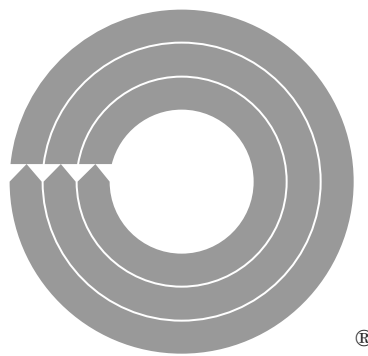


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Environmental Impacts of Emerging Contaminants

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Congress on Assessing and Mitigating Environmental Impacts of Emerging Contaminants

Presented by

Renewable Natural Resources Foundation

at

American Geophysical Union Headquarters

Washington, D.C.

December 1–2, 2005

Sponsored by

U.S. Geological Survey

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Congress Program Committee

Chair: Sarah Gerould, Contaminant Biology Program, U.S. Geological Survey (Society of Environmental Toxicology and Chemistry); **Deen Boe**, Society for Range Management; **Robert Day**, RNRF Executive Director; **Richard Engberg**, American Water Resources Association; **Peter Folger**, American Geophysical Union; **Albert Grant**, RNRF Chairman; **Cathy O’Riordan**, American Geophysical Union; **Brian Parsons**, Environmental & Water Resources Institute, American Society of Civil Engineers; **Howard Rosen**, Society of Wood Science

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Sarah Gerould served most capably as chair of the congress program committee. Sarah brought extensive knowledge and experience to the table. She presently serves as Bureau Program Coordinator of USGS's Contaminant Biology Program. Of course, the congress program was a group success and benefited from participation by all program committee members (listed on page 3).

Working group chairs presided at each of four sessions and prepared summaries that have been incorporated into this report. Serving as chairs were: **Michael Focazio** (USGS),

Sarah Gerould (SETAC, USGS), **Carl Orazio** (USGS) and **David Trauger** (Virginia Tech).

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Executive Summary

Introduction

Recent news accounts report the decline of amphibian populations worldwide, the feminization of male fish, and other disturbing trends. Our increasing use (and accompanying environmental releases) of various man-made compounds is suspected of contributing to these trends. No ecosystem is spared from potential effects from these compounds—flame retardants and other persistent anthropogenic compounds have been found even in the bloodstream of arctic polar bears.

U.S. Geological Survey (USGS) scientists recently published data on the existence of contaminants in American streams.¹ The scientists measured the concentrations of 95 organic wastewater contaminants in water samples from a network of 139 streams in 30 states representing multiple surrounding land uses. Contaminants were found in 80 percent of the streams sampled—with many samples containing multiple contaminants. Contaminants detected include steroids, nonprescription drugs, insect repellent, detergent metabolites, fire retardants, antibiotics, hormones, prescription drugs, and fragrances. For most of the compounds detected, there is no basis for limiting potentially

harmful effects—water quality standards, drinking water standards, maximum contaminant levels (MCLs) or other standards do not exist.

Recognizing the pervasiveness of and the lack of knowledge about contaminants, directors of the Renewable Natural Resources Foundation (RNRF) called a national “Congress on Assessing and Mitigating Environmental Impacts of Emerging Contaminants.” Further, evidence of the increasing environmental impacts of these compounds made explicit the need for increased knowledge and understanding within the professional and scientific community. Thus, the congress brought together a select group of professionals from RNRF member organizations and leaders from government, industry, academia, and nongovernmental organizations (see Appendix A). Delegates met December 1–2, 2005, at the headquarters of the American Geophysical Union in Washington, D.C. (see Appendix B for a copy of the congress program).

Specific goals of the congress were to raise awareness of emerging contaminants and their impacts, and to develop findings and recommendations through interdisciplinary discussion. To achieve these goals, the congress focused on the following objectives:

- Examining research and monitoring programs, and identifying adjustments required to better understand, predict, and mitigate potential impacts of emerging contaminants on human, ecosystem, and wildlife health.

- Examining current regulatory control mechanisms for a variety of emerging contaminants to identify regulatory strengths and deficiencies, and to offer potential solutions.
- To build understanding of the issue, identify the roles and responsibilities of various communities, including professional and scientific societies, public health organizations, academia, NGOs, industry, government, and the public.

Following discussion of the objectives and background information (including four case studies) in plenary sessions, delegates were divided into small working groups. These working groups examined critical issues and possible solutions in greater depth. Findings and recommendations of congress delegates do not necessarily reflect policies and views of RNRF, its member organizations, or the sponsoring agencies.

Contaminants of Concern

Pesticides and Agrochemicals

By their very use, pesticides and other agrochemicals are introduced directly into the environment. Before the development of synthetic chemicals for the control of pests, compounds such as arsenic, lead, mercury, cyanide, creosote, and tars were used. These compounds posed significant threats to the environment. The introduction of chlorinated hydrocarbons was thought to be an improvement. However, their high chlorine content made many of

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them highly persistent in the environment. They can be very toxic to aquatic species and chronic toxicity problems have been observed, particularly in birds and mammals.

The Environmental Protection Agency (EPA) recognized the need to regulate these persistent, lipophilic, bioaccumulative chlorinated hydrocarbons and to encourage the development of more biodegradable compounds.

Concerns about carcinogenicity, groundwater contamination, and acute toxicity problems shaped the development of pesticides.

Endocrine disruptors have become one of the more recent chemical classes of concern. As each new concern is raised, efforts are made to develop compounds to address to these concerns.

The synthetic pyrethroids provide an example of pesticide development, and are indicative of some of the concerns facing the environment (their development is described in the report). Several new classes of insecticides also have been developed. Some of them are very biodegradable and have mechanisms of action (MOAs) specifically targeted to insects; others are more persistent and have non-selective MOAs. New natural products also are being introduced into the market—many with highly selective MOAs.

The use of pesticides, hormones, and other agrochemicals raises numerous concerns. How persistent are they? What are the transformation products? How bioavailable are they? How selective are their MOAs? What are the potential non-target effects (humans, wildlife, aquatic and marine species, invertebrates, microbial communities) associated with their use?

Pharmaceuticals and Personal Care Products

Pharmaceuticals and personal care products (PPCPs) are a diverse group of chemicals comprising all human and veterinary drugs, diagnostic agents,

“nutraceuticals,” and other consumer chemicals such as fragrances, sunscreen agents, and excipients (“inert” ingredients in PPCP formulation and manufacturing). Thousands of distinct chemical entities in numerous (and increasing) therapeutic classes and end uses are considered PPCPs. Large numbers—by their very nature—are highly biologically active. In general, most are not regulated water pollutants.

PPCPs can enter the environment by a number of means. Domestic sewage is a major source. Portions of most ingested PPCPs are excreted primarily via urine and feces. The excreted PPCPs and derivatives can escape degradation in municipal sewage treatment facilities. The undegraded molecules then are discharged into receiving surface waters or groundwater.

Externally applied products that are not absorbed may be discharged directly to surface waters or to water treatment facilities as they are dislodged or washed off. Other potential routes include leaching from municipal landfills following disposal of unused products, the direct discharge of raw sewage, sewage discharge from cruise ships, runoff from confined animal feeding operations (CAFOs) and medicated pet excreta and other agricultural losses.

PPCPs detected in the USGS study include antibiotics, caffeine, pain relievers, antidepressants, and steroids.

The ramifications of PPCP introduction into the environment can be significant—particularly in the aquatic ecosystem. Any chemical that is introduced into aquatic ecosystems can lead to continual, multigenerational exposure for aquatic organisms. Even if the introduced compound easily biodegrades, the continual input from treated sewage may impart PPCPs with “pseudo-persistence.” The impacts of PPCPs in the environment on non-aquatic species are largely unknown, particularly when present in mixtures or at low concentrations. The poten-

tial for subtle effects raises serious concerns.

Industrial and Household Chemicals

The production and use of industrial chemicals have long been associated with society’s desire to improve life. However, some of these chemicals have proven to be harmful to human, ecosystem, and wildlife health (e.g., asbestos, PCBs, and dioxins). One group of compounds of increasing concern is the brominated flame retardants.

As increasing amounts of construction materials, furniture, and appliances were being made of plastic, concerns regarding the danger of fire, rapid ignition, fast flash-over times, and the spread of fire grew. Flame retardants were introduced into the products to mitigate some of these concerns. Because of their high efficiency and low cost, brominated flame retardants use has surpassed the use of other flame retardants. These chemicals appear in significant quantities of consumer products including electronics, carpeting, and foam containing products such as mattresses, car upholstery, and furniture.

The structures of some PBDE (a type of brominated flame retardant) metabolites are similar to the thyroid hormone thyroxine (T4), and some forms may disrupt the endocrine system. EPA scientists and other researchers expect that certain PBDE congeners likely are carcinogens, induce liver enzymes, may affect neurological, developmental, and reproductive systems, and likely are endocrine disruptors. Mammalian toxicity studies have shown decreases in thyroid hormones T4 and T3, delayed onset of puberty in female offspring, developmental neurotoxicity in mice, and neoplastic nodules in the livers of rats.

Understanding how PBDEs enter the environment is crucial for efforts to minimize exposure to both humans and wildlife. Potential sources include PBDE or polymer production sites, re-

leases from products during use, and disposal or recycling of used products.

Some of these compounds, which are ubiquitous in the U.S., have been banned in Europe. Several states have taken the lead in regulatory efforts to ban or limit the use of certain PBDEs.

Nanomaterials

Nanotechnology has been touted as the next industrial revolution. Yet, significant unknowns have raised concerns about potential releases into the environment and the impacts on human, ecosystem, and wildlife health. A vast number of nanoparticles are new chemical forms of common chemical elements. Because of their size, nanomaterials exhibit unique mechanical, electronic, photonic, and magnetic properties that may differ greatly from macroscopic versions of the same compounds.

Nanoparticles already appear in many consumer products, including cosmetics, sunscreens, wrinkle-free clothing, and food. High technology products also are being introduced.

As the quantity of nanomaterials introduced into the environment continues to skyrocket, concerns have been raised about the potential impacts on human health and the environment. The ability to image, measure, model, and manipulate matter on the nanoscale to exploit new properties and functions presents significant challenges, not only for the materials scientist, but also for those who seek to monitor and assess the effects of nanoparticles in the environment. Far less effort has gone into determining potential effects, although EPA and others have begun to support this kind of research. Preliminary studies have shown that these particles have the ability to enter vital organs including the brain.

Traditional methods of monitoring toxicity and dose concentrations would not be appropriate. Measuring effects presents additional challenges since the toxicological literature on nano-

particles currently is so limited. Once these materials enter the environment, they are not easily detected and no effective clean-up methods exist.

The ability of federal agencies to adequately regulate nanomaterials has been a subject of concern by many. Agencies believe they have the ability to regulate these materials under existing statutes. Many delegates expressed doubts about that, and had significant concerns about the numerous unknowns associated with nanotechnology.

Findings and Recommendations

Monitoring Needs

Measuring the effectiveness of regulatory activities and focusing research on topics of greatest concern is essential to the efficient use of limited resources. Environmental monitoring helps provide these measurements and this focus, yet, it chronically suffers from inadequate funding. Monitoring is useful in identifying the extent of contamination or identifying new potential contaminants of concern. It provides the vital function of helping determine if regulatory controls have adequately protected human health and the environment.

- More comprehensive and integrated monitoring systems are needed. Monitoring should include all environmental matrices including water, soil, air, sediment, biota, and food. Estuarine and marine coastal areas also must be included in any national monitoring plan. Ecosystem monitoring programs should integrate the tracking of individual organisms and populations with aspects of physical and biological habitats.
- More monitoring efforts should be based upon hypothesis-driven approaches and include scientifically based, defensible, and testable adaptive designs. More emphasis should be placed upon conducting

monitoring that assists in answering specific scientific questions rather than for compliance purposes in response to various environmental regulations.

- Long-term stability and support is necessary for monitoring programs to realize their full potential. They must be recognized as part of the solution, not merely as a mechanism for identifying problems.
- Partnerships and collaborations among stakeholders make use of limited resources and assure that necessary monitoring goals are achieved—they should be expanded, combined, and encouraged.
- Scientists should increase advocacy efforts for monitoring programs. In light of increasingly tighter budgets, members of Congress and the Office of Management and Budget are looking for justification to support monitoring activities. A coordinated response from the scientific community is necessary.
- New and unique funding mechanisms to support monitoring activities should be explored including fees on new chemical introductions, a per-pound tax on chemical production, or setting aside a percentage of fines levied for non-compliance with environmental laws.

Research Needs

Monitoring and research are complementary. As monitoring reveals the extent and effects of contaminants in the environment, research is necessary to determine the implications of such information. Additionally, understanding the fate, toxicity, and MOAs of compounds is critical to streamlining the regulatory process and predicting future compounds of concern.

- Improved coordination and sharing of information are necessary. A global contaminants entity with

subgroups focused on specific contaminant types should be formed. Such an entity could work to categorize existing research projects and outcomes to help identify gaps in knowledge.

- Federal agencies need to improve information, data, and research sharing. This could be accomplished by establishing an inter-agency working group to share information needs and address how to better integrate management and research.
- Scientists need to develop better methods for assessing the fate and effects of emerging contaminants. New or modified QSARs and models are necessary. Measurements beyond the LD₅₀ are necessary—subtle effects should be considered, and better links between acute tests and chronic effects must be established.
- Research should focus on receptors and effects in the environment rather than on individual chemical-by-chemical effects. Research designed to relate MOAs and receptors of test species with other species will help fill some of the gaps.
- The investigatory time span should extend beyond individual life cycles to examine generational effects. Evolutionary screening tools can help answer questions related to the microevolutionary impacts of contaminants. More reliable biomarkers are necessary, and connections between biomarker response and organism response should be established.
- More funding is necessary for baseline and preliminary research, which aid in the prioritization of health and environmental effects. Tax incentives could be created to encourage industries to form alliances that would support necessary research.

Regulatory Issues

Regulations are designed to protect society's interests either directly by prohibiting unwanted behavior or effects, or indirectly by encouraging a particular outcome through market forces, competition, or other means. Working-group members examined direct and indirect means to protect human health and the environment from unintended consequences of the use of chemicals.

- The current legal and regulatory framework does not predispose or encourage regulatory bodies to work together to incorporate information on exposures from chemical uses that they do not regulate. Assessments of exposures should include all sources of the chemical, and all chemicals sharing a common MOA.
- Current regulations appear to discourage the development of safer alternatives to older, more hazardous chemicals. New chemicals designed to replace existing chemicals with greater toxicity should receive special consideration such as quicker agency turnaround or fewer testing requirements to encourage development of safer alternatives. Removing the distinction between new and existing chemicals also would improve the incentives for developing safer alternatives.
- The periodic review of all chemicals (perhaps every five years) could help ensure that new information on uses, safety, disposal, and concentrations in the environment are considered in decision making on future uses of chemicals.
- Data on chemical production and disposal of waste should be made public, thus raising awareness of waste-minimization opportunities within industry, and encouraging public oversight.
- The Food and Drug Admini-

stration's (FDA) categorical exclusions may not be universally adequate—some pharmaceuticals such as hormones likely have effects below the one part-per billion (ppb) level. Additionally, concentration measurements should include all sources of the compound and all compounds with similar MOAs.

- Delegates were interested in development of programs to foster proper disposal of pharmaceuticals but recognized that there are several associated difficulties. FDA, EPA, and the Drug Enforcement Administration (DEA) should work with state and local agencies to issue guidance to industry, the public, and medical care providers regarding the proper disposal of pharmaceuticals.

Public and Professional Education Issues

A public that is educated about contaminant issues will increase the likelihood of having informed public policy and actions. Support for research and monitoring will increase as the public comes to better understand the many unknowns surrounding chemicals. Public support also will increase with knowledge of risks to human and ecological health.

- All available mechanisms should be employed to inform the public about contaminant issues, including fact sheets, websites, speakers' bureaus, expert witness databases, advisory boards, and public service announcements. Key audiences such as teachers, journalists, and elected officials should receive extra attention.
- USDA Extension Service networks at land grant universities should be mobilized to provide assistance to urban dwellers on environmentally related problems. Homeowner education is critical to deal with problems ranging

from pharmaceutical disposal to proper lawn maintenance.

- Instilling knowledge on proper pharmaceutical disposal is important. Efforts also should focus on key audiences including health-care providers, veterinarians, pharmacists, agriculture/aquaculture industries, and insurance companies. Building understanding of pollution and how everyone contributes through individual actions also is key.
- Professional and scientific societies should engage science teachers to ensure that basic concepts are part of the curriculum. Societ-

ies should become more active in state and local environmental education initiatives through their chapter networks and volunteers.

- Restoring public support for higher education can make communication efforts easier. Academic research scientists should make their research visible and relevant to the public. They should translate results into social contexts, economic impacts, and other values that are important to people.
- Universities should moderate the balance in tenure policies relative to publications and activities directed to recognizing societal out-

comes that emphasize impacts and relevance. Barriers to interdisciplinary and multidisciplinary collaborations must be overcome.

- Professional and scientific societies should become more active advocates concerning environmental issues. Public skepticism about “honest brokers” will persist in controversial issues—especially when the economic and political stakes are high. Peer review, interdisciplinary participation, and partnerships including society members and industry representatives can help overcome this skepticism.

Assessing and Mitigating Environmental Impacts of Emerging Contaminants

Emerging Contaminants: Extent and Impacts

Before offering potential solutions to perceived problems with emerging contaminants, it is essential to examine current assessment and mitigation efforts. Sarah Gerould, coordinator of the Contaminant Biology Program at the U.S. Geological Survey (USGS) and chair of the congress program committee, provided an overview of emerging contaminants including what is known and what questions remain. See <http://www.rnrf.org/2005cong/gerould.pdf>.

“Emerging contaminants” can be defined as:

- A new substance, chemical, metabolite or microorganism; or
- An older substance with a newly expanded distribution or altered release, newly recognized or poorly known effects, or a newly detected presence in the environment.

As indicated by a USGS study, contaminants have been detected in a number of U.S. streams.² See Figure 1. Equally disturbing is the relative ineffectiveness of wastewater treatment facilities to remove certain of these contaminants before discharge into receiving waters. While the removal of antibiotics can be significant, anti-epileptics are virtually unaffected by treatment processes. The removal efficiency for contraceptives varies—zero

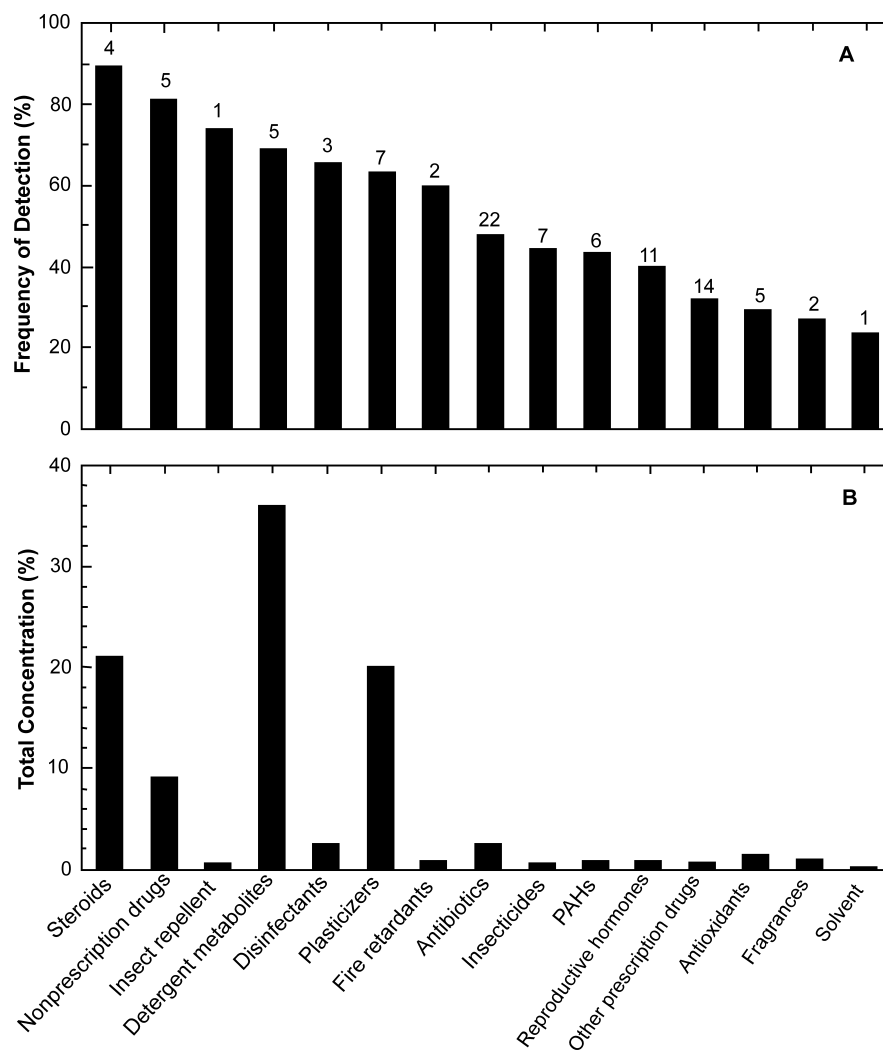


Figure 1. Frequency of detection of organic wastewater contaminants in USGS sampling by general use category (A), and percent of total measured concentration of organic wastewater contaminants by general use category (B) Number of compounds in each category shown above the bar. Source: Kolpin et. al., see note 1.

to 85 percent of estradiol is removed. For blood lipid regulators, only the metabolites are removed.³ In addition, problematic chemicals also may accumulate in municipal sludge, thereby posing a potential threat to both aquatic and terrestrial environments.⁴

The presence of these contaminants raises questions about the effects that contaminants have on wildlife and ecosystems, the ability to understand the environmental fate of these contaminants, and current regulatory efforts to control their introduction into the environment.

Fully understanding the effects of contaminants is extremely difficult. Researchers must consider effects on both individuals and the community or the ecosystem as a whole. However, as the scope of the examination increases, so too does the complexity and degree of uncertainty in the assessment. To further complicate the assessment, effects from confounding factors such as multiple contaminants, disease, other stressors, and emigration and immigration must be considered. In the field, these confounding factors make establishing proof impossible, though some degree of surety can be established by pursuing multiple lines of evidence—researchers must reconcile results based on laboratory tests with effects found in the field.

Determining the environmental fate of compounds is necessary to formulate the appropriate regulatory response and to gauge persistence in the environment. Understanding the fate of contaminants requires characterizing physical or chemical properties such as solubility in water or lipids, sorption to biota or sediments, volatilization into the air, and the compounds' metabolites and degradates.⁵

Today, the regulation of contaminants is a patchwork of laws with various mechanisms for action spread across several agencies and compartmentalized programs. Pertinent laws include the Clean Air Act; Clean Wa-

ter Act; Safe Drinking Water Act; Comprehensive Environmental Response, Compensation and Liability Act (CERCLA); Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); Toxic Substances Control Act (TSCA); Food Quality Protection Act, Federal Food, Drug and Cosmetic Act (FFDCA); and National Environmental Policy Act (NEPA). The resulting regulations have diverse means of applicability:

- Some list contaminants subject to regulation while others establish categories of chemicals.
- Some require pre-market approval, others pre-manufacture notification, and still others rely on voluntary schemes.
- The burden of proof sometimes lies with the manufacturer, sometimes with the regulator.
- The best available technology is required by some, a specific regulated use by others.
- Some require cost-benefit analysis, others prohibit them.
- Various risk-assessment mechanisms also are used.

Assessing the risk of particular contaminants is an extremely complex task. Toxicologists and regulators have developed a variety of mechanisms to fit within the existing regulatory structure. Quantitative structure activity relationship (QSAR) models use the known effects of well-studied compounds with known structures to develop models that predict effects for new or hypothetic compounds based upon structural information. See text box. A tiered testing regime is used under FIFRA—the results from an initial round of requested tests may trigger additional testing requirements. For pharmaceuticals and veterinary drugs, the Food and Drug Administration (FDA)—under NEPA—seeks a determination of no significant impact through mitigation measures specified on the label. In post-market risk assessment under the Clean Water Act, cu-

mulative loads in the form of total maximum daily loads (TMDLs) and water quality criteria and standards are useful in regulating contaminants entering water.

As the diversity of regulations shows, contaminants can be divided into multiple categories. The congress relied on case studies to examine some of these categories; their regulation; means of introduction into the environment; impacts on human, wildlife, and ecosystem health; and potential future issues. The case studies focused on pesticides and other agrochemicals, pharmaceuticals and personal care products, industrial and household chemicals (particularly brominated flame retardants), and newly developing materials (specifically, nanomaterials).

Pesticides and Agrochemicals

By their very use, pesticides and other agrochemicals are introduced directly into the environment. Joel Coats, professor of entomology and toxicology at Iowa State University, provided an in-depth examination of pesticides, their regulation, development, impact on the environment, and other concerns. See <http://www.rnrf.org/2005cong/coats.pdf>.

Since the Environmental Protection Agency's (EPA) inception, many factors have contributed to a progression of concerns and responses in the development and regulation of pesticides. Such factors include the focus from within EPA, the enforcement and amendment of FIFRA, public opinion about the state of the environment and regulatory strategies, scientific data, and lobbying efforts.

Before the development of synthetic chemicals for the control of pests, compounds such as arsenic, lead, mercury, cyanide, creosote, and tars were used. These compounds were very rudimentary and posed significant threats to the environment. The introduction of chlo-

Understanding the Chemical Universe and Environmental Monitoring

To assess risk from compounds in a comprehensive and holistic manner, it is essential to understand the actual chemical universe—all known and potential chemicals that may exist in the environment. In October 2005, over 26 million organic and inorganic substances had been documented, and nearly 9 million were commercially available.⁶ This represents a 12 percent increase over the prior year. Approximately 240,000 of these substances are inventoried or regulated by governments worldwide—that is less than three percent of those commercially available, and less than one percent of the known chemical universe.

The universe of potential chemicals, those that possibly could be synthesized and those that already exist but which have not yet been identified, is infinite. If the possibilities are limited to 30-atom structures of just carbon, nitrogen, oxygen, or sulfur, over 10^{60} possible structures can be formed! Even more compounds can be conceived if the number of elements considered is increased to include other heteroatoms (e.g., phosphorus and halogens), or if the particle size is considered to make the chemical unique, as is the case with nanoparticles.

Understanding exposure also requires reliance on environmental monitoring. However, given the significant size of the chemical universe, the spectrum of chemicals identified in a sample represent a small proportion of those present, and their significance to the overall risk to a given receptor is unknown. Environmental monitoring is limited by analytical techniques and the expectations of the monitoring entity—typically only those compounds targeted have the potential to be identified and quantified. Further, as we are able to detect lower and lower concentrations, the probability of finding additional distinct chemicals increases. At very low concentrations, the off-the-cuff truism “everything can be found everywhere” may apply.⁷

rinated hydrocarbons was thought to be an improvement because they were inexpensive and had relatively low mammalian toxicity. However, their high chlorine content made many of them highly persistent in the environment. Typically, they are relatively insoluble in water and tend to accumulate in fats. Chronic toxicity problems, particularly in birds and mammals, have been observed.⁸ Additionally, chlorinated hydrocarbons can be very toxic to aquatic species. Examples include DDT, dieldrin, and lindane.

EPA recognized the need to regulate these persistent, lipophilic, bioaccumulative chlorinated hydrocarbons and to encourage the development of

more biodegradable compounds. Thus, more biodegradable compounds such as organophosphorus and carbamate insecticides were registered. These compounds, however, had other characteristics that were not as favorable.

Concerns of carcinogenicity were manifested in the Delaney Clause, which allowed the banning from food sources or water supplies any chemical that was shown to cause cancer in any organism at any dose. This led to increased research emphasis and regulation based on carcinogenicity.

Groundwater contamination became a concern as many water-soluble compounds were shown to leach through the soil into the underlying groundwa-

ter. More water-soluble compounds were of great interest. Acute toxicity problems became known as some of the organophosphates and carbamates were found to be extremely toxic even though they were biodegradable and had few residue problems.⁹ Endocrine disruptors have become one of the more recent chemical classes of concern. As each new concern is raised, efforts are made to develop compounds to address to these concerns.

The synthetic pyrethroids provide an example of pesticide development, and are indicative of some of the concerns facing the environment. The synthetic pyrethroids initially were based on a natural product from chrysanthemums native to southwest Asia. The naturally occurring compound is very biodegradable and hydrolyzable. The toxicity to mammals also is low—a dose lethal to half of the test organisms (LD_{50}) of 1000-2730 mg/kg body weight in rats and 273-800 mg/kg in mice (see the text box for a discussion on the meaning of LD_{50}). Chemists have synthesized many variants of the natural form. The first generation of synthetics was designed to be more stable—their mammalian LD_{50} still were not of great concern. The introduction of the synthetic pyrethroid, permethrin, was a big step towards photostability but the compound remained degradable (mammal LD_{50} 400-4000 mg/kg). Newer structures such as cyfluthrin, cyhalothrin, tralomethrin, and bifenthrin have become even more stable as halogens have been added to their structures. This increased stability raises concerns about the persistence and potency of the compounds and negates some of the reasons why pyrethroids were considered attractive alternatives to chlorinated organics. Further, as compounds are more heavily halogenated, concerns about toxicity increase—particularly for aquatic ecosystems. With these changes in structure, the synthetic pyrethroids have become photostable, persistent, lipophilic, and significantly

more toxic (LD_{50} ~35-100 mg/kg)—very similar to some of the chlorinated hydrocarbons. The pyrethroids' mechanism of action (MOA) is not specific to insects—thus, they have the potential to affect many types of organisms, and are particularly toxic to fish. The pyrethroids operate by preventing the sodium gates from closing in nerves, resulting in repeated nerve impulses.

Several new classes of insecticides also have been developed. Some of them are very biodegradable and have MOAs specifically targeted to insects; others are more persistent and have

non-selective MOAs. New natural products, such as *Bacillus thuringiensis israelensis* also are being introduced into the market—many with highly selective MOAs. However, cost has been a factor in their further penetration of new chemicals into the market. Transgenic proteins are being used in crops for insecticidal properties, herbicide tolerance, or biopharming. Use of some of these proteins can reduce the need for pesticides.

Bacillus thuringiensis (Bt) is a spore-forming soil bacterium that produces insecticidal endotoxins. Its use has

quadrupled from 1998 to 2002, raising concerns about the number of unknowns associated with its use. Degradation of the toxin produced in plant material and soil is poorly understood. Further, there are wide variations in its persistence data because residue analysis is particularly difficult. The bioavailability of the endotoxin is a significant question for risk assessors.

Veterinary antibiotics and other pharmaceuticals also are an area of recent concern. Their presence has been detected in many waters, but at low concentrations (parts-per-billion to parts-per-trillion). Questions have been raised about their persistence in the environment and possible contributions to the development of drug-resistant microbes.¹⁰ Additional questions have been raised about other effects that they may have on endocrine disruption and microbial communities in the environment and in the gut of animals.

The use of pesticides, hormones, and other agrochemicals raises numerous concerns. How persistent are they? What are the transformation products? How bioavailable are they? How selective are their MOAs? What are the potential non-target effects (humans, wildlife, aquatic and marine species, invertebrates, microbial communities) associated with their use?

Pharmaceuticals and Personal Care Products

Pharmaceuticals and personal care products (PPCPs) are a diverse group of chemicals comprising all human and veterinary drugs, diagnostic agents, “nutraceuticals,” and other consumer chemicals such as fragrances, sunscreen agents, and excipients (“inert” ingredients in PPCP formulation and manufacturing). Christian Daughton, chief of the Environmental Chemistry Branch in EPA's Office of Research and Development laboratory in Las Vegas, provided a comprehensive overview of PPCPs, their origins in the environ-

Determining Risk: QSARs and LD_{50} s

Quantitative Structure Activity Relationship (QSARs) models and the Lethal Dose 50 (LD_{50}) are important tools that toxicologists use to begin assessing the physical and chemical properties, fate, and toxicity of chemical compounds. While these tools can provide valuable insight into a compound's toxicity, the usefulness of the information is limited. They are best used for prioritizing research and regulation in the face of limited resources and data gaps.

QSARs are computer models that predict how a chemical will behave based on its structure and the structures of compounds with known effects. This allows prediction of the toxicity without extensive laboratory testing. Should the QSAR reveal concerns, further testing of the compound in the laboratory would be warranted. These models are particularly important to EPA as they allow for a preliminary assessment of novel compounds for which little test data are available. While QSARs are extremely valuable, they are effective only for structures with known toxicological effects. New compound types, such as nanoparticles, should not be assessed using QSARs. Little is known about the effects of materials with these or similar structures. As you will see elsewhere in this report, nanoparticles do not exhibit the same characteristics as their molecular components. New QSARs for these materials will need to be developed.

A very basic assay used for testing toxicity is the LD_{50} . This measurement reflects the amount of a compound that kills 50 percent of the test organisms in one exposure in a given period. The dose measurement is the amount of substance that enters the body. While important for determining acute effects of a single, large-dose exposure to a compound, the assay is not helpful for examining chronic or long-term effects requiring more complex testing. Somewhat more information would be provided if the whole dose response curve were used in order to determine a LOEL (Lowest Observed Effect Level). The LD_{50} is used for chemicals orally ingested, dermally absorbed, or injected in the mg/kg range. A related measurement is LC_{50} , the concentration necessary to kill 50 percent of the test organisms. The lower the LD_{50} or LC_{50} , the more acutely toxic the substance.

ment, their effects, and potential concerns for the future. See <http://www.rnrf.org/2005cong/daughton.pdf>.

While PPCPs likely have been present in the environment since their commercial introduction, it is the understanding of the significance of their occurrence that only now is beginning to be understood. Initial investigations into PPCPs as environmental pollutants began in Europe in the 1980s. With increased monitoring and research in the U.S., the literature has grown exponentially since 2000. The overall issue comprises numerous facets involving expertise from a broad spectrum of disciplines ranging from human health to ecology.

Thousands of distinct chemical entities in numerous (and increasing) therapeutic classes and end uses are considered PPCPs. Large numbers—by their very nature—are highly biologically active. In general, most are not regulated water pollutants.

PPCPs can enter the environment by a number of means. Domestic sewage is a major source. Portions of most ingested PPCPs are excreted primarily via urine and feces. Both the parent compound and its metabolites may be bioactive. Conjugates formed in the body may be hydrolyzed back to the parent drug compound in sewage treatment plants. As indicated previously, the excreted PPCPs and derivatives can escape degradation in municipal sewage treatment facilities. The undegraded molecules then are discharged into receiving surface waters or groundwater. All municipal sewage will contain PPCPs regardless of location—only the types, quantities, and relative abundances of individual PPCPs will vary by geography.

Externally applied products that are not absorbed may be discharged directly to surface waters or to water treatment facilities as they are dislodged or washed off. Other potential routes include leaching from municipal landfills following disposal of un-

used products, the direct discharge of raw sewage, sewage discharge from cruise ships, runoff from confined animal feeding operations (CAFOs) and medicated pet excreta and other agricultural losses.

Some contaminants may be introduced into the environment by multiple mechanisms—some personal care products contain conventional pollutants and some drugs may be used as pest control agents. Ayurvedic and folk remedies can contain metals such as lead. Skin lightening creams and disinfectant soaps can contain mercuric iodine and ammoniated mercury. Lice and tick shampoos can contain lindane and permethrins. Shampoos and soaps can contain alkylphenolic surfactants. Caffeine has been used for the control of frog pests in Hawaii, and acetaminophen has been helpful in controlling brown tree snakes in Guam.

The ramifications of PPCP introduction into the environment can be significant—particularly in the aquatic ecosystem. Any chemical that is introduced into aquatic ecosystems can lead to continual, multigenerational exposure for aquatic organisms. Even if the introduced compound easily biodegrades, the continual input from treated sewage may impart PPCPs with “pseudo-persistence.” Crucial defense mechanisms of aquatic organisms such as efflux pumps may be inhibited. The potential also exists for the presence of subtle effects even at parts-per-billion levels (ppb).

The potential for subtle effects raises serious questions. Could immediate biological actions on non-target species be imperceptible but nonetheless lead to adverse impacts because of sustained, low-level effects over long periods? Could subtle effects accumulate so slowly that major outward change cannot be ascribed to the original cause? The causes of population declines and changes in community structure are difficult to diagnose, in any case. Effects too subtle for direct de-

tection may go unnoticed thereby presenting a challenge to risk assessment. Advances are necessary in developing new aquatic toxicity tests to better ensure that such effects can be detected. Examples of subtle effects include the inhibition of sperm activity in certain aquatic organisms by calcium channel blockers; various drugs at the parts-per-million (ppm) level and below can affect collagen metabolism in fish leading to defective or blocked fin regeneration; and antiepileptic drugs have the potential to be human neuroteratogens which can lead to neurodegeneration.

Another considerable long-standing challenge and area needing expanded research is understanding the many unknowns associated with effects from simultaneous exposure to multiple chemical stressors over long periods of time. See the accompanying text box for a discussion of the complexity associated with chemical mixtures and other sources of exposure.

As human population grows and new technologies are developed, new concerns about PPCPs could emerge. As pressure grows to re-use wastewater, increasingly shorter recycling loops will be necessary. Ever-shortening spatial and temporal hydrologic connectivity between the point of wastewater discharge and the point of use for drinking will pose serious challenges for ensuring human safety and for framing how risk is perceived by the public. Biopharming and the impact of engineered nanoscale materials and structures and other applications of nanotechnology (particularly nanomedicine) raise many unknowns about the fate of bioactive compounds in and ramifications for the environment.

PPCPs provide a unique perspective on humans’ interconnectedness with the environment. Their occurrence in the environment mirrors the intimate, inseparable, and immediate connection between the actions and activities of individuals and their environment.

Their origins in the environment are due to the worldwide, universal, frequent, and highly dispersed but cumulative usage by multitudes of individuals. They also reveal many interesting facts about the public's understanding of risk. For instance, the practice of applying high concentrations of chemicals to the skin as dermal products is deemed acceptable while low concentrations of the same chemicals in the environment are deemed unacceptable. The approaches used by social scientists are needed to adequately communicate risk—science cannot do it alone.

Industrial and Household Chemicals

The production and use of industrial chemicals have long been associated with society's desire to improve life. However, some of these chemicals have proven to be harmful to human, ecosystem, and wildlife health (e.g., asbestos, PCBs, and dioxins). One group of compounds of increasing concern is the brominated flame retardants. Carl Orazio, branch chief of environmental chemistry, USGS Columbia Environmental Research Center, provided an overview of flame retardants (specifically brominated flame retardants) including their history, exposure levels, monitoring efforts, regulatory efforts, and ongoing research efforts. See <http://www.nmf.org/2005cong/orazio.pdf>.

The story of brominated flame retardants as emerging contaminants begins in the 1960s when the polymer industry entered a time of rapid expansion. As increasing amounts of construction materials, furniture, and appliances were being made of plastic, concerns regarding the danger of fire, rapid ignition, fast flash-over times, and the spread of fire grew. Flame retardants were introduced into the products to counteract some of these concerns (nearly 200 different types exist). Choosing a flame retardant for a particular application requires careful

matching to the base polymer to assure that the desired characteristics and properties are maintained.

Some flame retardants work by physically coating the fuel. This mechanism leads to cooling and formation of a protective layer of solid or gas that shields the combustibles or by diluting the combustibles or gases thus re-

ducing ignition. The most effective flame retardants (like the brominated flame retardants) interfere with the combustion process. During the combustion process, highly reactive H and OH radicals are released. The brominated flame retardants release reactive bromine, which binds to these radicals thus stopping the heat generation pro-

Complexities in Risk Assessment: Mixtures and Sensitivities

Currently, the pre-market regulation of compounds largely focuses on individual compounds. However, water samples from across the country reveal that contaminants rarely occur in isolation.¹¹ Therefore, organisms and ecosystems are exposed to numerous compounds and other stressors (disease, noise, predation, etc.) that individually may have no noticeable impact, but when present in mixtures may have observable effects.

Understanding the toxicological effects of mixtures is extremely difficult—several processes may be causing observed effects. Additive effects from multiple agents sharing common MOAs may cause individual concentrations to combine to exceed the effects level. Interactive effects, especially synergism, may cause the combined effects to exceed the sum of the individual effects. Significant research is needed in this area to understand and predict the toxicological effects of mixtures. The use of genomics may ultimately help scientists to understand these interactions.

Gauging the sensitivity of organisms to specific contaminants (and mixtures) also is very complicated. Risk assessors must be cognizant of many potential factors related to sensitivity. Toxicant-induced loss of tolerance (TILT) occurs when an initial exposure sensitizes the organism, and subsequent exposures to levels below those previously tolerated trigger symptoms. Susceptible genetic outliers also may exist within a species. Hormesis is the occurrence of effects below the purported no observed effect level (NOEL)—the paradoxical U or J shaped dose response curve. Conversely, continual exposure will favor individuals that are not adversely affected, and populations may change in response to these exposures. Answering when and why such dose effects occur can help improve predictive abilities and lead to more effective regulation.

Delegates and speakers identified other unknowns in need of study. Comparatively little research currently is performed at extremely low concentrations. However, some agents may have the ability to produce previously unrecognized effects at ultra-trace concentrations. Predicting potential effects depends on the ability to understand what characteristics make an organism susceptible (the receptor repertoire) and the mechanisms by which compounds disrupt the normal functions of an organism (MOA). The receptor repertoires of non-target species are poorly characterized—variations across species and their unknown overlaps with humans lead to questions regarding potential effects. Additionally, the MOAs of the vast majority of compounds are not fully understood—even for humans.

cess and reducing the available supply of flammable gases.

Because of their high efficiency and low cost, brominated flame retardants use has surpassed the use of other flame retardants. Approximately 75 commercial brominated flame retardants are manufactured. However, polybrominated diphenylethers (PBDEs) account for 60 percent of the brominated flame retardant market. PBDE commercial formulations are classified and named according to the average number of available bromines on the PBDE (formulations from highest to lowest level of bromination: Deca-, Octa-, and Penta-). Deca-PBDE is the most common representing 80 percent of worldwide PBDE production. Deca-PBDE primarily is used in electrical applications, including electronic equipment, and in backcoating of textiles. Octa-PBDE is used in plastic housings and smaller components in office equipment. Penta-PBDE is used in foam products (i.e., upholstery, car seats, mattresses, etc.) and can account for up to 30 percent of the foam's weight.

The range of some PBDE characteristics is similar to PCBs with high lipophilic character, low water solubility, and low volatility. They generally are predicted to sorb to soil and sediment with limited water solubility. In the air, they primarily sorb to particulates rather than existing in the vapor phase. While the higher brominated PBDEs are relatively larger, environmentally immobile, and less bioavailable, they can undergo debromination becoming more mobile, more volatile, more bioavailable, and perhaps more toxic. This debromination may occur due to sunlight exposure, metabolism, or anaerobic degradation.

The structures of some PBDE metabolites are similar to the thyroid hormone thyroxine (T4), and some forms may bind to the transthyretin transport protein, which is involved in the endocrine system by carrying T4 in the plasma to target tissues. EPA scientists

and other researchers expect that certain PBDE congeners likely are carcinogens, induce liver enzymes, may affect neurological, developmental, and reproductive systems, and likely are endocrine disruptors. Mammalian toxicity studies have shown decreases in thyroid hormones T4 and T3, delayed onset of puberty in female offspring, developmental neurotoxicity in mice, and neoplastic nodules in the livers of rats.

Awareness of PBDE contamination began in the early to mid 1990s as environmental chemists began finding unknown bioconcentrated contaminants in fish and wildlife. These contaminants turned out to be PBDEs. A Swedish study using archived breast milk samples from the 1970s to the late 1990s found a dramatic increase in PBDEs while other contaminants, like DDT and PCBs, were trending downward. A similar study in North America found PBDE levels in breast milk ten to 20 times European levels, with a doubling every two to five years. Researchers also found that the levels of PBDEs in fetuses and mothers are comparable indicating that fetuses were exposed to PBDEs during development.

Recent studies indicate that human exposure likely is through indoor air and diet. A study of U.S. indoor air found ten to 10,000 ppb total PBDEs in dust. A food basket survey found levels to be as high as 2835 pg/g in chicken liver, 616 pg/g in fish, 190 pg/g in meats, 180-680 pg/g in cheese and dairy products, and approximately 10 pg/g in milk. Generally, U.S. food had PBDE levels 20 times higher than food in Europe.

Understanding how PBDEs enter the environment is crucial for efforts to minimize exposure to both humans and wildlife. Potential sources include PBDE or polymer production sites, releases from products during use, and disposal or recycling of used products. Streams receive waste from textile in-

dustries, polymer trimmed scraps are sent to landfills, and wastewater is sent to water treatment plants. While in use, certain PBDE containing products may release PBDEs, exposing the user and contaminating the environment. PBDE containing products are dumped, landfilled, incinerated, or stored for recycling.

Leachate from landfills was found to contain ten to 100 ng/L of total PBDEs. Wastewater treatment plant sludge contains thousands of ng/L of various PBDEs. Leachate and sludge can move into surface water, ground water, and the air. Concerns about recycling and dismantling processes also have been raised.

In the automobile recycling industry, fabrics and foam from the seats and dashboard are shredded for eventual recycling. These shredded piles remain exposed to the elements with the potential for leaching of PBDE and other contaminants. Nearly thirty million computers are thrown out every year in the U.S. alone, many of which are sent to China and India for dismantling. While awaiting dismantling and recycling, PBDEs may be released as vapors, particulates, or leachate. Computer recycling involves the extraction of parts that can be used again while the remainder is burned or buried, potentially releasing hazardous substances into the environment. A study of electronics dismantlers showed decreased thyroid hormone levels as compared to other occupations. Several computer manufacturers have voluntarily phased out the use of PBDEs.

Tracking PBDEs in the environment back to their initial source is difficult. It requires a forensic chemical analysis approach. Various forms of PBDE are subject to degradation and loss processes, so the mixture found is unlikely to retain the characteristic signature of the initial commercial mixture.

Several regulatory efforts are underway to ban or limit the use of certain PBDEs. In 2003, California began

Reducing Exposure to PBDEs

Many household and workplace items from chairs and couches to computers contain PBDEs. Delegates expressed concern that many people (including many of them) had no idea of how to determine if items contained PBDEs and where PBDE-free products could be purchased.

Despite a growing body of research on PBDEs and their impact on human health and the environment, scant resources exist for consumers interested in reducing their exposure. As indicated elsewhere in this report, penta- and octa-PBDEs already are being phased out in many states, which likely will prompt product manufacturers to develop new products that will be available nationwide. However, deca-PBDE-containing products may still be produced. Europe is requiring deca-PBDE-free computers and televisions, which may end up benefiting the rest of the world.

Following are some pointers for reducing exposure to PBDEs:

- Eat a heart-healthy diet low in fat and high in vegetables, fruit and whole grains (PCBs, PBDEs, dioxins, and other bioaccumulating, persistent organic pollutants tend to reside in animal fats)
- Keep household and workplace dust down. Use a HEPA filter vacuum that traps fine particles of dust, soot, and pollen, or wet-mop regularly, and keep your home or office well ventilated.
- Carpets: Vacuum regularly and consider replacing carpets and underlayments (a trap for allergens and sources of PBDEs). Washable throw or area rugs made from natural fibers are good substitutes for wall-to-wall carpeting, which collects dust and chemicals.
- Furniture: Consider removing worn-out, damaged foam furniture, especially if the foam is exposed, loose, and crumbling. Ask about the composition of seating and cushions to make sure they do not contain chemical flame retardants. Non-synthetic fibers such as naturally flame retardant wool make good alternatives.
- Mattresses: Check the consumer label to see if it contains polyurethane foam. If so, ask the manufacturer if the foam contains PBDEs, and if it does, consider purchasing a tightly woven allergen barrier to reduce leaching. When choosing a new mattress, look for a natural fiber mattress with a wool wrap and California's Bureau of Home Furnishings TB106 standard to assure you have a safe natural fiber mattress.
- Computers and televisions: Keep computers and televisions turned off when not in use to avoid heating up and burning off flame retardants. Regularly clean electronics and nearby surfaces with a cloth. When retiring an old computer, choose a reliable recycler or charity (IBM, HP, and Dell have recycling programs for all computer brands; Ebay and the Rethink Initiative offer ways to sell, donate, and recycle old electronics, see <http://rethink.ebay.com>). Look for new electronics with metal cases or inherently flame resistant plastic such as Toshiba's polyphenylene sulfide or NEC's biobased plastic. Look for products certified by Europe's TCO label, Germany's Blue Angel, or the Nordic Swan (may require research to match model numbers as products sold in the U.S. may not have the labels).
- Retailers: Ikea products have been PBDE free since 2001 (mattresses, carpets, furniture, <http://www.ikea-usa.com>); Electronics companies removing PBDEs from products include: Apple, Canon, Dell, Fujitsu, HP, Hitachi, IBM, Intel, Panasonic, Motorola, NEC, Philips, Seimens, Sony, and Toshiba. See <http://www.thegreenguide.com> for other PBDE-free product sources.

Sources:

McRandle, P.W., Learning Hazards: Toxic Fire Retardants and How to Avoid Them in Consumer Products and Food. The Green Guide, 2005.

Greenpeace UK, The Chemical House, <http://www.greenpeace.org.uk/Products/Toxics/chemicalhouse.cfm>

phasing out the manufacture, processing, and distributing of products containing penta- and octa-PBDE, with a complete ban by 2008. Several other states are following California's lead. Japan has instituted a voluntary phase out of penta- and octa-PBDE, and the European Union banned penta- and octa-PBDE effective August 2004. The sole U.S. manufacturer of penta- and octa-PBDE reached a voluntary agreement with EPA and ceased production of penta- and octa-PBDE in December 2004.

Key activities currently underway at EPA include assessing the risks and potential substitutes of penta- and octa-PBDE, assessing and evaluating deca-PBDE, and tracking developments concerning other brominated flame retardants.

Continuing research on PBDEs is necessary, particularly in the following areas:

- Determining the toxicities of different PBDE forms and mixtures;
- Environmental degradation rates of various PBDEs;
- Mobility of PBDEs in soils and leachate from landfills;
- Occurrence and distribution of PBDEs in the environment;
- Detrimental effects of PBDEs on fish and wildlife; and
- Implications of incineration of PBDE containing products including the possible production of halogenated dioxins and furans.

Nanomaterials

Nanotechnology has been touted as the next industrial revolution. Yet, significant unknowns have raised concerns about potential releases into the environment and the impacts on human, ecosystem, and wildlife health. E. Clayton Teague, director of the National Nanotechnology Coordination Office, provided an overview of the technology, described the role of the federal government in addressing con-

cerns and encouraging research, and discussed the regulatory mechanisms available.

Today, much of the nanotechnology development effort is aimed at understanding and controlling matter at dimensions of one to 100 nanometers (nm)¹² and to integrate those properties and functions into systems spanning from the nano to macroscopic scales. New products result from research to understand, create, and use structures, devices, and systems that have fundamentally new properties and functions because of their nanoscale structure. The ability to image, measure, model, and manipulate matter on the nanoscale to exploit these properties and functions presents significant challenges, not only for the materials scientist, but also for those who seek to monitor and assess the effects of nanoparticles in the environment. Far less effort has gone into determining potential effects, although EPA and others have begun to support this kind of research.

A vast number of nanoparticles are new chemical forms of common chemical elements (e.g., fullerenes or nanotubes of carbon, titanium dioxide, zinc oxide, and other layered compounds). Because of their size, nanomaterials exhibit unique mechanical, electronic, photonic, and magnetic properties that may differ greatly from macroscopic versions of the same compounds. Chemical reactivity of nanoparticles also is greatly different from macroscopic forms, but not well understood. The difference in chemical reactivity may be partially due to the increase in surface area per unit mass—approximately 1,000 m²/g.

Nanoscale particles have long existed and been the subject of concern (e.g., ultra-fine and nanoscale particles from welding fumes and smelters). Inhalation of such particles has proven harmful. However, engineered nanoparticles do exhibit key differences—they can be engineered and manufac-

tured in controlled ways, the tendency to conglomerate can be controlled, and they may exist in a particular shape, such as a nanotube.

Nanotechnology development is expected to progress through four phases. The development of passive nanostructures such as coatings, nanoparticles, nanostructured metals, polymers, and ceramics is estimated to have begun during 2000. Today, development is beginning on active nanostructures such as 3-D transistors, amplifiers, targeted drugs, actuators, and adaptive structures. By 2010, systems of nanosystems such as guided assembling, 3-D networking and new hierarchical architectures, robotics, and evolutionary systems are expected to be underway. Finally, around 2015 to 2020, molecular nanosystems including molecular devices by design, atomic design, and emerging functional systems could emerge.

Nanomaterials already appear in many consumer products, including tennis rackets, bicycle frames, and tennis and golf balls. High technology products such as thin films for bonding different kinds of materials, biocompatible materials for medical applications, and quantum dots for tracking activities within cells also are being introduced.¹³

As nanotechnology continues to develop, concerns have been raised about the potential impacts on human health and the environment. Traditional methods of monitoring toxicity and dose concentrations, such as accumulated mass, would not be appropriate. Better measurements could include particle number, density or particle counts on a surface area basis, if microscopy is the only way to accurately measure the particles. Assessment must account for surface reactivity. Measuring effects presents additional challenges since the toxicological literature on nanoparticles currently is so limited.

In October 2000, the federal government formed the National Nano-

technology Initiative (NNI) to reap the full benefits of the new technology and address some of the concerns. NNI is a collaborative, multi-agency, crosscutting program among 24 federal agencies to enhance knowledge creation and development and application of nanotechnology in support of agencies' missions. Interagency efforts are fostered through communication, coordination, and joint programs. The planning, management, and coordination of the initiative is overseen by the National Science and Technology Council's Nanoscale Science, Engineering, and Technology subcommittee (NSET). The National Nanotechnology Coordination Office serves as the secretariat of the subcommittee providing technical and administrative support.

Much of the current NNI research is designed to understand the nature of nanomaterials and their interaction with environmental and biological systems with respect to both potential beneficial uses and those that might be potentially harmful. In addition to this basic research, research directed toward risk related studies of nanomaterials currently in use is being conducted (approximately \$38.5 million has been allocated).

The Nanotechnology Environmental and Health Implications Working Group is a multi-agency subgroup of NSET, chaired by FDA, that addresses some of the environmental and health concerns associated with nanotechnology. It is a forum for the exchange of information across agencies and to facilitate the communication, identification, prioritization, and implementation of environmental, health, and safety research.

The working group's efforts have resulted in the development of position statements by regulatory agencies of how they are interpreting their regulatory authority with respect to nanotechnology materials and products. The National Institute for Occupational Safety and Health (NIOSH), the Consumer Products Safety Commission (CPSC), and FDA already have produced such statements.¹⁴ An EPA white paper on nanotechnology currently is in draft form and is expected to be released in June 2006.¹⁵ Preliminary recommendations for working with nanoengineered materials were issued by NIOSH.¹⁶ A research needs document developed with input from industry and non-governmental organizations (NGOs) was in the final stages of review at the time of the congress.¹⁷

The ability of federal agencies to adequately regulate nanomaterials has been a subject of concern by many. However, agencies believe they have the ability to regulate these materials under existing statutes (including TSCA, Clean Air Act, Clean Water Act, FIFRA, and waste management statutes at EPA; FFDCA at FDA; workplace safety standards at NIOSH and the Occupational Safety and Health Administration (OSHA); consumer products safety regulations at CPSC; and food and packaging regulations at the Department of Agriculture (USDA) and FDA). International efforts to work with and understand nanotechnology also are underway. The U.S. National Science Foundation is involved in a dialog with 26 countries on the safe development of the technology, the Organization for Economic Cooperation and Development (OECD) has convened meetings, and the International Organization for Standardization (ISO) is establishing technical committees on nomenclature and environmental, health, and safety concerns.

(Many delegates expressed significant concern about the numerous unknowns associated with nanotechnology—a discussion of the concerns specific to nanotechnology is presented on page 21.)

Opportunities and Obligations Regarding Nanomaterials

Nanotechnology promises a variety of uses from wastewater treatment to medical devices. Yet, concern is growing about potential impacts on human, wildlife, and ecosystem health. Working groups offered specific recommendations for dealing with the many unknowns.

The ability to answer some of the questions posed by nanotechnology requires the ability to characterize, detect, and quantify their presence in the environment. However, analytical capabilities presently are extremely limited. Delegates expressed concern that tons of nanomaterials are being introduced into commerce and the environment with little knowledge of the environmental impacts. Once these materials enter the environment, they are not easily detected and no effective clean-up methods exist.

Existing regulatory assessment methods like QSARs likely will need to be modified to accommodate nanoparticles' unique structures and characteristics. Further research on structures and physical properties is necessary. Research on collateral materials produced during manufacturing and materials used during production also should be performed. Tests and models used with other pollutants should be examined for potential applicability to nanoparticles (e.g., air quality models for predicting inhalation exposure). All testing should reflect the life-cycle of the compound and toxic metabolites, not just the life of the product utilizing the technology.

Researchers need more information on how size and structure influence different kinds of metabolic properties in organisms so that they can assess the appropriate toxico-

logical endpoints. Research on solubility, transport, and bioactivity should be the top priority to allow characterization of potential environmental and human health risks. Developing reliable methods for quantifying nanoparticles in environmental media is a mandatory first step in determining exposure and fate.

Existing environmental fate and effects data should be made public—the state of nanoscale science would benefit, and the public would be more likely to trust companies that manufacture and use nanomaterials. Industry consortia should be formed to promote data sharing and collaborative research, thus reducing costs (and duplication) of necessary research. While exact production volumes should be protected as confidential business information, the public has a right to know the approximate volumes of nanomaterials produced in order to aid regulation, research, and monitoring.

Requirements regarding material safety data sheets (MSDSs) should be revised to indicate that nanoparticle properties could be unlike molecules with the same formula. Protocols for detection and quantification should be required for regulatory submission and should be included in each MSDS.

Regulation of nanomaterials provides an opportunity to create a regulatory process that incorporates lessons learned from previous endeavors. Nanomaterials are unlike any other material currently regulated and federal agencies are struggling to catch up with the quick pace of development.

Agencies are attempting to assess the risks and benefits of nanomaterials and regulate them using existing laws and regulations. However, agencies are applying these

regulations without the experience and knowledge that they have for other compounds subjected to the same regulations. The piecemeal approach creates inconsistencies among regulating agencies—FDA may have one set of standards for nanoparticles in food additives while the USDA has a different standard for nanoparticles in food packaging materials.¹⁸ Further, the current approach perpetuates the media-by-media regulation of contaminants that fails to recognize the interconnectedness of air, water, and soil (EPA is looking to the Clean Water Act, Clean Air Act, and waste management statutes to provide regulatory guidance).

Delegates were concerned that current regulatory frameworks are inadequate to assess nanomaterial compounds with vastly different structures and properties than those compounds in existing regulated materials. Many questions arise regarding EPA's ability to assess comprehensively the toxicity or environmental fate properties of new chemical substances.

Nanomaterials are so profoundly different from other regulated substances that they should have their own regulatory process. Cobbling together pieces from existing regulatory processes is a prescription for failure. A comprehensive and holistic approach to nanomaterial regulation should be implemented.

In order to avoid a public backlash similar to one generated by the release of genetically modified organisms (GMOs), the federal government and nanotechnology industry must know and report environmental impacts and health effects, and assure that other critical questions are answered before proceeding full-speed ahead.

Improving Understanding and Regulation: Findings and Recommendations

Following the presentations on different classes of emerging contaminants, delegates were given the opportunity to discuss their concerns and offer recommendations for improvement. The discussions were held in small working groups with delegates from diverse geographic, disciplinary, and employment backgrounds. The groups focused on four topics of concern across all contaminant types—monitoring needs, research needs, regulatory issues, and public and professional education issues.

Monitoring Needs

Measuring the effectiveness of regulatory activities and focusing research on topics of greatest concern is essential to the efficient use of limited resources. Environmental monitoring helps provide these measurements and this focus, yet, it chronically suffers from inadequate funding. Monitoring is useful in identifying the extent of contamination or identifying new potential contaminants of concern. It provides the vital function of helping determine if regulatory controls have adequately protected human health and the environment.

Delegates did offer recommendations for improving monitoring effectiveness. A significant focus was on the

need for more comprehensive and integrated monitoring systems. Monitoring should include all environmental matrices including water, soil, air, sediment, biota, and food. Estuarine and marine coastal areas also must be included in any national monitoring plan—the National Oceanic and Atmospheric Administration (NOAA) should apply its expertise in this area. Baselines need to be established, and standardized testing protocols and detection methods for each media are needed.

Monitoring solely for contaminants is not enough. Biological assessments should be included. Thus, ecosystem monitoring programs should integrate the tracking of individual organisms and populations with aspects of physical and biological habitats. For example, endocrine disruptor contaminant monitoring should be coupled with monitoring for reproductive impacts to organisms and populations. Sensitive subpopulations should be considered in monitoring design and hypothesis testing. Impacts to functions not conserved across organisms, but ecologically important such as photosynthesis or metamorphosis also should be considered. Integrating biological and contaminant monitoring could be useful in the development and testing of models that can simulate the occur-

rence of emerging contaminants and the associated health impacts for a range of spatial and temporal scales.

If monitoring results show unexpected concentrations or effects, research incorporating multiple lines of evidence should be conducted to determine if effects can be attributed to a specific contaminant. A national strategy enabling anticipation of the classes or groups of contaminants for which we should monitor should be developed. This strategy can include analysis of archived mass spectra, the use of existing under-utilized databases (e.g., Superfund), and could spark a preservation and archival system of samples for future analysis based on advances in technology that could produce valuable trend data. To assure that scientists are not caught off guard, delegates recommended that companies develop detection methods at the time of product development or launch. Additionally, the sensitivity of analytical detection methods must be developed to allow for determination of residue concentrations potentially present in the environment.

More monitoring efforts should be based upon hypothesis-driven approaches and include adaptive designs that are scientifically based, defensible, and testable. More emphasis should be placed upon conducting monitoring

that assists in answering specific scientific questions rather than the current approach for compliance purposes in response to various environmental regulations. Monitoring systems should be designed to test specific hypotheses about environmental contamination occurrence, sources, transport, and health effects. Few monitoring systems exist that are useful in testing these hypotheses. Those that do exist generally are local research projects by academicians or government scientists that do not address broad national-scale issues over long periods.

Monitoring activities associated with mitigation and remediation efforts also should be increased in order to build understanding of their effectiveness and for use in future mitigation efforts.

Long-term stability and support is necessary for monitoring programs to realize their full potential. They must be recognized as part of the solution, not merely as a mechanism for identifying problems. Delegates offered many potential solutions to address their recommendations and assure strong comprehensive monitoring programs.

For example, partnerships and collaborations among stakeholders make use of limited resources and assure that necessary monitoring goals are achieved—they should be expanded, combined, and encouraged. Existing national or regional partnerships such as the Integrated Ocean Observing System (IOOS)¹⁹ and efforts in the Great Lakes can serve as models.

Scientists should increase advocacy efforts for monitoring programs. In light of increasingly tighter budgets, members of Congress and the Office of Management and Budget are looking for justification to support monitoring activities. A coordinated response from the scientific community is necessary.

New and unique funding mechanisms to support monitoring activities should be explored including fees on

new chemical introductions, a per-pound tax on chemical production, or setting aside a percentage of fines levied for noncompliance with environmental laws.

Many delegates recommended making USGS the national monitoring agency for emerging contaminants to institutionalize monitoring on a nationally consistent basis. This would eliminate the need for grant-driven monitoring at the local level, which can be highly variable in terms of funding, commitment, comprehensiveness, and quality. This would result in nationally consistent quality assurance/quality control (QA/QC) protocols. USGS also could produce national reports on the state of the environment.

Research Needs

Monitoring and research are complementary. As monitoring reveals the extent and effects of contaminants in the environment, research is necessary to determine the implications of such information. Additionally, understanding the fate, toxicity, and MOAs of compounds is critical to streamlining the regulatory process and predicting future compounds of concern. Delegates made numerous recommendations on research questions that need to be answered, and opportunities for enhancing the overall research enterprise.

Improved coordination and sharing of information are necessary. A global contaminants entity with subgroups focused on specific contaminant types should be formed. Such an entity could work to categorize existing research projects and outcomes to help identify gaps in knowledge. A priority list of emerging concerns with known and recently discovered chemical contaminants should be created and maintained. A panel of interdisciplinary experts could help build a framework to guide research and funding similar to the Global Endocrine Disruptor Re-

search Inventory—an international effort to report the state of science in endocrine disruptors by consolidating references and research in a single location.²⁰ A larger effort incorporating research on all potential contaminants should be implemented.

Federal agencies need to improve information, data, and research sharing. This could be accomplished by establishing an interagency working group to share information needs and address how to better integrate management and research. Requests for proposals should be better coordinated across agencies.

Scientists need to develop better methods for assessing the fate and effects of emerging contaminants. New or modified QSARs and models are necessary, particularly for the assessment of new compounds or materials like nanoparticles. Measurements beyond the LD₅₀ are necessary—subtle effects should be considered, and better links between acute tests and chronic effects must be established. Non-animal based alternatives to toxicological testing also need further development.

Critical pieces of research are necessary to fill gaps in our understanding of toxicological effects on organisms. The lack of species-specific toxicology data is troubling—test species are used to predict effects on other species with little understanding of the actual correlation (e.g., data from fish are used to predict toxicological effects in amphibians). Rather than focusing on individual chemical-by-chemical effects, research should focus on receptors and effects in the environment. Research designed to relate MOAs and receptors of test species with other species will help fill some of the gaps. Molecular biology techniques such as genomics and proteomics have great potential, but will require significant expansion to realize that potential. Studies should begin at the organism level and work out in either direction

to the genomics level and the ecosystem level. The adaptation and incorporation of ecological models needs to be expanded for both genomic and ecosystem level studies.

A better appreciation of individual chemicals' and mixtures' sub-lethal toxicological MOAs are critically important to assessing the potential risks that chronic, low-level exposure may present to human and ecosystem health. For example, a presumably insignificant sub-lethal impairment of some ecosystem constituents can alter predator-prey relationships, which may cause a ripple effect and lead to shifts in community dynamics elsewhere in the foodweb, typically higher up in the trophic hierarchy.

The investigatory time span should extend beyond individual life cycles to examine generational effects. Evolutionary screening tools can help answer questions related to the microevolutionary impacts of contaminants. More reliable biomarkers are necessary, and connections between biomarker response and organism response should be established. Connections at the ecosystem level also should be investigated. Screening methodologies should test during different stages in development to develop the most realistic assessments.

Results from field studies and laboratory studies need reconciliation. Researchers and professional organizations, in association with government and industry, should develop standardized microcosm studies that characterize baselines and monitor for and describe changes—organisms are not independent. Impacts from multiple stressors must be examined. Analytical fingerprints of complex mixtures need to be developed and correlated to toxicity studies.

Delegates expressed considerable concern about the decline in research funding and changes in employment patterns. Government funding of natural resources research has declined

since its peak about 35 years ago, and the downward trend is expected to continue. Baseline and preliminary research aid in the prioritization of health and environmental effects—more funding is necessary. Additional research focused on the needs discussed above also are in need of funding. Some delegates recommended considering the Swedish model for advancing critical research and assuring necessary funding—establish national goals and design funding to meet those goals. Discussion of Sweden's efforts is featured in the text box on page 29.

Ecotoxicology expertise in government and academia also is suffering. Individuals trained in ecotoxicology largely are becoming consultants due to limited positions available in academia. Thus, basic research suffers as potential researchers leave universities to become consultants. Future talent pools also suffer due to limited expertise within academic institutions to teach rising ecotoxicologists. If available research funds increase and priorities are established, there will be a greater need for these positions.

Governments also are losing critical talent as the existing workforce retires, and funding to replace retirees is inadequate. See RNR's special report on "Federal Natural Resources Agencies Confront an Aging Workforce and Challenges to Their Future Roles."

Delegates offered several potential solutions to the challenges facing research. Tax incentives could be created to encourage industries to form alliances that would support necessary research. Such alliances should allow for the participation of stakeholders outside industry including professional and scientific organizations, government agencies, environmental organizations, and citizen groups. Educational efforts that change the public's perception of unknown chemicals and raise awareness about the effects of contaminants could lead to calls for increased funding. An in-depth discus-

sion of public education related to emerging contaminants appears below.

Regulatory Issues

Regulations are designed to protect society's interests either directly by prohibiting unwanted behavior or effects, or indirectly by encouraging a particular outcome through market forces, competition, or other means. Working-group members examined direct and indirect means to protect human health and the environment from unintended consequences of the use of chemicals.

Delegates expressed concerns about the efficacy of the general regulatory regime for chemicals as well as specific regulatory programs. They observed that the current legal and regulatory framework does not predispose or encourage regulatory bodies to work together to incorporate information on exposures from chemical uses that they do not regulate. Assessments of exposures should include all sources of the chemical, and all chemicals sharing a common MOA.

Current regulations appear to discourage the development of safer alternatives to older, more hazardous chemicals. Under TSCA for example, all new chemicals must meet more stringent requirements than those for existing chemicals, thus creating a disincentive to replace existing chemicals with less toxic new chemicals. New chemicals designed to replace existing chemicals with greater toxicity should receive special consideration such as quicker agency turn-around or fewer testing requirements. Removing the distinction between new and existing chemicals also would improve the incentives for developing safer alternatives. This would make the approval process for chemicals with lower toxicity easier relative to more toxic chemicals regardless of when they were first introduced. A "Green Seal" type program also could encourage the de-

velopment and marketing of safer chemicals. Drugs and other chemicals should be encouraged to be durable but not persistent and designed for safe disposal and use.

The periodic review of all chemicals (perhaps every five years) could help ensure that new information on uses, safety, disposal, and concentrations in the environment are considered in decision making on future uses of chemicals. However, delegates recognized that the significant size of the chemical universe means testing and regulation requires prioritization—perhaps based upon recommendations from a group like the Interagency Testing Committee under TSCA. Harmonizing testing requirements with requirements of other OECD members could reduce the burden on industry and allow money allocated for testing to produce more test results.

Regulators and legislators should implement additional requirements. Data on chemical production and disposal of waste should be made public, thus raising awareness of waste-minimization opportunities within industry, and encouraging public oversight. Laws governing each group of chemicals should include reasonable specifications on the kind of monitoring and research information that is necessary to eliminate or limit the use of chemicals that adversely effect human health or the environment. Persistence is an important factor in the regulation of chemicals, but life-cycle assessments should be a required part of regulatory decision making.

While examining specific regulatory processes, delegates did offer some recommendations. They expressed support for the tiered testing approaches used in FIFRA and Europe's REACH (Registration, Evaluation, and Authorisation of Chemicals). Also, they believed that the burden of proof should lie with the manufacturer (as in FIFRA) rather than the regulator (as in TSCA). The Data Quality Act also was viewed as limit-

ing the ability of agencies to use valid data. More standardized methods are needed, particularly for terrestrial organisms and non-lethal endpoints. An expert working group should be established to validate methods and allow standardization at EPA. Approaches to risk assessment developed at FDA and the European Medicines Agency could be models.²¹

Pharmaceuticals and NEPA

FDA's regulation of the environmental effects of drugs is based on NEPA. Under NEPA, federal agencies are required to consider the environmental impacts of their actions and decisions and take steps to ensure that environmental values are respected. Based upon these requirements, all FDA decisions regarding the approval of new drugs must consider the environmental impacts of such an approval. However, FDA has established categorical exclusions where environmental effects are assumed to be minimal.

One such exception is if the predicted release to the environment is less than one ppb. Delegates were concerned that the one-ppb threshold may not be universally adequate—some pharmaceuticals such as hormones likely have effects below this level. Although FDA can request more information when it deems necessary, delegates believe that the one ppb cut-off should be contingent upon absence of pharmacodynamic effects at that concentration. Further, as recent studies indicate, many pharmaceuticals pass through wastewater treatment and continually enter water bodies, resulting in long-term, pseudo persistence and chronic exposures. This situation should be a wake-up call to re-examine FDA's environmental responsibility. An advisory panel should be established to re-examine the one-ppb threshold. Future decisions should be based upon an understanding of concentrations at which effects occur during chronic exposures, and persistence

(or pseudo-persistence) and disposal patterns. Additionally, concentration measurements should include all sources of the compound and all compounds with similar MOAs. Intermediates and metabolites also should be considered if they are metabolically active. Such measurements also should be re-examined and revised when usage patterns increase beyond the initial assessment due to the introduction of a generic or over-the-counter formulation.

Finally, drug registrations may not have adequate mechanisms for taking action on registered compounds that turn out to have environmental effects. For NEPA to be effective as a regulator of chemicals, FDA must take an active role in soliciting and incorporating broad public participation.

Drug Disposal Programs

Delegates were interested in the development of programs to foster proper disposal of pharmaceuticals but recognized that there are several associated difficulties. Take back programs could be a good vehicle for public outreach and education about how their actions affect the environment. However, delegates raised concerns regarding compliance with requirements of the Controlled Substances Act and other regulations. FDA, EPA, and the Drug Enforcement Administration (DEA) should work with state and local agencies to issue guidance to industry, the public, and medical care providers regarding the proper disposal of pharmaceuticals. If necessary, recommendations for regulatory or statutory changes should be developed. Also, technical sheets and directions included with medicines should provide guidance on proper disposal of unwanted pharmaceuticals.

Pesticides and FIFRA

Pesticides are subject to regulation under FIFRA by the EPA. Under FIFRA, manufacturers are required to

register a new pesticide or new use of a pesticide before it can be sold or distributed. Before issuing a registration, EPA requires the manufacturer to conduct tests to ensure that the pesticide can be used with a reasonable certainty of no harm to human health or unreasonable adverse effects to the environment. EPA also conducts a re-registration program to assure that older pesticides meet current safety standards.

Delegates recognized the importance of testing and assessment requirements that establish a high standard for manufacturers. However, the working group recommended that EPA rather than manufacturers should conduct necessary testing rather than relying on industry produced data. A mechanism for industry funding for such a program could be developed.

The distinction between pesticides regulated by EPA and veterinary drugs regulated by FDA sometimes is blurred, leading to regulatory confusion. Additional difficulties exist. For example, FIFRA requires both a cost-benefit analysis and compliance with laws that prohibit such an analysis (e.g., the Endangered Species Act). Better guidance is needed about how to consider ecological impacts.

Finally, emergency exemptions from full registration should be limited by both time and number to assure that compounds are not approved year after year in lieu of performing necessary testing.

High Production Volume Challenge Program

EPA, OECD, and Japan have implemented a voluntary program to make publicly available a complete set of baseline health and environmental effects data on high production volume (HPV) chemicals. This data is to be collected for each chemical on EPA's list of HPV chemicals. The program is successfully obtaining baseline screening toxicities from industry for most of the target chemicals. The amount of

participation by industry, the International Chemical Council Associations, and the American Chemistry Council is encouraging—a very constructive partnership has been formed. However, EPA and the international community must prepare to move forward with other methods for obtaining necessary information should these voluntary efforts not succeed.

Public and Professional Education Issues

A public that is educated about contaminant issues will increase the likelihood of having informed public policy and actions. Support for research and monitoring will increase as the public comes to better understand the many unknowns surrounding chemicals. Public support also will increase with knowledge of risks to human and ecological health.

Thus, all available mechanisms should be employed to inform the public about contaminant issues, including fact sheets, websites, speakers' bureaus, expert witness databases, advisory boards, and public service announcements. Video games and prime time television shows conveying environmental knowledge should be developed. A dynamic spokesperson like Bill Nye the Science Guy can introduce complex contaminant issues to the public. Delegates recognized the importance of efforts to bring science into American households through networks like Animal Planet and the Discovery Channel. Zoos, museums, and aquaria also offer excellent outreach venues.

USDA Extension Service networks at land grant universities should be mobilized to provide assistance to urban dwellers on environmentally related problems. Homeowner education is critical to deal with problems ranging from pharmaceutical disposal to proper lawn maintenance. The Home*A*Syst program can serve as a model.²²

Education efforts should focus on several key concepts. Instilling knowledge on proper pharmaceutical disposal is important. Efforts also should focus on key audiences including healthcare providers, veterinarians, pharmacists, agriculture/aquaculture industries, and insurance companies. Building understanding of pollution and how everyone contributes through individual actions also is key. Such efforts should include identification of what is at stake concerning personal health and well-being. Real solutions and actions that make a difference and which adapt to local needs should be included.

Communication efforts could be more strategic and yield greater results by focusing on people who are most likely to change their habits with increased information rather than those who are resistant due to political, philosophical, or other reasons. Key audiences such as teachers, journalists, and elected officials should receive extra attention.

An environmental education clearinghouse would promote the sharing of excellent, already available materials, lesson plans, and programs. Professional and scientific societies should engage science teachers to ensure that basic concepts are part of the curriculum. Emphasis should be placed on grades three through six as an excellent period during which to shape environmental values and influence parents. In addition, societies should become more active in state and local environmental education initiatives through their chapter networks and volunteers.

Professional and scientific societies should work with the media to ensure that critical issues related to contaminants receive adequate and proper coverage. More knowledgeable environmental journalists are needed. Collaborations with the Society of Environmental Journalists should be undertaken. The Society of Environmental Toxicology and Chemistry's

(SETAC) journalism education initiative was identified as a positive step. Peer-reviewed case histories can be developed for use by the media.

Many scientists have concerns about working with the media. Concerns include misrepresentation of comments or taking them out of context, the sensationalizing or polarization of issues to sell rather than inform, and the significant efforts necessary to respond to inaccurate reports that affect personal, professional, and institutional reputations.

Scientists and their professional societies should work with elected officials to develop policies based on the best available scientific information. Programs like Nonpoint Education for Municipal Officers (NEMO) can serve as a model.²³

Restoring public support for higher education can make communication efforts easier. Academic research scientists should make their research visible and relevant to the public. They should translate results into social contexts, economic impacts, and other val-

ues that are important to people. Scientists must improve their communications with lay people. They should avoid “dumbing down” information, but make it understandable and useful to the public. Requirements by the National Science Foundation to include outreach activities in research projects are positive, but the results of such efforts are not routinely evaluated.²⁴

Universities also should moderate the balance in tenure policies relative to publications and activities directed to recognizing societal outcomes that emphasize impacts and relevance. Barriers to interdisciplinary and multidisciplinary collaborations must be overcome.

Professional and scientific societies should work to develop a broad understanding and acceptance of the precautionary principle in business, industry, and government.²⁵ This principle is especially important regarding new processes and products. Also, industry should be encouraged to develop a sustainable vision of the future supporting the development of environmen-

tally responsible formulations and processes (particularly when many are shown to help the bottom line).

Joint meetings among professional and scientific societies will foster better communication and collaboration on contaminant issues.

Finally, societies should become more active advocates concerning environmental issues. Public skepticism about “honest brokers” will persist in controversial issues—especially when the economic and political stakes are high. Peer review, interdisciplinary participation, and partnerships including society members and industry representatives can help overcome this skepticism. Professional and scientific societies should work to facilitate a broad societal understanding of sustainability principles. They should lead the transformation of the societal ethic to one that recognizes intergenerational responsibilities, universal environmental justice and equality, economics based on life-cycle costs, and ethics guiding long-term outcomes over short-term expediency.

Existing Programs Provide Valuable Lessons

Past experiences with environmental contaminants (e.g., DDT, PCBs, etc.) should provide valuable lessons for how to deal with new chemicals entering the marketplace and chemicals already in commerce. Mary O'Brien, author of *Making Better Environmental Decisions: An Alternative to Risk Assessment*, provided a thoughtful examination into how our environmental relationship with chemicals could be improved. See <http://www.rnrf.org/2005congb/obrien.pdf>.

Two essential aspects relevant to new chemicals are the need to develop better chemicals, products, and processes than we have developed in the past, and to move away from the use of old chemistry and

engineering processes. Addressing environmental problems with chemicals means altering some current social processes. Four existing programs help illuminate a path toward sustainable and respectful relationships with new and old chemicals—each is only a partial solution that can be built on to develop a comprehensive path forward.

TSCA New Chemicals Review

At the heart of TSCA is EPA's authority to require manufacturers and importers to submit information before manufacturing and distribution of new chemicals (Pre-manufacture Notification or PMN). However, manufacturers and importers are not required to test their chemicals before submitting

PMNs. In fact, as of 1999, less than half of all PMNs were accompanied by any human toxicity data, less than five percent with any ecotoxicity data, one to five percent had chemical or environmental fate data, and less than one percent had bioaccumulation or biodegradation data.

TSCA's strength is that the act partially compensated for the limited available data by providing a low threshold—a chemical may present an unreasonable risk—for EPA to restrict production pending testing. However, once a chemical enters commerce, the threshold is higher—a chemical will present an

Continued on next page.

unreasonable risk—for EPA to take regulatory action.²⁶

By 2004, about 32,000 PMNs had been submitted. Orders for more testing were issued 1,200 times, requirements of new PMN submission with significant new uses 1,200 times, over 1,600 PMNs were withdrawn when faced with some action, and 300 times the submitter undertook some voluntary testing. Thus, regulatory action was taken on just 12 percent of the PMNs submitted. However, only about half of the approved chemicals actually enter the marketplace.

The PMN process has yielded several positive outcomes:

- During the multidisciplinary, new-chemicals review process, EPA provides deterrent signals and guidance to manufacturers through informal communication and negotiation.
- There have been no challenges to EPA requests for more testing information.
- EPA has identified about 45 categories of chemicals that are similar in molecular structure; physical, chemical, or biological properties; use; or mode of entrance into the human body. This helps focus reviews for potential problems.
- EPA has developed software and training programs to encourage manufacturers to conduct upfront analysis of the physical properties and potential health risks of substances as well as exposures before submission for review.
- One benefit that has not been quantified is the number of chemicals not entering commerce because manufacturers anticipated problems getting past the PMN process.

While the PMN process has identified new chemicals that could later cause problems, it is likely that over 99 percent of all chemical production

by volume today involves old chemicals that never were reviewed for their potential harm before entering commerce. New chemicals review could be strengthened greatly with greater data requirements as production volume increases.

Several important principles from TSCA need to be extended to other regulatory programs: the precautionary initial threshold for agency action, the deterrence from submitting potentially harmful chemicals, and agency guidance toward safer chemicals and production methods. Adapting TSCA's new chemical review process to greening the other 99 percent of chemical production in the U.S. is an essential next step. Massachusetts provides an example of how such an effort can develop.

Massachusetts' Toxics Use Reduction Act

Massachusetts' Toxics Use Reduction Act of 1989 helps manufacturers identify and implement alternatives to the use of old toxic chemicals and processes. Authors of the act recognized that, in contrast to manufacturers of chemicals, users of chemicals have no stake in the particular chemicals they use—they simply want the function or service that the chemical provides.

Under the act, manufacturing firms using specific quantities of about 1,300 industrial chemicals must undergo a systematic process to identify alternatives to reduce the use of those chemicals and to reduce waste. The firms must identify ways to redesign production processes and products through toxics use reduction methods such as chemical substitution, process changes, product changes, and improved management. Alternatives assessments must be signed by a certified planner and made public. Firms also must produce an input-output accounting of the chemicals, thus, leading to an under-

standing of how each chemical is used in production and any inefficiencies in its use.

University and state technical assistance providers use fees paid by the firms using the subject chemicals to provide technical and research support. Despite additional requirements and costs, industry supports the process. In the program's first ten years, the total amount of toxic and hazardous waste has been reduced by 58 percent and the use of targeted chemicals has been reduced by more than 40 percent. Around 550 firms have been continuous participants since the program began. The act saved Massachusetts' industry \$15 million from 1990 to 1997, not including worker and public health and environmental benefits.

Unfortunately, the act does not focus on low volume chemical users such as dry cleaners, and does not address chemicals in products—particularly those coming from out-of-state. However, the program implements several important requirements that should shape future programs. It requires the assessment of safer chemical alternatives, fees on toxic chemicals provide technical support and research for companies trying to reduce their use of toxic chemicals, record keeping allows for toxics use reduction and economic benefits to be reliably tracked, and it builds positive toxics-use reduction relationships with toxics using companies.

Green Chemistry and Engineering

Green chemistry and green engineering are fields of knowledge and practice that provide the necessary foundation for a thorough redesign of our relationship to both new and old toxic chemicals, products, processes, and systems. Such programs are being developed by EPA and in universities.

Green chemistry is the design of chemical products and processes that

reduce or eliminate the use and generation of hazardous substances. It relies on twelve principles articulated by Anastas and Warner:²⁷

1. Prevent waste
2. Design safer chemicals
3. Design less hazardous chemical syntheses
4. Use renewable feedstocks
5. Use catalysts, not stoichiometric reagents
6. Avoid chemical derivatives
7. Maximize atom economy
8. Use safer solvents and reaction conditions
9. Increase energy efficiency
10. Design chemicals and products for benign degradation
11. Analyze syntheses in real time to prevent pollution
12. Minimize the potential for accidents

While green chemistry focuses on the design and production of chemicals, green engineering focuses on the design of industrial processes, products, and systems. Green engineering principles reflect the principles of green chemistry.²⁸

1. Strive for as inherently benign material and energy inputs and outputs as possible
2. Prevent waste
3. Design separation and purification operations to minimize energy consumption and materials use
4. Maximize mass, energy, space, and time efficiency
5. Design products, processes, and systems to minimize inputs and avoid overproduction
6. Design complex products for reuse, simple products for value conserving recycling or beneficial disposition
7. Design for durability for the intended life of the product, rather than persistence
8. Avoid unnecessary capacity or capability
9. Minimize material diversity

10. Link local material and energy flows

11. Design products, processes, and systems so components can be reused or reconfigured

12. Use renewable material and energy inputs

As green chemists, engineers, processes, products, systems, and training opportunities become more familiar and available, more legislation requiring manufacturers to use green chemistry and engineering becomes feasible.²⁹ Two pieces of proposed legislation exemplify this through use of the substitution principle.

The Substitution Principle

Substitution means replacing a hazardous chemical with a safer or non-hazardous chemical, or replacing the chemical's function with a product redesign or system change. Substitution is based on a comparative assessment of alternatives to problem chemicals; uses inherent hazards assessment rather than risk assessment, to compare materials or processes; forces innovation in product design and system change through use of green chemistry and engineering; and implements the precautionary principle, as it is not necessary to wait for elusive proof of damage if alternatives with less hazardous intrinsic properties are available.

REACH is the first regulatory system for chemicals that removes the distinction between older chemicals and new ones. It is being used in Europe to institute the substitution principle. Chemicals deemed to be of very high concern would be subject to authorization, which first identifies and prioritizes the chemicals, and then allows industry to make a case for their continued use on the basis that alternatives do not exist, or are excessively expensive.

"An Act for a Healthy Massachusetts: Safer Alternatives to Toxic

Chemicals" would provide for the identification of safer alternatives for ten priority chemicals or chemical groups. Technical and grant support to users of these chemicals also would be provided as they seek to meet deadlines for substituting safer alternatives. Re-employment assistance and vocational training would be provided if workers become unemployed due to the substitution of safer alternatives. The public could access a list of products containing the safer alternatives. Other priority chemicals could be added to the program. A multi-stakeholder Safer Alternatives Oversight Board would oversee implementation.

Societal Vision: Sweden

A large societal vision for improving human's relationship with their environment is possible. In 1999, the Swedish parliament adopted 15 national quality objectives to be obtained within one generation.³⁰ By 2003, the parliament set 71 interim targets. The objectives are:

1. Reduced Climate Impact
2. Clean Air
3. Natural Acidification Only
4. A Non-Toxic Environment
5. A Protective Ozone Layer
6. A Safe Radiation Environment
7. Zero Eutrophication
8. Flourishing Lakes and Streams
9. Good-Quality Groundwater
10. A Balanced Marine Environment
11. Thriving Wetlands
12. Sustainable Forests
13. A Varied Agricultural Landscape
14. A Magnificent Mountain Landscape
15. A Good Built Environment

If we articulate a large vision for a deeply respectful relationship with the world, including with chemicals, we are far more likely to actually try to get there. And if we try, we are far more likely to succeed.

Endnotes

1. Kolpin, D. et. al., Pharmaceuticals, Hormones, and other Organic Wastewater Contaminants in Streams 1999–2000: A National Reconnaissance. *Environmental Science & Technology*, 2002, 36:1202-1211.
2. See note 1.
3. Heberer, Occurrence, Fate, and Removal of Pharmaceutical Residues in the Aquatic Environment: A Review of Recent Research Data. *Toxicology Letters*, 131:5-17.
4. Heidler, J., A. Sapkota, and R. U. Halden (2006): Partitioning, Persistence, and Accumulation in Digested Sludge of the Topical Antiseptic Triclocarban During Wastewater Treatment. *Environmental Science & Technology* (In Press).
5. Degradates, short for “degradation products,” is a relatively new piece of jargon developed by environmental scientists to incorporate all transformation products from a compound.
6. Indexed by the American Chemical Society’s Chemical Abstracts Service in their CAS Registry, excluding bio-sequences such as proteins and nucleotides.
7. See also Daughton, C.G. “Emerging” Chemicals as Pollutants in the Environment: a 21st Century Perspective. *Renewable Resources Journal*. Vol. 23, No. 4. Winter 2005-2006.
8. Chronic toxicity refers to effects that result from exposure over time.
9. Acute toxicity refers to effects that result from a recent exposure and typically are more serious than chronic effects (e.g., death).
10. The occurrence of antibiotic-resistant pathogens in the environment may be linked more to the sloughing of antibiotics from humans and animals receiving therapeutic treatment rather than to the occurrence of trace residues of antibiotics in the environment.
11. See note 1, and reports from the USGS’s National Water Quality Assessment (NAWQA) at <http://water.usgs.gov/nawqa>.
12. A nanometer is about ten times the diameter of a hydrogen atom, or ten thousand times smaller than the diameter of a human hair.
13. See <http://www.nanotechproject.org> for a list of products containing nanoparticles.
14. For copies of these statements, see <http://www.cdc.gov/niosh/topics/nanotech/position.html>, <http://www.cpsc.gov/LIBRARY/CPSCNanoStatement.pdf>, and <http://www.fda.gov/nanotechnology/regulation.html> respectively.
15. At the time of publication of this congress report, the draft white paper from EPA was being circulated for review. Readers are encouraged to examine the draft and final (when released) documents, which should be available at <http://www.epa.gov/osa/nanotech.htm>.
16. See http://www.cdc.gov/niosh/topics/nanotech/nano_exchange.html.
17. The paper likely will be available at the NNCO website upon release, <http://www.nano.gov>.
18. Current agencies tasked with regulatory authority are: EPA (TSCA, Clean Air Act, Clean Water Act, and waste management statutes), FDA (FFDCA), NIOSH and OSHA (workplace safety standards), CPSC (consumer products safety regulations), and USDA (food and packaging regulations).
19. For a discussion on the Integrated Ocean Observing System and regional ocean observing systems see RNRF, 2005. Building Capacity for Coastal Solutions. Ryan M. Colker and Robert D. Day, Eds. Bethesda, Md.
20. See http://oaspub.epa.gov/pls/gedri/pack_edri.All_Page.
21. See <http://www.fda.gov/nctr/science/divisions/biometry.html> and <http://www.emea.eu.int/pdfs/human/swp/444700en.pdf>.
22. See <http://www.uwex.edu/homeasyst>.
23. See <http://www.nemo.uconn.edu>.
24. Additional information on science communication relative to PPCPs can be found at <http://epa.gov/nerlesd1/chemistry/pharma/comm.htm>.
25. Some useful references about the Precautionary Principle can be found at <http://epa.gov/nerlesd1/chemistry/ppcp/relevant.htm#ThePrecautionaryPrinciple>.
26. Of the more than 75,000 chemicals in commerce, EPA has placed restrictions on just five types of chemicals: PCBs, fully halogenated chlorofluoroalkanes, certain chlorinated dibenzo-p-dioxins, asbestos, and hexavalent chromium.
27. Anastas & Warner, 1998. Green Chemistry: Theory and Practice. Oxford University Press.
28. Anastas & Zimmerman, 2003. Design Through 12 Principles of Green Engineering. *Environmental Science and Technology*. March:95A-101A.
29. Recommendations have been made as to how pharmaceutical design, packaging, marketing, and distribution could be altered to minimize environmental pollution. See the two-part monograph on the “Green Pharmacy:” <http://epa.gov/nerlesd1/chemistry/ppcp/images/green1.pdf> and <http://epa.gov/nerlesd1/chemistry/ppcp/images/green2.pdf>. This approach followed the cradle-to-cradle design framework of McDonough and Braungart, which builds and expands on the concepts of green engineering/chemistry.
30. See <http://www.miljomal.nu/english/objectives.php>.

Appendix A: List of Delegates

Joy Bartholomew Executive Director Estuarine Research Federation Port Republic, MD	Virginia Cunningham Director, Sustainable Development GlaxoSmithKline King of Prussia, PA	Tim Fannin Division of Environmental Contaminants U.S. Fish and Wildlife Service Hadley, MA	Albert Grant Chairman, RNRF Board of Directors Potomac, MD
Marsha Black Associate Professor, Environmental Health and Science University of Georgia Athens, GA	Rebecca Daniels ASPH/EPA Fellow U.S. Environmental Protection Agency Research Triangle Park, NC	Brenna Finn Associate Bergeson & Campbell, PC Washington, DC	Barbara Grimes Non-Point Source Pollution Program Coordinator North Carolina Division of Environmental Health Raleigh, NC
Dominic Brose** Graduate Research Assistant University of Maryland College Park, MD	Christian Daughton Chief, Environmental Chemistry Branch National Exposure Research Laboratory U.S. Environmental Protection Agency Las Vegas, NV	Suzanne Fitzpatrick Senior Science Policy Analyst U.S. Food and Drug Administration Rockville, MD	Timothy Gross Research Physiologist/ Ecotoxicologist Florida Integrated Science Center U.S. Geological Survey Gainesville, FL
Susan Bruninga Manager of Regulatory Affairs National Association of Clean Water Agencies Washington, DC	Robert Day Executive Director Renewable Natural Resources Foundation Bethesda, MD	Michael Focazio* Office of Water Quality U.S. Geological Survey Reston, VA	Anik Guertin Environmental Health Assessment Officer Health Canada Ottawa, Ontario, Canada
G. Allen Burton Director, Institute for Environmental Quality Wright State University Dayton, OH	John Dernbach Policy Office Director Pennsylvania Department of Environmental Protection Harrisburg, PA	Peter Folger Director, Outreach American Geophysical Union Washington, DC	Rolf Halden Assistant Professor Center for Water and Health Johns Hopkins University Baltimore, MD
Joel Coats Professor of Entomology Iowa State University Ames, IA	William Eckel Agronomist Office of Pesticide Programs U.S. Environmental Protection Agency Arlington, VA	Kesha Forrest Environmental Protection Specialist U.S. Environmental Protection Agency Washington, DC	J. Ronald Hass Senior Scientist AMI & More Durham, NC
Ryan Colker Director of Programs Renewable Natural Resources Foundation Bethesda, MD	Robert Eganhouse Research Chemist U.S. Geological Survey Reston, VA	John French Patuxent Wildlife Research Center U.S. Geological Survey Laurel, MD	Patty Hass AMI & More Durham, NC
Keith Cooper Professor, Biochemistry and Microbiology Rutgers University New Brunswick, NJ	Charles Eirkson III Toxicologist/Team Leader, Center for Veterinary Medicine U.S. Food and Drug Administration Rockville, MD	Sarah Gerould* Bureau Program Coordinator, Contaminant Biology Program U.S. Geological Survey Reston, VA	Michael Hoffman AMI & More Bethesda, MD
John Cosgrove President AXYS Analytical Services Sidney, British Columbia, Canada		Nancy Golden Division of Environmental Quality U.S. Fish and Wildlife Service Arlington, VA	Matthew Hull Research Scientist Luna Innovations Inc. Blacksburg, VA
Kent Crawford U.S. Geological Survey New Cumberland, PA			Craig Hulse Chemist Patuxent Wildlife Research Center U.S. Geological Survey Beltsville, MD

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Laboratory
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Associate Director for
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Arlington County Water
Pollution Control Board
Arlington, VA

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Chief, Program
Analysis & Support
Pennsylvania
Department of
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Risk Assessor
Virginia Department of
Environmental Quality
Richmond, VA

Robert Masters
Hydrologist
National Ground Water
Association
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Moira McKernan
Biological Science
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U.S. Food and Drug
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U.S. Soap and Detergent
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College Park, MD

Tamim Younos
RNRF Board of Directors
Interim Director, Virginia
Water Resources Research
Center
Blacksburg, VA

* Working Group Chair

** Working Group Recorder

Appendix B: Congress Program

Congress on Assessing and Mitigating Environmental Impacts of Emerging Contaminants

Thursday, December 1, 2005		Friday, December 2, 2005
9:00–9:05 am Welcome & Opening Remarks Albert A. Grant , RNRF Chairman	11:35–12:05 pm Case Study II: Pharmaceuticals Christian Daughton , Chief, Environmental Chemistry Branch, National Exposure Research Laboratory, Environmental Protection Agency, Las Vegas, Nev.	9:00–9:35 am How Can We Improve Our Environmental Relationship with New Chemicals? Mary O'Brien , author, <i>Making Better Environmental Decisions: An Alternative to Risk Assessment</i> , Eugene, Oregon
9:05–9:15 am Conference Context & Goals Robert D. Day , RNRF Executive Director	12:05–12:35 pm Discussion/Questions	
9:15–9:50 am Introduction to Emerging Contaminants and Unintended Consequences Sarah Gerould , Congress Chair and Bureau Program Coordinator, Contaminant Biology Program, U.S. Geological Survey, Reston, Va.	1:45–2:15 pm Case Study III: Industrial Chemicals—Brominated Flame Retardants Carl Orazio , Chief, Environmental Chemistry Branch, Columbia Environmental Research Center, U.S. Geological Survey, Columbia, Mo.	9:35–10:00 am Discussion/Questions 10:00–10:10 am Explanation of Working Group Procedures Ryan M. Colker , RNRF Director of Programs
9:50–10:15 am Discussion/Questions	2:15–2:45 pm Discussion/Questions	10:30–11:40 am Working Group Session I
10:15–10:45 am Case Study I: Pesticides and Metabolites/ Degradates—Synthetic Pyrethroids Joel Coats , Professor of Insecticide Toxicology, Iowa State University, Ames, Iowa	2:45–3:15 pm Case Study IV: Nanoparticles Clayton Teague , Director, National Nanotechnology Coordination Office, Arlington, Va.	11:40–12:40 pm Working Group Session II
10:45–11:15 am Discussion/Questions	3:15–3:45 pm Discussion/Questions	1:40–2:40 pm Working Group Session III
	3:45–4:30 pm Delegate Roundtable Discussion: Lessons from Regional Efforts	3:00–4:00 pm Working Group Session IV
		4:00–4:30 pm Necessary Next Steps and Concluding Remarks Robert D. Day , Executive Director, Renewable Natural Resources Foundation

Appendix C: Background Materials Bibliography

In advance of the congress, delegates were provided with a notebook of background materials. These materials featured reports and information items from federal agencies, and recognized authors and organizations on topics to be discussed at the congress. Many delegates commented on the usefulness of the information and the fact that it had not previously been assembled in a cohesive manner. A bibliography of these items along with internet sites (where available) is provided below.

INTRODUCTION

Pharmaceuticals, Hormones, and Other Organic Wastewater Contaminants in U.S. Steams, 1999-2000: A National Reconnaissance. Kolpin et. al. *Environmental Science & Technology*, 2002, v. 36, no. 6. <http://pubs.acs.org/subscribe/journals/esthag/36/i06/es011055j.pdf>.

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INDUSTRIAL CHEMICALS: BROMINATED FLAME RETARDANTS

Summaries of Environmental Laws Administered by the EPA: Toxic Substances Control Act, Schierow, Linda. Congressional Research Service. <http://www.ncseonline.org/nle/crsreports/briefingbooks/laws/k.cfm>

Brominated Flame Retardants in the Environment. USGS. November 2004. <http://www.cerc.usgs.gov/pubs/center/pdfDocs/PBDE.pdf>.

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LESSONS LEARNED

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ABOUT RNRF

Purposes

The Renewable Natural Resources Foundation (RNRF) was incorporated in Washington, D.C., in 1972, as a non-profit, public, tax-exempt, operating foundation. It was established to:

- Advance sciences and public education in renewable natural resources;
- Promote the application of sound scientific practices in managing and conserving renewable natural resources;
- Foster coordination and cooperation among professional, scientific and educational organizations having leadership responsibilities for renewable natural resources; and
- Develop a Renewable Natural Resources Center.

The foundation represents a unique, united endeavor by outdoor scientists to cooperate in assessing our renewable resources requirements and formulating public policy alternatives.

Membership

RNRF's members are professional, scientific and educational organizations interested in sustaining the world's renewable natural resources. The foundation is governed by a board of directors comprised of a representative from each member organization. The directors also may elect "public interest members" of the board. Board members are listed on the back cover of the journal. Individuals may become Associates for an annual contribution of \$50 or more.

Programs

RNRF conducts national meetings, congressional forums, public-policy round tables and briefings, and international outreach activities. It also conducts an annual awards program to recognize outstanding personal, project and journalistic achievements. More information about RNRF's programs is available at www.rnrf.org.

Renewable Resources Journal, first published in 1982, promotes communication among RNRF's represented disciplines. The journal is provided to the governing bodies of RNRF member organizations, members of the U.S. Congress and committee staffs with jurisdiction over natural resources, federal agencies, and universities. Tables of contents of all volumes of the journal are available at RNRF's web site.

Center Development

The Renewable Natural Resources Center is being developed as an office and environmental center for RNRF's members and other nonprofit organizations. The Center is located on a 35-acre site in Bethesda, Maryland, where lawns and forested buffers provide an exceptional work environment.

The master site plan for the Center contemplates additional construction—including a 16,500 square foot conference and common-services facility. Organizations may either lease or purchase their offices. The Center currently has approximately 52,500 square feet of office space.

RENEWABLE RESOURCES JOURNAL

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