Regulations for Nutraceuticals Conference. "Adulteration: An Industry Dilemma."

Washington, DC. October 22-23, 2007. Lorenz Rhomberg. Resources for the Future: "Uncertainty Modeling in Dose-Response."

Ann Arbor, MI. October 25-26, 2007. Perti J. Hakkinen. University of Michigan, Bernstein Symposium on Nanotechnology and Health: Evidence and Impact. "European Perspectives on Risk, Science, Policy, and Analysis."

San Antonio, TX. December 9-12, 2007. Lorenz Rhomberg. SRA Annual Meeting: "Interpreting Dioxin Exposure Data."

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Guest Editorial: Legal Implications of REACH

By Kathleen N. Strickland, Esq.

Though the long-term legal implications of REACH cannot be predicted, certain outcomes seem likely.

There is concern that REACH's public database of chemical health risks will spawn third-party liability litigation.

REACH requires comprehensive disclosure of chemical use and toxicity, particularly for substances of very high concern (SVHCs). Chemical Safety Reports, containing both hazard and risk information for all of a substance's identified uses, will be publicized. This process has far-reaching legal implications including:

- *Responsibility for Risk.* REACH requires manufacturers or importers to demonstrate either that the risks posed by substances can be controlled adequately, or that the benefits and lack of alternatives justify the risk. REACH requires Chemical Safety Reports to evaluate the risks of SVHCs and other high-volume substances. The manufacturer or importer must show how it limits exposure risks, particularly to vulnerable populations. REACH places the burden squarely on industry to ensure that the risks to human health and the environment are adequately controlled.

- *Quality and Accuracy of Registration Information.* Companies must be truthful in registration, including both favorable and unfavorable studies on a substance. If not, REACH agencies may question why a registrant omitted information included by competitors. Registration data must fulfill detailed REACH requirements and present a convincing case for a substance's approval. To avoid product liability claims, information must be accurate.

- *Heightened Product Liability Exposure.* REACH shifts responsibilities for chemical safety reporting to the chemicals industry. Thus, it may increase the manufacturers' or importers' civil liability. There is concern that REACH's public database of chemical health risks will spawn third-party liability litigation.

REACH creates an expectation of an increased duty of care from chemical manufacturers, importers, and downstream manufacturers to provide accurate registration information for "safe" consumer products in Europe. The information provided about a product should be the same information, whether the product is sold in Europe or the United States; otherwise the door will open for product liability claims.

- *Product Liability Implications.* Consumer product companies using chemicals with known risks may face civil liabilities, particularly where safer substitutes exist. New testing may reveal new safety issues, increase civil liability, and trigger product recalls. REACH imposes a duty of care upon all manufacturers or importers not to harm a product user. For added brand protection, downstream users (DUs) of substances in consumer products would be wise to test key product constituents or have suppliers guarantee the adequacy of their test procedures.

- *Product Liability and Contractual Issues.* Contracts between manufacturers of REACH-regulated chemicals and DUs may include requirements to communicate safety information down the supply chain and downstream substance uses back up the supply chain. Upstream industry may renegotiate supply contracts, requiring disclosure of all downstream uses: a potential concern for DUs with proprietary substance use. In renegotiating supply contracts, manufacturers may also try to mitigate product risks by excluding or limiting liability for recall costs or third-party claims, placing the responsibility on the downstream user for the accuracy of the information of their use of a product as reported under REACH.

There will no doubt be substantial liability and product safety issues facing companies in order to comply with REACH. Prompt preparation will help companies meet such legal challenges expeditiously.

The author is a partner at the law firm of Ropers, Majeski, Kohn & Bentley and can be reached at kstrickland@ropers.com.

In the next issue:

Sustainability: Products, Packaging, and Our Environmental Footprint

Implications of Carbon Trading for Climate Change

Alternatives to Fossil Fuel

Guest Editorial: The Role of Sustainability in Remedy Selection

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G R A D I E N T
TRENDS
Risk Science & Application

Produced by:

Gradient Corporation

20 University Road

Cambridge, Massachusetts 02138

Phone: (617) 395-5000

Fax: (617) 395-5001

Internet: trends@gradientcorp.com

Printed on recycled paper with soy inks 