

# Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter

Vol. 8, No. 1

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## FROM THE CHAIR

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Welcome to the Pesticides, Chemical Regulation, and Right-to-Know Committee. Our Committee has been extremely busy since we kicked off our new ABA year last September. Here is a brief rundown of activities in which we are engaged, and we urge Committee members and others to let us know if you wish to become involved in any of the following activities:

■ **Nanotechnology QTs Series**—The committee, along with many other Section of Environment, Energy, and Resources Committees, has organized a series of eight Quick Teleconferences (QT) on nanotechnology. The first QT was on Oct. 26, entitled *A Science Primer on Nanotechnology*. Guests included Drs. Sunil K. Garg, The EcoShelf Group, Inc.; Kristin M. Kulinowski, International Center of Nanotechnology; and John Balbus, Environmental Defense. The second QT was on Nov. 16, entitled *Nanotechnology: What You Need To Know On the Law, Regulation, and Science Policy Overview*, and featured Dr. Jennifer Sass, Environmental Defense; Mr. Jim Alwood, United States Environmental Protection Agency (EPA); and Mr. Bill Gullledge of the American Chemistry Council Nanotechnology Panel. The third QT is scheduled for Jan. 16, 2007, and will focus on nanotechnology and the

Clean Air Act (CAA). Mary Ellen Ternes has already assembled an all-star panel to lead the discussion on air and nano issues. Confirmed panelists include Bob Martineau; Waller Lansden, former air attorney in EPA's Office of General Counsel (OGC); and Patrice Simms, Environmental Defense. The remaining QTs that are scheduled are:

- Feb. 15, 2007: *Nanotechnology and the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)*.
- March 29, 2007: *Nanotechnology and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*.
- April 26, 2007: *Nanotechnology and the Clean Water Act (CWA)*.
- May 24, 2007: *Nanotechnology and the Toxic Substances Control Act (TSCA)*.
- June 21, 2007: *Nanotechnology and Innovative Management Systems*.

■ Vice Chair Larry Cullen organized and moderated a QT on Oct. 19 entitled *Protecting Endangered Species: The Court Throws the ESA Counterpart Regulations Overboard*. Janice Walton acted as co-moderator and the panelists included former EPA General Counsel Ann Klee; Mark Dyner, OGC; Patti Goldman, Earth Justice; and Steven Quarles, Crowell & Moring.

**Pesticides, Chemical Regulation, and  
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Vol. 8, No. 1, January 2007  
James C. Chen, Editor**

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- **Keystone**—The committee also is sponsoring a session at the 36th Annual Conference on Environmental law (Keystone) on nanotechnology. Program details are evolving and committee members are urged to attend the conference.
- **ABA Annual Meeting**—The committee has also prepared and submitted on behalf of the Section a plenary session at the ABA Annual Meeting in San Francisco next August. The proposal is entitled *The Role of the Legal Profession in the Responsible Development of Nanotechnology*, and if accepted, would feature a discussion on four topics challenging the legal profession, including: human health and environment issues, right to privacy and Fourth Amendment searches, IP protection for nanotechnology innovations and the ethical implications of nanotechnology.
- **Mid-Term Elections**—The committee also organized a QT on Nov. 13 to explore the implications of the mid-term elections on environment, energy and resource issues. QT moderator Richard M. Gold, Holland & Knight, discussed election results with Michael Bloomquist, Esquire, Deputy General Counsel, Energy and Commerce Committee, U.S. House of Representatives, Washington, D.C.; Robert M. Simon, Democratic Staff Director, Energy and Resources Committee, U.S. Senate, Washington, D.C.; Martin A. Spitzer, J.D., Ph.D., Professional Staff, Science Committee, U.S. House of Representatives, Washington, D.C.; and Andrew Wheeler, Majority Staff Director and Chief Counsel, Environment and Public Works Committee, U.S. Senate, Washington, D.C.

Committee members are urged to get involved. If you think a subject merits discussion and wish to organize a QT or other program, please let Programs Vice Chair Larry Culleen or me know.

Thanks for your interest and thanks for all your wonderful ideas and help. We look forward to continuing our success this year.

## **NANOMATERIALS—THEY MAY BE NEW, BUT ARE THEY NEW CHEMICALS FOR TSCA PURPOSES?**

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**Mark Duvall**  
*The Dow Chemical Company*

Nanotechnology is an emerging area of chemistry, biology, engineering and materials science involving engineered materials with at least one dimension of less than 100 nanometers. A nanometer is a billionth of a meter. At that small scale new properties can emerge that can be both useful and hazardous. The Environmental Protection Agency (EPA) has been considering for some time how it can regulate nanomaterials under its various statutes, particularly the Toxic Substances Control Act (TSCA).

### **Nanomaterial Notice Requirements Under Section 5 of TSCA**

EPA can review the health and environmental effects of nanomaterials before they hit the market through the notice submission requirements of Section 5 of TSCA. Under Section 5, a person subject to the notice requirements must submit a notice to EPA at least 90 days prior to beginning non-exempt manufacture (or, in some cases, processing) of a chemical. (Exemptions apply for nanomaterials regulated under certain statutes other than TSCA, or for those manufactured for research and development purposes, etc.) The notice must contain readily available information on potential health and environmental effects of the chemical and potential exposure. After reviewing the information in the notice, EPA can decide to take no action, or, if it can make the requisite findings, it can issue an order (typically a consent order) limiting the conditions of manufacture (or processing) until adequate information is developed to allow a determination of whether the chemical will pose an unreasonable risk to health or the environment.

This notice submission requirement applies to new chemical substances, defined as those not on the TSCA Inventory (Inventory) and not exempt. In that case the notice is called a premanufacture notice (PMN). The same requirement also applies to uses of existing chemicals (those on the Inventory) that EPA

determines by rule are both new and significant in terms of their health and environmental risks. In that case the notice is called a significant new use notice (SNUN). EPA uses the same form for both a PMN and a SNUN.

This significant new use rule (SNUR) authority applies only once EPA has issued a rule declaring a use of an existing chemical, or category of existing chemicals, to be a significant new use. In contrast, all new chemicals are subject to the notice requirement unless exempt. To date, EPA has not issued any SNURs for nanomaterials, but it has reviewed some PMNs for nanomaterials.

### **Are Nanomaterials New Chemicals?**

EPA is said to be working on guidance, to be released in 2007, on how to classify nanomaterials as new or existing chemicals. In the meantime, nanomaterial manufacturers may want to draw on prior EPA guidance prepared for macro-scale materials to help them determine whether or not they must submit a PMN prior to commercial manufacture.

In TSCA terms, the question is whether a nanomaterial has the same “particular molecular identity” as a chemical that is listed on the Inventory. If so, it is an existing chemical; if not, it is a new chemical. “Particular molecular identity” is a function of chemical name, formula and structure.

Differences in properties are not a consideration, except for combinations of chemicals listed on the Inventory as combinations. The TSCA term for these combinations is substances of unknown or variable composition, complex reaction products and biological materials (UVCB substances). Some Inventory listings of UVCB substances do use properties, such as boiling point, to identify the combination as a unique substance. For nanomaterials that are not combinations, however, properties do not enter into consideration in deciding whether they are new or existing chemicals.

EPA is likely to regard nanomaterials having the same chemical composition and structure as existing chemicals, such as nanoparticles of gold, to be existing

chemicals. These nanoscale versions of existing chemicals may have unique properties (for example, gold particles appear to be orange, red, purple or blue at different sizes below 100 nanometers). Nevertheless, EPA's previous guidance indicates that new properties, and perhaps new hazards, are not a basis for classifying nanomaterials as different chemicals than their macro-scale counterparts on the Inventory.

Typically, nanoparticles need to be combined with other materials for their properties to be useful. For example, nanofilms and nanoarrays have been developed to exploit the properties that come with small size. Nanocolloids formed of nanoparticle cores and nanometer-thick silica shells are used to stabilize metal clusters and semiconductor particles. Nanocomposites are combinations of diverse materials having a nanoscale phase, commonly as an additive. Where there are no chemical bonds between the nanomaterials and the other chemicals in the combinations, EPA is likely to regard the combinations as mixtures. Under TSCA, a mixture is not a chemical substance (unless it was formed through a chemical reaction, as with many UVCB substances). Thus, EPA is likely to regard a combination that includes nanomaterials that are not chemically bonded to other components as an exempt mixture. The individual components of the mixture would need to be assessed individually as to whether they are new or existing chemicals.

Nanopolymers, such as dendrimers, have many potential useful applications due to their unique structures. Their TSCA status, however, would likely be considered by EPA under its guidance for how polymers of any size are classified as new or existing chemicals. Generally, this involves a determination of whether for a given polymer there is an Inventory entry for a polymer naming all monomers and other reactants used at over two percent to make the polymer. If so, that Inventory entry applies to all polymers made with those monomers and other reactants, despite differences in size, structure, molecular weight, and other factors.

Nanomaterials with new chemical compositions are likely to be regarded by EPA as new chemicals. For

example, a buckyball (a kind of buckminsterfullerene) is a molecule consisting of 60 or more carbon atoms in the form a soccer ball. There is no chemical on the Inventory with a molecular formula of  $C_{60}$ , so EPA is likely to regard such a buckyball as a new chemical. As another example, a nanomaterial may be functionalized by covalently bonding a reactive moiety to it to make the combined material more reactive. For TSCA purposes, EPA is likely to consider the combined material as one chemical. If that combined chemical is not listed on the Inventory, EPA would consider it to be a new chemical (unless exempt).

Nanomaterials with new chemical structures are also likely to be regarded by EPA as new chemicals. Carbon nanotubes, for example, can be characterized as graphene sheets coiled up into long tubes consisting of carbon atoms in a lattice structure. Due to their new structures, EPA is likely to regard carbon nanotubes not as graphite or carbon, which are existing chemicals, but as new chemicals.

Nanotube manufacturers may not agree that their products are new chemicals. Some material safety data sheets for nanotubes offered for sale on the Internet identify the nanotubes as graphite or carbon. Nanotubes are already used in consumer products such as tennis racquets and other applications due to their unusual strength. Nanomaterial manufacturers may want to have pre-notice conferences with EPA to get advice on whether PMNs are required for their products.

This analysis is incomplete and, obviously, unofficial. EPA should provide guidance to regulated entities on how it views particular kinds of nanomaterials for TSCA purposes. When it does issue guidance, it should consider some sort of mechanism for allowing manufacturers whose products turn out to be new chemicals to file PMNs without penalty. One such mechanism might be to make the guidance become effective one year from publication.

## **The SNUR Option**

For those nanomaterials that are considered to be existing chemicals, EPA can still use its SNUR authority to require submission of notices prior to

commercial manufacture or processing. This involves issuance of a SNUR through rulemaking. While EPA would prefer to avoid rulemaking where possible, the SNUR procedural requirements are not so onerous that EPA should give up on using this authority where appropriate.

SNUR rulemaking involves basic notice-and-comment rulemaking under the Administrative Procedure Act, and SNURs are reviewed under the deferential “arbitrary and capricious” test.

To issue a SNUR, EPA must conclude that a use is new and significant in terms of health or environmental risk, but the level of record evidence required for a SNUR is much lower than that required for a rule under Section 6 of TSCA, or even a test rule under Section 4.

EPA may regulate categories of nanomaterials rather than individually by nanomaterial. Categories may be based on chemical structure; physical, chemical or biological properties; mode of entrance into the human body or the environment; or any other suitable basis for classification.

In previous SNUR rulemaking EPA has been careful to ensure that the use being regulated is new, in that it is not ongoing (resuming a discontinued use is a new use under some SNURs). But EPA can also define a new use as manufacture in an amount greater than is currently being produced, or environmental release in an amount greater than is currently being released, etc. Thus, the fact that a nanomaterial or category of nanomaterials is already in commerce does not necessarily preclude EPA in appropriate cases from requiring submission of a SNUN prior to engaging in the defined new use.

### **The Nanomaterial Bottom Line**

Nanomaterials may be subject to PMN requirements, but there is uncertainty about classifying nanomaterials as new or existing chemicals. Nanomaterial manufacturers should consult with EPA prior to non-exempt manufacture. EPA should provide guidance (and help for manufacturers who may have mistakenly

considered that their products were not subject to PMN requirements).

Even if nanomaterials are considered existing chemicals, EPA can still require submission of a notice, thus giving it the same review opportunity and regulatory options that it has for new chemicals. This involves promulgation of one or more SNURs. The procedural requirements for SNUR rulemaking are the least onerous of any rulemaking under TSCA. Where health and environmental concerns warrant, EPA should consider promulgating appropriate SNURs.

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Pesticides, Chemical Regulation,  
and Right-to-Know  
Committee Newsletter

### **LIKE TO WRITE?**

The Pesticides, Chemical Regulation, and Right-to-Know Committee welcomes the participation of members who are interested in preparing this newsletter.

If you would like to lend a hand by writing, editing, identifying authors or identifying issues, please contact the editor, James C. Chen, at (202) 624-2570 or [jchen@crowell.com](mailto:jchen@crowell.com).

Back issues of this newsletter can be found at [www.abanet.org/enviro/committees/pesticides/newsletter/archive.html](http://www.abanet.org/enviro/committees/pesticides/newsletter/archive.html).

## **BATES AT ONE YEAR: AN EFFECTIVE RESOLUTION TO FIFRA PREEMPTION?**

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**James C. Chen**  
**Ashley Rivera**

In 2005, the U.S. Supreme Court addressed the breadth and scope of the preemption provision contained in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as it applies to common law tort claims. *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). As currently codified, the preemption provision contained in FIFRA provides that states may regulate the sale or use of any federally registered pesticide provided that “[s]uch State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.” U.S.C.A. § 136v(b). In the absence of instruction in the legislative history on how to interpret § 136(v)(b), pre-*Bates* courts of appeals had looked to *Cipollone v. Liggett Group, Inc.* for guidance in tort litigation against pesticide manufacturers. 505 U.S. 504 (1972). *Cipollone* interpreted the term “requirement” in the Public Health Cigarette Smoking Act of 1969 to preempt certain common law tort claims and federal appellate courts had extended this reasoning to FIFRA litigation. Not all courts of appeals applied *Cipollone* in the same way, leading to a split among the various federal circuits.

In *Bates*, a group of Texas peanut farmers alleged that their crops were severely damaged by a newly-marketed weed killer developed by Dow Agrosciences, LLC (Dow). The farmers claimed that Dow knew or should have known that use of the product in soils of a certain pH would damage peanut crops, but that Dow nevertheless claimed both on the product label and in oral sales pitches that the product could be used in all soil types. *Bates*, 544 U.S. at 434. The Texas farmers sued under several legal theories including strict liability, negligence, fraud, breach of express warranty and violation of the Texas Deceptive Trade Act. The district court and the U.S. Court of Appeals for the Fifth Circuit read the FIFRA preemption provision to preempt any state law claims in which “a judgment against Dow would induce it to

alter its product label.” *Dow Agrosciences v. Bates*, 332 F.3d 232, 331 (5th Cir. 2003). The Supreme Court reversed this holding, however, rejecting the “inducement test” employed by the Fifth Circuit as too broad. Instead, the Supreme Court articulated a two-part test for FIFRA preemption, holding that for a state rule to be pre-empted:

[f]irst, it must be a requirement “for labeling or packaging;” rules governing the design of a product, for example, are not preempted. Second, it must impose a labeling or packaging requirement that is “in addition to or different from those required under this subchapter.”

*Bates*, 544 U.S. at 444. The Supreme Court was quick to distinguish this outcome from the decision in *Cipollone* by citing the “rather obvious textual differences between the two preemption clauses.” *Id.* at 446. In *Cipollone*, the statute at issue referenced express “requirements” whereas FIFRA’s preemption provision was more narrowly drafted. As a result, the Supreme Court held that an overly broad application of the FIFRA preemption provisions was not warranted.

When the *Bates* decision was first handed down, speculation existed that the decision would spawn an excessive amount of express FIFRA preemption litigation for products liability. To date, this has not been the case. Only a handful of lower courts have had the opportunity to apply *Bates* to FIFRA preemption issues. For example, in *Peterson v. BASF Corp.*, the Minnesota Supreme Court applied *Bates* to uphold the liability of an herbicide manufacturer for engaging in fraud, deception and unconscionable conduct in violation of the New Jersey Consumer Fraud Act (NJCFRA). 711 N.W.2d 470 (Minn. 2006). In *Peterson*, a group of farmers alleged that BASF misled them into buying a more expensive product than the one they needed by means of deceptive advertising, articles in trade press and oral misrepresentations to North Dakota authorities regarding the Environmental Protection Agency’s (EPA’s) authorized uses of the product. *Id.* at 481. The court in that case held that the farmers’ claims were not preempted by FIFRA as asserted by BASF.

*Id.* The court specifically held that the farmers' claims were based on the manufacturer's marketing and advertising actions, not on the content of the product label itself. The court also noted that this conduct was analogous to the oral sales representations at issue in *Bates*, concluding:

The [Supreme] Court's rejection of the effects-oriented inducement test and its refusal to view regulation of oral statements, even those that mirror label language, as requirements for labeling or packaging, demonstrate that state regulation must be very directly related to labeling and packaging in order to invoke FIFRA preemption.

*Id.* at 479. Another case to apply the narrower *Bates* preemption standard to FIFRA litigation was *Mortellite v. Novartis Crop Protection, Inc.* 460 F.3d 483 (3d Cir. 2006). In *Mortellite*, blueberry farms and farmers sued Novartis claiming that an insecticide produced by the company damaged their plants when the insecticide was combined with a commonly used fungicide. The farmers asserted claims for strict liability, negligence, fraud, breach of warranty and breach of NJCFA. The Third Circuit, noting that *Bates* considered an almost identical question, held that the strict liability, negligent testing and breach of express warranty claims did not impose labeling requirements and thus could not conflict with FIFRA. The court pointed out:

While success on these claims may induce Defendant to change the label, this "attenuated pressure" does not amount to a "requirement" within the meaning of FIFRA's preemption provision. In other words, a manufacturer may change its label as a result of a verdict against it, but it is not *required* to do so.

The Third Circuit further held that the farmers' claims of negligent misrepresentation, fraud and breach of NJCFA, which were based on *oral* misrepresentations made to them by Novartis, were not preempted by FIFRA since these claims did not impose any specific labeling or packaging requirements. To the extent that the farmers' claims of negligent misrepresentation, fraud and breach of NJCFA were based on *written*

misrepresentations in brochures and marketing materials, such claims were preempted by FIFRA only to the extent that the claims relied on written misrepresentations that qualified as "labels" or "labeling" as defined by FIFRA. Because this question had not been fully briefed by the parties, the court remanded the case to the district court for consideration of whether the alleged written misstatements fell within FIFRA's labeling definition.

In addition to exploring the question of express FIFRA preemption, a few courts have also considered issues of implied FIFRA preemption. For example, in *Wuebker v. Wilber Ellis Co.*, the U.S. Court of Appeals for the Eighth Circuit held that state law products liability claims were neither expressly nor impliedly preempted by FIFRA. 418 F.3d 883 (8th Cir. 2005). *Wuebker* involved a farmer who sustained personal injuries when he came into contact with an insecticide. The farmer brought four claims: defective design, breach of implied warranty of fitness for a particular use, breach of implied warranty of merchantability and recklessness for failing to add coloring to the insecticide so that it could be detected when it came into contact with human skin. The court held that these claims, as pleaded, were not preempted because, "like those approved by the Supreme Court in *Bates*, the rules underlying them do not require anything in the way of labeling or packaging." *Id.* at 887. Although *Bates* only addressed express FIFRA preemption, the *Wuebker* court also declined to apply an implied FIFRA preemption defense to these facts. The court found that although there was a specific EPA regulation authorizing manufacturers to distribute the pesticide at issue without adding color, the regulation did not indicate whether EPA meant for the requirement to be a "regulatory floor or ceiling." *Id.* at 888. Because the court could not conclude that it was the "clear and manifest purpose of the EPA" to prohibit states from requiring colorization, it held that the "presumption against preemption obliges us to conclude that the [EPA] regulation does not preempt the *Wuebker*'s claims." *Id.*

Another case to consider express and implied FIFRA preemption questions is *Fox v. Cheminova, Inc.* 387 F. Supp. 2d 160 (E.D.N.Y. 2005). In this case,

commercial lobstermen from New York and Connecticut brought a class action suit against the manufacturers and producers of pesticides and insecticides for control of mosquito populations. The plaintiffs alleged that the defendants' caused a massive lobster die off in plaintiffs' fishery and brought negligence, public nuisance, strict products liability, defective design, manufacturing defects and failure to warn claims. Although the court declined to find summary judgment on either express or implied FIFRA preemption grounds, the court noted, "[t]he parties fail to flesh out the precise contours of the State labeling laws and thus this Court has no grounds upon which to decide the factual issue as it is presented in this case."

In addition to shaping future FIFRA preemption litigation, *Bates* has implications for the general framework of administrative law as well. Justice Breyer's concurrence in *Bates* stressed the role that EPA can play in determining FIFRA's "future implementation." *Bates*, 544 U.S. at 455. Specifically he noted that EPA enjoys the authority,

within ordinary administrative constraints to promulgate agency rules and to determine the preemptive effect of those rules in light of the agency's special understanding of "whether (or the extent to which) state requirements may interfere with federal objectives."

*Id.* at 454 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 506 (1996)). EPA has not yet publicly reacted to this invitation. Although there has undoubtedly been lobbying on the part of some of the agency's constituencies to issue a rule on this matter, thereby preempting a "crazy-quilt of anti-misbranding requirements," EPA has yet to make its intentions known. *Id.* at 455 (quoting Brief for Respondent 16).

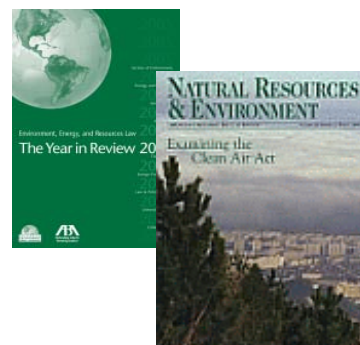
Given how recently *Bates* was decided, it remains to be seen what the impact of this decision will have on FIFRA preemption, both in terms of ensuing court decisions and the EPA's regulatory framework. Thus far, *Bates* has served to broaden the liability of the regulated community. It remains to be seen whether the "crazy-quilt" of state requirements will become a reality.

*James Chen* is a partner and *Ashley Riveira* is an associate in the Environment and Natural Resources Group of the law firm of *Crowell & Moring, LLP*. Jim's practice includes specialization in the areas of FIFRA, TSCA, EPCRA, the Clean Air Act, corporate audits and due diligence, and general environmental regulatory compliance. Ashley's practice includes environmental law and international dispute resolution. Both can be reached at (202) 624-2500 or [jchen@crowell.com](mailto:jchen@crowell.com) or [ariveira@crowell.com](mailto:ariveira@crowell.com).

**THE YEAR IN REVIEW AND NR&E  
AVAILABLE ONLINE AT  
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Section members are able to view *The Year in Review 2005* and *Natural Resources & Environment* in the Section Members Only portion of the Section Web site. The online version of *The Year in Review 2005* contains all chapters found in the paper copy, each in .pdf format. *NR&E* online contains all articles found in the paper copy, created in .pdf format. Past issues dating back to 2002 can be found in the archives page.

As a member of the Section, you have access to view both *The Year in Review 2005* and *NR&E* after logging onto the Web site with your ABA Member ID number and password.



## EPA ADVANCES VOLUNTARY NANOSCALE MATERIALS STEWARDSHIP PROGRAM

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### Lynn L. Bergeson

Over the past several months, the U.S. Environmental Protection Agency (EPA) has made significant progress advancing its Nanoscale Materials Stewardship Program (NMSP). In October, Office of Prevention, Pesticides, and Toxic Substances Assistant Administrator Jim Gulliford sent a letter to stakeholders inviting them to participate in the NMSP, which is a voluntary program that EPA's Office of Pollution Prevention and Toxics (OPPT) will manage under its Toxic Substances Control Act (TSCA) authority. According to the letter, EPA's goal is "to implement TSCA in a way that enables responsible development of nanotechnology and realizes its potential environmental benefits, while applying sound science to assess and, where appropriate, manage potential risks to human health and the environment presented by nanoscale materials." EPA states that developing a Stewardship Program will help EPA meet this goal "by generating information and providing a sound, scientific basis for risk assessment and risk management."

In the future, EPA will announce the following opportunities for public input, including:

- Public scientific peer consultations to discuss risk management practices and characterization for nanoscale materials (the first of which was convened in Washington, D.C. on Oct. 19-20, 2006);
- An overall framework document describing the TSCA program for nanoscale materials;
- A document on distinguishing the TSCA Inventory status of "new" versus "existing" chemical nanoscale materials;
- A concept paper describing EPA's thinking for the NMSP, as well as an Information Collection Request to collect data under the NMSP;
- Workshops examining the pollution prevention opportunities for nanoscale materials; and
- A public meeting to discuss these documents and NMSP elements.

As part of the process, EPA is creating an e-mail distribution list to notify interested stakeholders of all opportunities for public involvement. To subscribe to the list, stakeholders should go to [www.epa.gov/oppt/nano/nano-contact.htm](http://www.epa.gov/oppt/nano/nano-contact.htm). EPA will also provide notification of public involvement opportunities through its Web site at [www.epa.gov/oppt/nano](http://www.epa.gov/oppt/nano), by letter, or the *Federal Register*, as appropriate.

The Section of Environment, Energy, and Resources, as you know, has played an important part in the responsible development of nanotechnology. Earlier this year, Section lawyers briefed then EPA General Counsel Ann Klee on how each of the core environmental statutes would address the potential risks nanotechnology may pose to human health and the environment. The eight briefing documents are an excellent resource for anyone wishing to understand better the scope of federal statutory authority over engineered nanoscale materials and the implications of nanotechnology applications. All briefing papers are available at [www.abanet.org/environ/nanotech/](http://www.abanet.org/environ/nanotech/).

Building on the success of these EPA briefings, the committee is also sponsoring, with other Section committees and organized co-sponsors, eight Quick Teleconferences (QT), one on each of the topics of the eight briefing papers. Thus far, two QTs have taken place, one on Oct. 26 (science basics) and another on Nov. 16 (law, regulation and policy of nanotechnology). The next QT is scheduled for Jan. 16, 2007, on nanotechnology and the Clean Air Act. See the remaining schedule in the "From the Chair" column.

If anyone wishes to engage on nanotech issues, please let me know at [lbergeson@lawbc.com](mailto:lbergeson@lawbc.com). The coming year will offer tremendous opportunities for Section members to get involved in this exciting and important topic.

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## **PROSPECTS FOR CHEMICAL MANAGEMENT REFORM IN 110TH CONGRESS**

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**Malcolm D. Woolf**

### **ABA SECTION OF ENVIRONMENT, ENERGY, AND RESOURCES**

#### ***Calendar of Section Events***

##### **Litigation Teleconference Series: A Practitioner's Guide to Citizen Suit Litigation**

Jan. 16, 2007

##### **Nanotechnology Teleconference Series: The Clean Air Act and Nanotechnology**

Jan. 16, 2007

##### **Environmental Science Teleconference Series: Wetland Science and Assessment**

Feb. 8, 2007

##### **25th Annual Water Law Conference**

Feb. 22-23, 2007

San Diego, California

##### **36th Annual Conference on Environmental Law**

March 8-11, 2007

Keystone, Colorado

##### **15th Section Fall Meeting**

Sept. 26-30, 2007

Pittsburgh, Pennsylvania

***For more information, see the  
Section Web site at  
[www.abanet.org/envIRON](http://www.abanet.org/envIRON) or  
contact the Section at 312/988-5724.***

Gerald Ford was president when U.S. chemical policy was last high on Congress' political agenda. That's about to change. A number of public health, economic and political developments are expected to converge during the next Congress to compel lawmakers to reevaluate the U.S. chemical management framework. While few predict that the 110th Congress will enact fundamental changes to the Toxic Substances Control Act (TSCA), the debate over how to modernize the U.S. chemical management laws likely will begin in earnest during the next Congress.

The first signs of this debate were evident in the 109th Congress. The Government Accountability Office (GAO) issued a report in June 2005 highlighting several significant deficiencies in TSCA. GAO found that "EPA has required testing of fewer than 200 of the 62,000 chemicals in commerce when EPA began reviewing chemicals under TSCA in 1979." The Environmental Protection Agency's (EPA's) new chemical program was found to be far more robust, yet GAO still concluded that "EPA lacks sufficient data to ensure that potential health and environmental risks of new chemicals are identified."

Responding to these concerns, lawmakers for the first time proposed legislation to modernize TSCA. S.1391, the "Kids Safe Chemicals" bill, was introduced in July 2005 by Sens. Lautenberg and Jeffords with the co-sponsorship of Sens. Boxer, Kerry, Corzine, Clinton and Kennedy. Congressman Waxman introduced companion legislation, HR 4308, in the House of Representatives. In addition, in July 2006, the U.S. Senate Environment and Public Works Committee held its first TSCA oversight hearing in a dozen years.

The forces prompting this congressional debate are likely to intensify during the next year because of the confluence of three factors. First, the European Union is widely expected to adopt a sweeping new chemical law in the next several months that will likely transform

the U.S. political dynamic on chemical issues. REACH, which stands for the Registration, Evaluation and Authorization of Chemicals, will require chemical companies to submit basic information on chemical products produced over certain volumes. Significantly, REACH applies to all chemicals manufactured in or imported into Europe. As a result, U.S. companies doing business in Europe will need to develop and make public basic health and safety data on the chemicals used in production. Since most U.S. chemical companies operate globally, REACH is likely to alter their traditional reluctance to modernize TSCA. In fact, REACH might create new business pressure to amend TSCA to promote global harmonization.

This transformation in the global political and economic landscape is occurring at the same time as scientific evidence mounts establishing widespread human exposure to unreviewed industrial chemicals. Hundreds of chemicals have been detected in the umbilical cord blood of babies across the United States. In addition, in 2005, the Centers for Disease Control and Prevention found adult human exposure to virtually every one of the 148 chemicals for which it tested. The mere detection of extremely low levels of industrial chemicals in blood and tissue samples does not indicate whether adverse health impacts are likely. Yet the biomonitoring data radically alters our assumptions about human exposure and raises significant questions about whether EPA has the tools needed to effectively evaluate and manage the risks posed by industrial chemicals.

The third factor prompting renewed congressional interest in U.S. chemical policy is the promise of nanotechnology. By intentionally engineering materials at the atomic or molecular level with novel properties, nanotechnology has the potential to revolutionize fields as diverse as health care, energy and manufacturing. Public (and investor) acceptance of nanotechnology depends on whether the government is perceived as exercising appropriate regulatory oversight of the potential public health and environmental risks posed by nanotechnology. Congressional desire to promote the safe use of nanotechnologies has promoted renewed interest in modernizing TSCA so that EPA is better able to evaluate and manage nanoparticles.

The 110th Congress will be at the confluence of these transformative public health, economic and political developments. As such, U.S. chemical policy is higher on the congressional agenda than at any time in decades. Instead of focusing on *whether* to modernize TSCA, the next Congress likely will debate *how best* to build a modern chemical management policy. Comprehensive TSCA reform remains unlikely, but much of its legislative history may be written during the upcoming Congress.

*Malcolm D. Woolf is director of the Natural Resources Committee for the National Governors Association and former counsel to the U.S. Senate Environment Committee. The views expressed here are those of the author and do not necessarily represent those of the National Governors Association.*

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# U.S. IMPLEMENTATION OF THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELING OF CHEMICALS

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**Lawrence Culleen**  
**Joseph Kakesh**

Several U.S. regulatory agencies have begun considering how to implement the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) into their own regulatory regimes. The purpose of the GHS is to facilitate international trade and increase the safe handling and use of hazardous chemicals through a worldwide, uniform system for classifying and labeling chemicals. The discussion below summarizes the GHS, highlights recent GHS implementation activities by the Occupational Safety and Health Administration (OSHA) and the U.S. Environmental Protection Agency (EPA), and explains some of the most significant differences between the GHS and the current regulatory regime in the United States for dealing with hazardous chemicals.

## **The GHS**

The GHS includes two related systems for regulating chemical hazards: (1) a system for classifying chemicals on the basis of their intrinsic hazards and (2) a system for communicating information about those hazards.

### ***Hazard Classification***

The GHS hazard classification system is divided into physical, health and environmental hazards, with further subdivisions or “hazard endpoints” within each class. A chemical also may be assigned to a “hazard category,” which is a measure of the degree of hazard the substance poses. Only intrinsic hazards—those for which exposure and risk are not taken into consideration—are analyzed to determine in which hazard class and hazard endpoint a chemical belongs.

As a self-classification system, the GHS does not specify which chemicals should be deemed hazardous.

Rather, it allows regulators to choose the scientifically rigorous methods they rely on to decide whether and how a chemical should be classified. The GHS is completely test and method-neutral for health and environmental hazards, but the GHS specifies acceptable test methods for physical hazards. Perhaps most importantly, the GHS does not require new testing to determine how to classify any chemical under the system.

### ***Hazard Communication***

The GHS hazard communication system imposes uniform labeling and safety data sheet (SDS) requirements for all hazardous chemicals, and it is meant to convey information appropriate for many different populations, including workers, consumers, transporters and emergency responders.

For labels, the GHS specifies certain standardized elements, including hazard symbols or pictograms, signal words and hazard statements. Each standard label element is tied to specific intrinsic hazard class and category. A chemical deemed to pose a health hazard with category 3 acute toxicity, for example, will have specific labeling requirements regardless of whether the label is to be seen primarily by workers or end-use consumers. Although the actual layout of the label elements is not specified in the GHS, the elements themselves, including the pictogram images, are specified.

The GHS requires a SDS for all hazardous chemicals. It contains very specific instructions regarding the information and layout of the SDS, including the number of hazard communication elements and the order in which the elements are presented. The required elements—there are 16 of them—include first aid measures, accidental release measures, physical and chemical properties, and ecological information.

Although it is limited to the classification and communication of intrinsic hazards and does not mandate a particular method or system of risk communication or exposure monitoring or control, the GHS is meant to work in concert with risk management systems. The GHS allows supplemental

information specific to different audiences to be included on labels, and it includes a chapter with suggestions for non-standardized precautionary statements and pictograms, product identifiers and supplier identification.

## **U.S. Implementation of the GHS**

The GHS involves a “building block” approach, which means that regulators can decide which elements of the GHS fit best within their current regulatory regime. For example, although the GHS includes label specifications for the environmental hazard of aquatic toxicity, OSHA could choose not to implement these specifications because they lie outside of OSHA’s traditional regulatory purview. The result of this approach within the United States is that different regulatory agencies may implement the GHS differently. What follows is a short summary of recent GHS implementation activities by certain U.S. agencies, with a particular focus on OSHA and EPA’s Office of Pesticide Programs.

## **OSHA**

OSHA published an advance notice of proposed rulemaking in the Sept. 12, 2006, *Federal Register* seeking public input regarding implementation of the GHS and its impact on the agency’s Hazard Communication Standard (HCS). OSHA also published a guide to the GHS, a PowerPoint presentation, and a detailed comparison of GHS and HCS provisions, all of which are available on its Web site. In addition, OSHA began a series of public meetings to discuss GHS implementation.

### ***Hazard Classification***

The biggest difference between the HCS and the GHS lies in hazard classification and categorization. The GHS has several health hazard endpoints for each hazard class, such as mutagenicity and target system toxicity, that the HCS does not specifically recognize. In addition, the GHS has different hazard category cutoff points than the HCS as well. Fully implementing the GHS would thus require significant revisions to the HCS, some of which OSHA has indicated it would not require.

OSHA indicated its hesitance to fully implement the GHS when comparing the GHS’s and the HCS’s differing treatments of acute toxicity. HCS criteria for this health hazard include only two hazard categories, “toxic” and “highly toxic,” whereas the GHS has five hazard categories. As a result, the cut-off values for the categories are not parallel between the HCS and the GHS. OSHA has questioned whether using all five categories for acute toxicity is appropriate for the HCS, noting that category 5 was intended for consumers, whereas category 1 was intended for the transportation sector. OSHA has indicated that it might create a voluntary or guidance standard for category 4 and 5 hazards and suggest rather than require GHS-appropriate hazard communication elements for these hazards. OSHA has suggested this alternative approach also might work for many other health hazard endpoints, including skin corrosion/irritation and respiratory and skin sensitization.

Like the GHS, HCS hazard classification is a self-classification process. Under the HCS most hazard classifications are made on the basis of a one positive study threshold, which allows classification on the basis of any study that reports statistically significant results according to scientifically established principles. For most hazard classes in the GHS, however, classification is made on the basis of the total weight of the evidence, which includes all relevant information bearing on the determination of toxicity. At this time, it is unclear whether OSHA intends to incorporate the GHS’s weight of the evidence standard or continue with the one positive study threshold standard for classifying chemical hazards.

### ***Hazard Communication***

Implementation of the GHS would require significant changes in OSHA’s labeling and MSDS requirements. The HCS is “performance-oriented,” which means that it does not specify particular words, symbols, or statements to be included on a label or MSDS. For labels, the HCS states only that a hazard warning must “convey the specific physical and health hazards, including the target organ effects, of the chemicals in the containers.” GHS label standards, however, are “specification-oriented,” which means that they provide detailed requirements for the wording and symbols to

be placed on any label depending on the hazard class and category of the substance or mixture. OSHA has indicated that, consistent with the building block approach, it will select the appropriate label elements from those provided in the GHS.

The changes for MSDS would be similarly significant. The few required MSDS information elements in the HCS can be provided in any format. The GHS has very specific formatting requirements for MSDSs, however, and it requires much more detailed information than the HCS. OSHA has stated that, consistent with the GHS's building block approach, it would only require MSDSs for those health classes and categories it regulates. OSHA has acknowledged the argument, however, that in order to serve the overall harmonization purposes of the GHS it might be necessary to incorporate all 16 elements of the GHS SDS standards even for those elements OSHA does not regulate.

## **EPA**

EPA's Office of Pesticide Programs (OPP) published a white paper in 2004 describing EPA's proposed approach to implementing GHS for its pesticide programs and, like OSHA, published a comparison of GHS and OPP hazard classification and labeling requirements. Both are available on EPA's Web site. OPP also held a public meeting in October 2006 to explain the GHS and gain public input into how to incorporate the GHS into EPA's current pesticide regulations.

OPP has clearly indicated that its consideration of how to implement GHS is limited in scope, stating in its 2004 white paper that, consistent with the GHS's building block approach, OPP intends to implement the GHS only in areas over which OPP has regulatory responsibility. OPP plans to implement GHS for all types of pesticides as defined by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) but to adopt GHS hazard classification criteria and label elements only for those hazard classes for which it currently requires pesticide product hazard labeling. OPP also indicated that, because the GHS focuses primarily on intrinsic hazard classification and communication, implementation of the GHS will not

impact OPP's existing system of risk assessment, management or mitigation measures.

## ***Hazard Classification***

Fully implementing the GHS would require significant revision of OPP's hazard classification and communication system. OPP uses signal words differently than the GHS and ties these words to different hazard categories. For example, whereas the GHS has five acute toxicity hazard categories, OPP has four. The result is different thresholds for each system's hazard category, and thus, different signal words and symbols as well. OPP has indicated that, despite these differences, it might incorporate the GHS's five hazard categories for acute toxicity and all corresponding GHS label elements as well. OPP has not indicated whether it would incorporate the GHS's signal words and hazard categories in other areas besides acute toxicity, where, in general, OPP uses three signal words to communicate varying hazard levels (danger, warning and caution) and the GHS uses two (danger and warning).

The GHS's hazard classification system is consistent with OPP's in that both use a weight of the evidence standard, and both use a self-classification process. OPP and the GHS cover widely different hazards, however, and OPP likely will not implement all GHS provisions. OPP classification and communication standards for environmental hazards, for example, are much broader than the GHS, which regulates only aquatic toxicity. It is not clear that OPP would implement the GHS's aquatic toxicity standards given the broad scope of its own environmental hazard regulation. On the other hand, the only physical hazard OPP specifically addressed in its labeling scheme is flammability (although OPP sometimes does require label language to address other physical hazards besides flammability). Thus, it is unclear whether OPP will implement GHS requirements for labeling for those hazards as well.

## ***Hazard Communication***

In general, OPP appears prepared to conclude that it should incorporate the majority of the GHS label provisions. The biggest impact of doing so would be

amending OPP's regulations to include signal words on labels for certain environmental or physical hazards, which OPP currently does not address. OPP has not provided any indication that it would even consider incorporating GHS provisions governing MSDS.

## Conclusion

It appears that OSHA and EPA's OPP intend to continue down the path toward implementing some aspects of the GHS within their respective regulatory schemes for hazard classification and communication. It also appears doing so will require issuing amendments to each agency's respective current body of regulations. However, opening the existing standards to public comment through the rulemaking process is likely to be a huge undertaking for both agencies and one which, curiously, is very unlikely to result in harmonized requirements between these two agencies, much less continentally or globally.

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## **REACH: PREPARING FOR IMPLEMENTATION**

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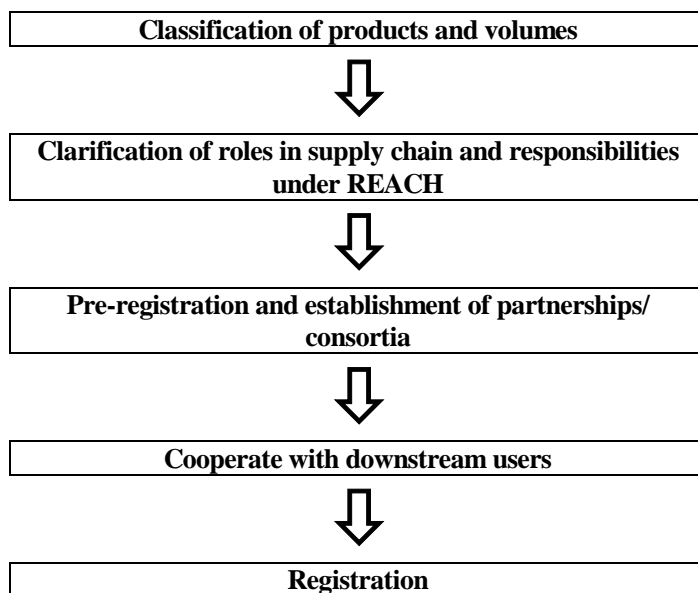
The current expectation is that Europe's new regulatory framework for the Registration, Evaluation and Authorisation of Chemicals (REACH) will be implemented in 2007. The European Council adopted its Common Position on the legislation June 27, 2006. On July 12, 2006, the European Commission issued a report in support of the Common Position. The Common Position will be discussed in a second reading in the European Parliament, although no date for this has been set, and it is expected that it will finally adopted before the end of 2006. REACH would then come into force by spring 2007 and the European Chemicals Agency would be established one year later.

As a result of the new framework, manufacturers and importers of chemicals that are placed on the market within the European Union (EU), as well as downstream users, need to begin to prepare themselves immediately for the new requirements.

Below we outline the steps that manufacturers and importers should be taking to ensure they are ready for REACH. We then describe how chemicals are classified under REACH, indicating when each category of substance should be REACH compliant and broadly summarize what companies are required to do under REACH depending on the functions they perform in the supply chain. Finally, we focus on the registration requirements that apply to manufacturers and importers of chemicals in the EU and the mechanisms that are being put in place to allow companies to participate in joint industry registrations.

### **How to Prepare for REACH?**

Table 1 illustrates the steps that manufactures and importers need to take in order to prepare for REACH, up to and including registration.



**Table 1**

<b>Volumes (tons per annum)</b>	1-10
	10-100
	100-1000
	1000+
<b>Hazardous chemicals</b>	CMR: carcinogenic, mutagenic or reproductively toxic
	PBT: persistent, bioaccumulative and toxic
	vPvB: very persistent and very bioaccumulative
	any substances of equivalent concern, <i>e.g.</i> , endocrine receptors

**Table 2**

As a first step manufacturers need to do an inventory of the substances they manufacture and import in the EU and classify them by reference to the type of substance and the volume imported.

Based on that exercise, they can then assess when they will need to be “REACH compliant,” based on the proposed timetable for implementation and establish what their obligations under REACH will be based on their role in the supply chain. In this respect, the most onerous requirements of registration fall on manufacturers and importers (although users and distributors are subject to REACH), and insofar as a

manufacturer or importer also operates as a downstream user or distributor, they will need to be aware of all REACH requirements.

For manufacturers and importers the requirements of registration are burdensome. They need to prepare comprehensive dossiers on their products and will need to collate information on exposure scenarios and provide information necessary for a full risk assessment and risk management determination. As explained below, measures are in process to enable manufacturers and importers to do this jointly with other manufacturers and importers. To this end,

Role in supply chain	Type of REACH requirements
Manufacturer/Importer (Supplier)	<ul style="list-style-type: none"> <li>➤ Develop chemical safety assessments (technical dossier, chemical safety report if &gt;10t)</li> <li>➤ Registration of chemical substances (&gt;1t)</li> <li>➤ Supply information to downstream users (safety data sheets)</li> <li>➤ Implement risk management measures</li> <li>➤ Keep information for 10-year period</li> </ul>
User	<ul style="list-style-type: none"> <li>➤ Implement recommended risk management measures</li> <li>➤ In certain cases, develop chemical safety assessments</li> <li>➤ Ensure that customers (<i>e.g.</i>, other industries and consumers) have all the information necessary to use their products safely</li> <li>➤ Communicate new information on hazardous properties and handling procedures to manufacturer / importer (or conduct own safety assessment and report to Agency)</li> <li>➤ Keep information for 10-year period</li> </ul>
Distributor	<ul style="list-style-type: none"> <li>➤ Ensure updated safety information is provided with the substances they sell</li> <li>➤ Pass on new information on hazardous properties and handling procedures to next actor up the supply chain</li> <li>➤ Keep information for 10-year period</li> </ul>

**Table 3**

manufacturers and importers need to gather information from downstream users and their sales teams should be encouraged to play an active role in this process.

### **Classification of Substances under REACH**

In classifying a manufacturer's or importer's own products, regard must be had to the amounts produced and the risk assessments attached to those products. REACH is being implemented in discrete phases, in line with the perceived risk of exposure. Accordingly, substances which are produced in the largest quantities and substances which pose the greatest hazards will be the first to be registered. The classifications of

substances under REACH can be broken down as in Table 2.

### **Different Responsibilities Depending upon Position in the Supply Chain**

The type of requirements a company has to adhere to under REACH will depend on the role that the company plays in the supply chain.

The main obligations under REACH are imposed at the level of manufacturers and importers who place a product on the market within the EU. However, where a manufacturer or importer also acts as user or distributor, additional requirements may have to be

Period	Volume (tons per annum)
12-18 months after entry into force	Pre-registration 1+
3 years after entry into force	1000+
	100+ for certain potential PBT/vPvBs (classification R50/53)
	1+ for CMRs
6 years after entry into force	100+
11 years after entry into force	1+

**Table 4**

met. Table 3 illustrates in simplified form the different roles in the supply chain that a company may have and the respective obligations attached to those roles.

### Registration Requirements

Registration is the requirement on manufacturers and importers of chemicals to obtain relevant information on their substances and to use that data to manage them safely. Registration is carried out by submitting a registration dossier to the central agency to be established. There is a general registration requirement on manufacturers and importers for substances manufactured or imported in quantities of 1 ton or above. Failure to register will mean that the substance cannot be manufactured or imported.

To compile the registration dossier, manufacturers and importers will need to obtain the necessary information on their substances to (a) assess the risk arising from the use of the substance and (b) draw up recommendations on use and handling to ensure that those risk are properly managed.

Two volume thresholds have been established which determine the level of information required. For substances manufactured or imported in quantities of 1 ton or more a technical dossier must be submitted to the agency. In addition, for substances manufactured or imported in quantities of 10 tons or more a chemical safety report must be submitted.

A technical dossier must contain information on: (1) properties, (2) uses, (3) classification and (4) safe use of the substance. Detailed rules are set out in REACH on the compilation of technical dossiers. Different levels of information is required for the volume bands 1 to 10 tons, 10 to 100 tons, 100 tons or more and 1000 tons or more. Generally, existing information can be used to compile the dossier and the framework is generally designed to limit the need for additional testing.

A chemical safety report documents the hazards and classification of a substance and the assessment of whether a substance is PBT or vPvB. For substances classified as dangerous or that are PBT or vPvB, the report must also describe exposure scenarios for specific identified uses of the substance. The exposure scenario sets out how substances are manufactured (incl. for example quantities used) or used (incl., for example, frequency and duration of operations) and recommended risk management measures, such as process control, emission control, personal protective equipment, and good hygiene and working practices. To identify the use made of a substance in addition to the manufacturer or importer's own use, downstream users must report their use upstream.

To facilitate the transition to the REACH framework, implementation of the registration requirement is done in several steps. First, a basic distinction is applied between (a) substances that are already listed in the European Inventory of Existing Commercial Chemical

Substances (EINECS) or those that have been manufactured in the Community but not placed on the Community market within the last 15 years—so-called phase-in products, and (b) substances not produced or marketed in the Community before the entry into force of REACH—so-called non-phase-in substances.

For phase in-substances, REACH foresees a transitional period ranging from 3 years to 11 years after entry into force, depending on volume-bands. To benefit from the transitional period, a process of pre-registration must be complied with, which involves submission of basic information to the agency such as name of the substance, identity of the manufacturer/importer and envisaged registration deadline. There are pre-registration deadlines of between 12 and 18 months following entry force. The volume bands and transitional periods are set out in Table 4.

For non-phase-in substances (and phase-in substances not pre-registered) registration must be completed before the substance can be marketed.

### **Data Sharing and Joint Submissions**

For pre-registration a systems of so-called Substance Information Exchange Forums (SIEFs) is set up. A SIEF will be established for each pre-registered substance and manufacturers and importers will be required to exchange information within the SIEFs to avoid duplication of testing required for registration. Manufacturers and importers should also agree on classification and labelling if differences exist.

SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies and arrange for them to be carried out.

Secondly, and also with the aim of limiting unnecessary testing, reducing the cost and increasing the efficiency of the registration system, REACH foresees that manufacturers and importers may, and in certain cases must, submit certain information jointly.

By default, where a substance is intended to be manufactured in the Community by one or more

manufacturers and/or imported by one or more importers, a “lead Registrant” shall first, and in agreement with the other Registrants, submit certain data on the hazardous properties of the substance and its classification. Then each Registrant shall individually submit information such as company details and production volume.

In addition, the Registrants may decide also to jointly submit the chemical safety report, to which end they establish consortia or partnerships within which they co-operate.

The intention is that Registrants will save money by co-operating on the preparation of the Registration Dossier, but they may opt out if the joint submission would result in excessive costs, if they cannot agree or if there is a risk of disclosure of information that would cause serious commercial harm.

Finally, it should be mentioned that concerns have been raised about the close interactions and partnerships of companies operating within data-sharing schemes and consortia and the extent to which they may raise competition concerns. In particular, companies will need to look closely at the following activities of the consortium:

- Terms and conditions of contracts used to join the consortium
- Determination of substances to be covered under the consortium and production methods (*i.e.*, if substances produced by different methods would fall with the same consortia)
- Uses of substances to be assessed
- Cost allocation
- Ownership rights for information with the consortium

### **Conclusion**

Preparation for REACH promises to be a significant undertaking for the chemical industry. However, it has become apparent that the span of REACH is so great and its onset so inevitable that the prudent course dictates immediate action to prepare for compliance.

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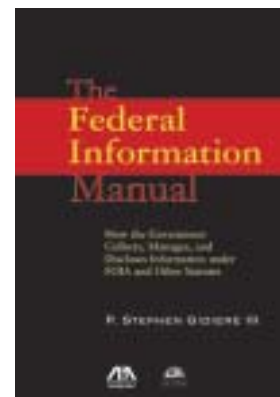
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