



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

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FROM THE CHAIR: SCIENCE UNDER SCRUTINY AND IN TRANSITION

Charles L. Franklin

The substantive scope of the Pesticides, Chemical Regulation, and Right-to-Know Committee (PCRRTK) is broad, covering legislative, regulatory, and judicial developments relating to the regulation and use of chemicals and pesticides in myriad industrial, commercial, and consumer products. If there is any one common element to these practice areas, it is the importance of sound science policy as a foundation for risk assessment, risk characterization, and risk management. If regulatory policy is about managing the competing health, environmental, and societal risks of modern life, science policy is about the process of identifying and measuring those risks in a world of incomplete information. This is not an easy task, and reasonable people can disagree with any given policy approach.

With that in mind, consider two science policy stories from 2011 that will continue to unfold in the new year.

Scrutiny of federal hazard assessment

methodologies: The U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program, managed by EPA's Office of Research and Development, has been a lightning rod for criticism for years, drawing both substantive and procedural critiques from stakeholders on all sides. Concern about the current IRIS process came to a head, however, in 2011, after the National Academy of Sciences (NAS) released a report criticizing aspects of

EPA's draft formaldehyde hazard assessment, concluding, inter alia, that the draft report was "not prepared in a consistent fashion," "lacks clear links to an underlying conceptual framework," and contained "[in]sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the weight of evidence, etc."

The NAS report reinforced concerns among industry stakeholders that EPA's hazard assessment process, revamped and streamlined in 2009, might be cutting corners, if not rendering biased conclusions. These concerns increased in June 2011, when the Department of Human and Health Services' National Toxicology Program (NTP) issued its 12th Report on Carcinogens, a report that raised the cancer classifications for both formaldehyde and another common chemical, styrene. Citing faults in the NTP's styrene analysis, and pointing to the earlier NAS critique of EPA's IRIS formaldehyde assessment, industry groups and congressional Republicans declared the administration's risk assessment process fundamentally flawed and called for delays in future action pending corrections. EPA and environmental advocates countered that while NAS had identified areas for improvement in the draft formaldehyde study, it had upheld most of the basic conclusions of the study, and had not rejected the entire report. EPA's announcement in September 2011 that it would make editorial changes to future IRIS reports, but would retain the same process, did little to reduce industry concerns.

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Lynn L. Bergeson, Editor**

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In late December, after a testy and partisan end-of-the-year legislative battle over budget and appropriations, Senate Democrats agreed in conference to include certain House riders addressing IRIS in an Omnibus Appropriations bill. The bill requires EPA to implement certain recommendations from the NAS formaldehyde critique, requires EPA to provide a progress report to Congress on implementation of the NAS recommendations by March 2012, and requires EPA to submit up to three additional risk assessments for NAS review. The bill also requires NTP to submit its formaldehyde and styrene reports to NAS for peer review. Notably, Democrats fought off a number of other more extensive requirements.

Since the compromise, federal policymakers have debated whether the IRIS and NTP rider debate was a win for administration foes or supporters. Regardless of one's perspective on that question, the bill ensures that these programs will continue to receive political, as well as scientific, scrutiny.

Transition to 21st-Century Toxicological Methodologies

While stakeholders continue to debate the merits of current hazard assessment tools and criteria, a separate effort is under way to revolutionize the way regulators assess chemical hazards. Some members may recall that in September 2010, the PCRRTK Committee hosted a program to discuss the federal government's "Tox21 Program," a partnership between EPA, the Food and Drug Administration (FDA), and the National Institute of Environmental Health Sciences to improve chemical screening efforts and reduce the reliance on extensive, time-consuming, and controversial animal testing. During the program, a blue ribbon panel of speakers spoke of the real and growing need for better, more efficient methods for developing health and safety data on chemicals approved for commerce in the United States—a challenge that is critical given the public push to modernize the Toxic Substances Control Act (TSCA) and improve data on the 80,000+ substances on the current TSCA inventory.

This program continues to make progress. In September 2011, EPA released a work plan for its Endocrine Disruptor Screening Program for the 21st Century, a program intended to replace all animal tests currently used to screen substances for endocrine disrupting effects with an alternative battery of laboratory (in vitro) and computer-based (*in silico*) testing over the next five years. In December 2011, EPA, the National Institutes of Health, and FDA initiated a joint effort under the Tox21 program to use robotic testing equipment and in vitro testing techniques to screen 10,000 compounds for potential toxicity.

If used correctly, these programs have the potential to increase the pace and efficiency of chemical prioritization efforts and, in the long term, chemical safety reviews. The lower cost and quicker results provided by these new methods could also reduce the inherent market barriers that traditional data call-in requirements have posed to industry, especially smaller business. Indeed, these new techniques could even pave the way for future agreement on a path forward on TSCA reform.

But here is where the science policy dilemma arises. . .

Putting Hazard Data in Context

These new Tox21 tests address hazard, not risk, and even then only at an initial screening level. Similarly, the much disputed IRIS and NTP reports speak only to the potential "hazard" or toxicity of the substances, not the likelihood of exposure or the resulting risk from any given use. Increasingly, however, some policymakers and stakeholders treat "hazard" or toxicity indicators as synonymous with "risk," such that the mere listing of a substance on one of a myriad of "chemicals of concern" lists constitutes a commercial death sentence for a substance or product. The state of California's Proposition 65, for example, imposes labeling requirements on any consumer product that contains even trace quantities of a substance it deems to be a carcinogen or reproductive toxicant, with no consideration of the relative risk of that substance over an unlisted alternative. California's recently released draft of its Green Chemistry Initiative consumer product regulation identifies over 3000 "chemicals of

concern,” cobbled together as a “list of lists” maintained by international, federal, and state officials.

But in a policy environment where the theoretical hazard of a substance is enough to create a de facto ban in the marketplace, how do policymakers ensure that new 21st-century screening tools will not be used to blacklist promising substances and materials based on some initial robotic tests? If reasonable people can disagree about the implications of extensively peer-reviewed epidemiological studies and animal data, is there any doubt that here will be disagreement on screening level assays?

The year 2012 will be one of continued scrutiny for EPA’s 20th-century hazard assessment techniques and those proposed for the 21st century. In both cases, however, policymakers need to remember that a substance’s toxicological qualities only speak to one part of a risk analysis. If there is one maxim 21st-century toxicologists should retain from the 16th century, it is the classic maxim, coined by Paracelsus, and often quoted on EPA’s own Web site: “the dose makes the poison.”

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ADDRESSING E-WASTE: A CHALLENGING AND GROWING PROBLEM

Rebecca Brown

Governments worldwide are starting to address the growing concern over the health and environmental consequences of electronic waste (e-waste). Improper handling of e-waste and little landfill space make recycling and reuse an appealing alternative to dumping.

In 2002, the European Commission (EC) proposed the Waste Electrical and Electronic Equipment (WEEE) Directive to address the issue of growing e-waste. *Recast of the WEEE Directive*, European Commission, http://ec.europa.eu/environment/waste/weee/index_en.htm (2011). In February 2003, the proposed legislation went into force. The original WEEE Directive required member states to create free e-waste collection initiatives in an effort to encourage consumers to recycle e-waste. In addition to the free e-waste collection initiatives, the WEEE Directive requires heavy metals used in electronics to be substituted for safer alternatives. Poor reporting numbers, complicated administrative enforcement, and the continuation of large amounts of e-waste ending up in inadequate electronic waste dumps, often outside the European Union (EU), led the EC to propose a recast of the WEEE Directive in 2008. *Proposal for a Directive of the European Parliament and of the Council on Waste Electrical and Electronic Equipment (WEEE) (Recast)*, EUR-LEX, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008PC0810:EN:NOT> (last visited Nov. 29, 2011).

The EC’s new proposed standards for the WEEE Directive would raise mandatory collection limits to a “65% collection rate set in function of the amount of electrical and electronic equipment (EEE) placed on the market in the preceding two years.” The new standards are set to go into effect in 2016; however, the EU, European Parliament and EC are discussing the achievability of these proposals. A safety provision of the new WEEE Directive allows for member states to make special arrangements through designated EU

committees that will allow them to achieve the WEEE Directive terms, in a manner that accommodates the state's situation. According to article 12 of the directive, member states have the responsibility to "encourage" producers to shoulder the entire collection cost that facilities incur by accepting EEE from private households. Article 14 allows producers to pass that fee down to consumers through a set fee that the consumer must pay at the time of purchase. 14. The last major modification is an annex that establishes shipping requirements for WEEE, ensuring that e-waste is not exported to overseas facilities that are unequipped to handle properly the waste.

Success or Failure of the WEEE Directive and Its Effects on the United States

The WEEE Directive offers a legal framework for extended producer responsibility (EPR). Instead of encouraging producers through financial incentives to achieve this goal, the EC requires member state cooperation. At this time, the United States does not now have a national law requiring EPR; however, many states have initiated their own laws regulating e-waste.

For example, California passed a law that is similar to the WEEE Directive. California's Electronic Waste Recycling Act of 2003 requires consumers to pay fees ranging from \$6 to \$10 on electronic purchases greater than four inches in diameter. *Electronic Waste Recycling Fee*, <http://www.calrecycle.ca.gov/electronics/act2003/Retailer/Fee/> (2011). Since the law's enactment, over 1 billion pounds of electronic waste have been recycled in the state. *E-waste law reaches a milestone: 1 billion pounds of computer junk recycled in California*, Paul Rogers, LA Times, <http://articles.latimes.com/2011/jun/11/business/la-fi-ewaste-2011011> (June 2011).

Some companies, such as Best Buy and Apple, are offering incentives of their own to encourage customers to recycle their old electronics. Best Buy allows for free recycling for all items with screens and Apple offers gift cards for its electronics that are in reusable condition. Success of the new WEEE standards will likely encourage more U.S. legislators to consider creating a national law requiring some form of

electronic recycling. The WEEE Directive may also encourage producers to create new, more environmentally friendly products, resulting in decreased recycling costs and reduced electronic waste in landfills.

While only time will be able to give consumers and electronic producers any certainty with respect to the how each EC member state will implement the new WEEE Directive, it is clear that this issue of e-waste is not going anywhere. In the U.S., there are few to no legal requirements that these products are actually recycled. The level of EPR remains to be seen as new legislation and consumer demand for recyclable products increase.

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***Trends*: Section newsletter now in new electronic format**

Trends can be found in a new electronic format at www.ambar.org/EnvironTrends. Individual articles will be posted in html format and will contain hyperlinks to important cases and other resources cited in the articles.

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Trends will be made available to Section members exclusively in electronic format. There are plans for continued optimization of the *Trends* electronic format to better serve Section members. The Section is also developing enhanced electronic formats for *Natural Resources & Environment* and *The Year in Review*.

EPA HOLDS FIFRA SAP MEETING TO CONSIDER DRAFT NOTICE OF INTENT TO CANCEL RODENTICIDE REGISTRATIONS

Lawrence Culleen and Shailesh Sahay

From November 1 to December 29, 2011, the U.S. Environmental Protection Agency (EPA) convened a meeting of its Federal, Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). The FIFRA SAP is a standing panel of experts that advises EPA on scientific issues concerning FIFRA matters. The late 2011 SAP meeting was convened to review EPA's Draft Notice of Intent to Cancel and Notice of Denial of Registrations for Certain Rodenticide Bait Products (Draft NOIC). FIFRA section 25(d) requires that EPA must submit such documents to the SAP "for comment as to the impact on health and the environment of the action proposed." FIFRA does not, however, bind EPA to follow the advice of the SAP even with respect to purely scientific issues.

The Draft NOIC in this matter would cancel pesticide registrations for 20 rodenticide products. EPA is seeking to cancel these registrations because the products do not conform to its 2008 Risk Mitigation Decision (RMD) for Ten Rodenticides, which was the culmination of a lengthy reregistration analysis begun by EPA in the 1990s. During 2011, a federal district court held that EPA could not exercise its enforcement authority and treat products as "misbranded" because they failed to conform to the RMD requirements in lieu of following the formal cancellation procedures embodied in FIFRA if EPA wishes to remove such rodenticide products from the market. *Reckitt Benckiser v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011). According to the Draft NOIC, the products in question are not compliant with the RMD because they are sold for residential use and either (1) are in the form of loose baits (such as pellets or grains) or are sold as bait blocks without tamper-resistant bait stations; or (2) contain the "second-generation" anticoagulant active ingredients brodifacoum or difethialone. In the Draft NOIC, EPA contends that the products in question present risks to children, pets, and wildlife. In addition to seeking to cancel these 20 registrations, the Draft NOIC also would deny registration applications for four rodenticide products for similar reasons.

It is EPA's practice to issue "charge questions" to the FIFRA SAP. These questions are intended to focus the SAP's deliberations on issues identified as important by EPA. Importantly, the statute does not require EPA to provide such questions, and the SAP's statutory obligation is not specifically limited to addressing only questions posed by EPA.

The rodenticide SAP meeting began with a series of presentations by EPA on the scientific analyses it performed to support the Draft NOIC. Reckitt Benckiser, the registrant of twelve of the products potentially subject to cancellation and two of the products subject to denial, followed with its own presentations regarding the validity of EPA's analyses. The Louisville Apartment Association and Bell Laboratories also made short presentations.

On December 29, 2011, the SAP issued "meeting minutes," which contain the panel's responses to EPA's charge questions as well as other analyses relevant to the Draft NOIC. The minutes identified several shortcomings in EPA's analysis, particularly with respect to its assessment of consumer use rodenticide products' risks to humans and pets and regarding EPA's assessment concerning wildlife risks.

Following receipt of the SAP's report, EPA also is expected to receive comments on the Draft NOIC from the U.S. Department of Agriculture and the Department of Health and Human Services. If EPA chooses to proceed with a final NOIC, the subject registrants will receive notice and have the opportunity to request a cancellation hearing before an EPA administrative law judge.

FIFRA cancellations proceedings have been very infrequent. This proceeding is being monitored carefully by practitioners and other interested parties as it may become a model for proceedings in the future years.

Documents relating to the SAP meeting, including the minutes, can be found at <http://www.epa.gov/scipoly/sap/meetings/2011/112911meeting.html>.

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PREDICTIONS FOR EPA'S OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Lynn L. Bergeson

Identified below are a few thoughts on what may be headed our way in 2012 from the U.S. Environmental Protection Agency's (EPA) Office of Chemical Safety and Pollution Prevention (OCSPP). The 2012 presidential election cycle will influence any activity by either party or the Administration over the next year.

Environmental issues are often used to make clear distinctions between the two parties, and this could lead to initiatives or pronouncements by either party intentionally driven to illustrate or exacerbate those differences. This will likely lead to some new initiatives and high profile decisions on the part of the administration, along with continued (and sometimes blistering) criticism from Republicans in Congress about the costs and impacts of environmental regulations on jobs and the economy. Regardless, 2012 will likely be an eventful year.

Congress

The Prospects for TSCA Legislation

The future prospects for any new Toxic Substances Control Act (TSCA) legislation are dim as the calendar moves closer to the 2012 election. On April 14, 2011, Senator Frank R. Lautenberg (D-NJ), chair of the Environment and Public Works Subcommittee on Superfund, Toxics, and Environmental Health, introduced the Safe Chemicals Act of 2011, which is intended to modernize TSCA to require chemical companies to demonstrate the safety of industrial chemicals and EPA to evaluate safety based on the best available science. The bill is co-sponsored by Senators Amy Klobuchar (D-MN), Charles Schumer (D-NY), and Barbara Boxer (D-CA). Lautenberg previously introduced TSCA reform legislation in the 111th Congress, the Safe Chemicals Act of 2010 (S. 3209).

Since Senator Lautenberg introduced the legislation in April 2011, staff from his office and the office of

Senator James Inhofe (R-OK), ranking member of the Senate Environment and Public Works Committee, co-hosted a number of meetings with chemical trade associations and industry, as well as separate meetings with environmental organizations. The first meeting, held on June 21, 2011, focused on chemical safety standards. Other meeting topics included data requirements and prioritization approaches. Senator Inhofe stated that he thought the meetings were very thoughtful and identified areas of common ground that warrant further discussion. The environmental groups and chemical industry representatives appear to have continued meetings to attempt to reach a consensus, but the content of such deliberations has been kept confidential and so it is not clear how far or near the opposing groups are in coming to any agreement (in whole or in part).

Most recently, on November 17, 2011, the Senate Environment and Public Works Committee and the committee's Superfund, Toxics, and Environmental Health Subcommittee held a hearing on the legislation. While all committee members continued to applaud and exhort the attempt at continued discussion and negotiation between the nongovernmental organization advocates and industry, some Democratic senators, especially Senator Cardin (D-MD), were critical of the American Chemistry Council (ACC) and the lack of a concrete alternative proposal developed and supported by the chemical industry. Senator Lautenberg indicated that he intends to bring his legislation up for a committee vote "in the near future" and would hope that consensus can be reached—with the implication that he will attempt to report his bill even if the industry has not agreed with the provisions in any pending legislation.

The prospects of legislation actually becoming law are increasingly remote, given that any successful bill would essentially need consensus in the full Senate—and must still overcome the lack of any legislative movement in the House of Representatives. At the same time, the tenor of the Senate hearing exhibited a bit more frustration on the part of Democrats with the lack of specific alternative language from the industry, language that would illustrate their idea of how to capture ACC's much-noted "10 Principles for Modernizing

TSCA” that have been discussed for more than two years. Whether this somewhat more caustic rhetoric on the part of some committee members helps or hurts the chances of any eventual legislation is not clear, it may signal that during the coming election year the issue of chemical testing and regulation may become a more visible, or at least more vocal, issue.

OCSPP Leadership and Election Year 2012

On October 25, 2011, OCSPP Assistant Administrator Stephen A. Owens announced his resignation from EPA. Since it is somewhat late in the president’s first term, it is unclear if the administration will be actively seeking to fill the OCSPP Assistant Administrator position with a new political appointee. In addition, the bitter partisan atmosphere on Capitol Hill has led to numerous holds on current nominees still awaiting Senate confirmation for many senior positions across many government agencies. Without senior political leadership in place, the fate of these issues may become even more unpredictable as election year considerations become only more important as November 2012 draws near. As a result, it is possible the administration may attempt to place a nominee if only to indicate that the OCSPP issues remain a priority and will not be lost in the larger dynamics of the 2012 election.

Jim Jones, the current deputy assistant administrator for the Office of Air and Radiation, was designated to serve as the new OCSPP acting assistant administrator, beginning December 1, 2011. Jones is a very familiar presence in OCSPP, as he has been with EPA for over two decades, including serving four years as the Office of Pesticide Programs (OPP) director (2003–2007) and four years as OCSPP principal deputy assistant administrator (2007–2011). His tenure also includes six months as OCSPP acting assistant administrator in 2009. Since Jones is very familiar with OCSPP and its operations, the transition to new leadership is expected to be straightforward.

Election year 2012 will likely see environmental issues among the wedge issues continually discussed by both Democrats and Republicans to help energize their base voters and paint some clear distinctions between the

candidates. The most attention will be focused on air pollution issues, not just climate change, with claims about the need for cleaner air as a health issue versus the adverse impact of expensive regulatory mandates.

The election itself will decide the fate of the larger debate, but in an election year, EPA will be driven to account for its accomplishments during the president’s first term in each media program, and some issues might be pressed to further sharpen the partisan divide or otherwise appeal to certain constituencies. As a result, even in OCSPP, there may be a renewed emphasis on environmental justice issues, potential health impacts on children, the potential for chemicals and pesticides to cause endocrine disruption, the potential impacts of genetically modified organisms or nano pesticides and chemicals, the need for developing green chemistry alternatives, and the like. What form these continued initiatives might take, or how strident the EPA tone may be at the time, will be partly driven by election year needs as November 2012 draws near.

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)/Food Quality Protection Act (FQPA)

2012 will likely see mostly a continuation of issues which have dominated EPA’s pesticide program during 2011. Most notable are issues surrounding both the Clean Water Act (CWA) and Endangered Species Act (ESA). One “new” issue, of a sort, that may take on more importance during 2012 is the cancellation notice EPA is expected to issue to prohibit and restrict certain rodenticide formulations. In a draft cancellation notice currently under administrative review, EPA proposes to cancel certain second-generation anticoagulant products sold to consumers, as well as other rodenticide products with packaging that EPA deems inadequate. Also, the Pesticide Registration Improvement Act (PRIA) will need to be reauthorized for EPA to continue to collect registration activity fees. Ordinarily, with support from the pesticide registrants, renewing PRIA would not be expected to be controversial. This year, however, it may encounter difficulties as anything to do with government revenues can become controversial and made more complex by overall budget issues on Capitol Hill. If PRIA is not

renewed for whatever reasons, it could have a severe and adverse impact on the ability of the pesticide program to make timely decisions on pending registration applications.

Budget Concerns/PRIA

Gridlock in Congress could lead to difficulty in reauthorizing PRIA, revenue from which provides a significant resource for EPA's pesticide program. This possibility is in addition to the virtual certainty that the pesticide program, the toxics program, and all media programs of EPA will be under increasingly tight budgetary constraints in the foreseeable future. The overarching debate about the federal deficit could result in significant reductions in domestic program discretionary spending. If attempts are made to reduce federal personnel costs by changes to the federal pension system, personnel ceiling reductions, or other measures, not only would morale suffer in general, but EPA could also see significant loss of personnel due to retirement or even reductions in force. If that happens, replacement hiring could be a significant problem in EPA's ability to maintain critical skills and generally backfill positions sufficiently to avoid delays in regulatory approvals and other programmatic activities.

Pesticide Enforcement Priorities for 2012

For 2012, EPA's stated enforcement goals are to pursue aggressively pollution problems that matter to communities and vigorous civil and criminal enforcement. Importantly for pesticide registrants, EPA's FY 2012 Office of Enforcement and Compliance Assurance (OECA) National Program Managers (NPM) Guidance provides two new national focus areas for enforcement of FIFRA: imports and supplemental registrations. According to Rosemarie Kelley, director of EPA's Office of Civil Enforcement's Waste and Chemical Enforcement Division, EPA is aware that supplemental registrants' labels are sometimes not consistent with the FIFRA registrants' label and is now targeting both the registrant and the supplemental registrant (distributor) for enhanced enforcement action. Under the NPM Guidance, regions are expected to choose an additional area of participation: fumigants/fumigation; worker safety; retail marketing; container-containment.

TSCA Reform and EPA's Enhanced Chemical Management Program

While EPA released two new chemical action plans in 2011, for methylene diphenyl diisocyanate (MDI) and related compounds, and toluene diisocyanate (TDI) and related compounds, this is half as many plans as were released in 2010 and 2009. EPA's emphasis on action plans was reported to be stretching thin the available resources of the Office of Pollution Prevention and Toxics. In September 2011, EPA announced a new approach for identifying priority chemicals for review and assessment under TSCA, and this is reportedly part of a broad new risk review program intended to replace the chemical action plans. In step 1 of the prioritization process, EPA plans to identify an initial group of priority chemicals for review by using a specific set of data sources to identify chemicals that meet one or more of the action plan priority factors. In step 2, EPA intends to refine that group by using a broader range of data sources to analyze further and select specific chemicals from the initial group for further assessment. EPA opened a discussion forum to obtain comments on the two-step prioritization process, and held a webinar on September 7, 2011, to present the process and discuss the prioritization factors and data sources.

Also throughout 2011, several important actions remain pending at the Office of Management and Budget (OMB). A key proposed action is EPA's effort to propose a "chemicals of concern" list under TSCA section 5(b)(4). The long-delayed proposed rule, which was submitted to OMB in May 2010, still remains under OMB review. It appears that this rule is being subjected to close scrutiny because of the policy implications of the creation of a "chemicals of concern" list, insofar as it is not identified as economically significant (that is, the annual impact of the rule on the economy is not "significant"—\$100 million or more—nor is it expected to have any material adverse effect on the economy, productivity, jobs, or related metrics). For a detailed review of the section 5(b)(4) list, please see an article entitled *TSCA Section 5(b)(4) "Chemicals of Concern" List: Questions, Issues, Concerns*, available at <http://www.lawbc.com/published-articles/P80/>.

In addition, the combined TSCA section 4 test rule and significant new use rule (SNUR) on certain polybrominated diphenyl ethers (PBDE) submitted to OMB on December 17, 2010, remain under review. EPA has submitted more recent rulemakings, including a proposed SNUR that would add nine chemicals (dyes) to the benzidine-based chemical substances (dyes) SNUR at 40 C.F.R. § 721.1660; create a SNUR for di-n-pentyl phthalate (DnPP); and create a SNUR for alkanes, C12-13, chloro. EPA also submitted a proposed SNUR concerning hexabromocyclododecane (HBCD) used in textiles. The PBDE action is particularly interesting in the way it will attempt to combine SNUR requirements with a test rule, thus forcing industry to choose to abide by the SNUR or confront potentially significant testing costs if a chemical such as decabrominated diphenyl ether (decaBDE) is to remain in the market.

The SNUR is also likely to break new ground with the inclusion within its scope of imported articles containing pentaBDE, octaBDE, and/or decaBDE. This represents the second time that EPA will attempt to handle importation of articles containing a chemical as a significant new use. The issue was first raised in the proposed SNUR on pentaBDE and octaBDE, but in issuing the rule EPA did not include imported articles within its scope. This is a potentially difficult and complex undertaking considering that it remains to be established that such importation is not ongoing and that EPA has stated it intends to allow continued recycling (“processing”) of PBDE-containing foam and plastics that would then be involved in domestic manufacture of new PBDE articles. EPA’s ability to get these actions through OMB in relatively intact form will, as with the chemicals of concern list, be telling.

EPA promulgated the much-anticipated final revisions to its inventory update reporting (IUR) modifications rule, now known as the chemical data reporting (CDR) rule. The CDR rule is intended to enable EPA to collect and publish information on the manufacturing, processing, and use of commercial chemical substances and mixtures on the TSCA chemical substance inventory. This includes current information on chemical substance production volumes, manufacturing sites, and how the chemical substances

are used. The CDR rule establishes the upcoming submission period, which will be from February 1, 2012, to June 30, 2012, and which will include submission of production information from 2010 and production, processing, and use information from 2011.

Regulation of Nanoscale Materials

EPA reportedly continues to work on a TSCA section 4 test rule to require chemical manufacturers of certain multiwall carbon nanotubes, certain clays (e.g., kaolin (including halloysite) and bentonite (including montmorillonite)), alumina, and spray-applied nanomaterials to conduct testing for health effects, ecological effects, and environmental fate, as well as provide material characterization data. EPA is also developing a SNUR for existing chemical nanoscale materials under TSCA section 5(a)(2). In addition, EPA is developing a proposal to require reporting and record keeping under TSCA section 8(a), which would require that persons who manufacture such nanoscale materials notify EPA of certain information, including production volume, methods of manufacture and processing, exposure and release information, and available health and safety data. While the SNUR and TSCA section 8(a) rulemakings were previously separate, EPA has combined them into a single rulemaking. In November 2010, EPA submitted a proposed rule regarding TSCA section 8(a) reporting to OMB, where it remains, and it is unclear how or whether EPA will incorporate this proposed rule into its “single rulemaking.”

As for Office of Pesticide Programs nano activity, in June 2011, EPA proposed several possible approaches for obtaining certain additional information on the composition of pesticide products. EPA focused particularly on information about what nanoscale materials are present in registered pesticide products, and defined “nanoscale material” as “an active or inert ingredient and any component parts thereof intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers (nm).” Under one approach, EPA would use FIFRA section 6(a)(2) to obtain information regarding what nanoscale material is present in a registered pesticide product and its potential effects on

humans or the environment. Under an alternative approach, EPA would obtain such information using a data call-in (DCI) under FIFRA section 3(c)(2)(B). According to EPA's June 17, 2011, *Federal Register* notice, EPA believes FIFRA section 6(a)(2) "is the most efficient and expedient administrative approach to obtaining information about nanoscale materials in pesticides and EPA would prefer to use this approach." The notice also proposes a "new approach" that EPA will use to determine on a case-by-case basis whether a nanoscale active or inert ingredient is a "new" active or inert ingredient for purposes of FIFRA and PRIA, even when an identical, non-nanoscale form of the nanoscale ingredient is already registered.

EPA's June 17, 2011, *Federal Register* notice represents a significant departure—and considerable improvement—over EPA's initial description of its intended "nano-pesticide," which appeared to reflect a preordained approach to require section 6(a)(2) reporting. For months EPA was dismissive of other options to obtain information under FIFRA that many believed more appropriate, including the FIFRA section 3(c)(2)(B) DCI approach. It remains to be seen how EPA will decide to proceed.

One last point would be to note the possible implications of the PRIA issues mentioned appropriately in the policy document. The PRIA category designation as a new chemical could result in a PRIA fee of almost a million dollars for any nano pesticide product declared as new and not an existing ("old" or me-too) product. The price distinction is obvious, but the underlying point is that policy determinations outside of PRIA, driven by how EPA articulates a final policy for reporting or to define the parameters of its regulatory vigilance, could have significant and far-reaching impacts on the development of the nanomaterials industry or the adoption of nanotechnologies in the pesticide industry.

EPA announced on December 1, 2011, that it is conditionally registering a pesticide product containing nanosilver as a new active ingredient. HeiQ AGS-20 is a silver-based antimicrobial pesticide product approved for use as a preservative for textiles. Textiles

will be by application of AGS-20 either as a surface coating or by incorporation into the starting materials. As members of the nano community know well, this is very good news and demonstrates that EPA is prepared to make regulatory decisions involving nanotechnology, even where, as here, they are likely to inspire controversy. Granted, the registrant and many in the pesticide community wish the final approval were swifter, with fewer tier I and tier II data requirements, and not time limited. These decisions should not detract, however, from the bigger picture and HeiQ's success in procuring the first FIFRA approval of a nano pesticide.

DTSC Nano Developments

Developments in California are also relevant. On October 31, 2011, the California Department of Toxic Substances Control (DTSC) released an "informal draft" Safer Consumer Products Regulations (SCPR). DTSC proposed these regulations after ten months of meetings following the California Secretary for Environmental Protection's December 2010 instructions to DTSC to stop working on issuing proposed regulations and instead "take additional time to be responsive to the concerns raised and revisit the proposed regulations." Memoranda providing background information are available online at <http://www.lawbc.com/regulatory-developments/green-chemistry>. Concerns raised in 2010 included the proposed exemption of certain chemicals; the decision to focus the first five years on children's products, personal care products, and household cleaning products; and the process by which "chemicals of concern" (COC) and "priority products" (PP) were identified and alternative assessments (AA) conducted. In the revised October 31, 2011, regulations, DTSC has removed exemptions for unintentionally added chemicals and chemicals for which there is "no exposure pathway," eliminated the initial focus for certain types of products, and expanded the criteria and processes by which COCs and PPs are identified and prioritized and AAs are conducted. In addition, while there had been a contemplated exemption for nanomaterials in the prior regulations, there is no mention of nanomaterials or any specific exemption for nanomaterials in these informal draft regulations. To the extent that any nanomaterials have not yet been

identified by regulatory agencies on the lists from which DTSC will derive the COC list, the nanomaterials will not, at least initially, be subject to these requirements.

The good news is the availability of the regulations now provides a useful snapshot of where the Green Ribbon Science Panel's thinking is, following months of deliberations. The bad news is this is a cumbersome "informal draft" regulation with many definitions, criteria, and procedures. Companies with consumer products in the stream of commerce in California will need to notify DTSC that its product is a PP (or cease to enter the product in the stream of commerce in California or satisfy a de minimis exemption); perform an AA and prepare a preliminary AA report and final AA report; and comply with any regulatory responses applicable to its product or that DTSC determines are necessary. Companies also may need to respond to information requests from DTSC, substantiate claims when information is submitted as trade secret, and potentially utilize the dispute resolution procedures to dispute certain actions taken by DTSC. DTSC provides that these responsibilities may be fulfilled by a consortium, trade association, etc., but does not provide in the regulations any conditions or criteria for how issues (e.g., formation, compensation) will be resolved.

While the potential impact of this regulation is expansive, and the initial list of COCs and initial list of PPs will be issued within 30 and 180 days of the effective date of the regulations, respectively, DTSC has noted that it anticipates the initial list of PPs will include only two to five products. In addition to opportunities now for companies to review and comment on these informal draft regulations and eventual draft regulations, the small number of products that will be subject to regulations initially may provide some opportunity for interested parties to understand how these regulations will be implemented and what changes or refinements may be needed.

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PESTICIDE TOLERANCES UNDER EPA REVIEW

Michelle Murphy

Registration review is under way for many pesticides. A key issue in this process is the safety of residues allowed on foods (i.e., tolerance levels). The review process works to ensure that pesticide use minimizes adverse effects. To meet this mandate, some tolerances may be lowered or suspended. For example, tolerance limits may be affected by recent studies of farming communities and drinking water contamination.

Review efforts address conventional pesticides, antimicrobials, biochemicals, and microbials. Agricultural pesticides, including sulfonylureas herbicides, neonicotinoids insecticides, and soil fumigants, are currently scheduled for review. The U.S. Environmental Protection Agency's (EPA) registration review activities are governed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In addition, the Federal Food, Drug, and Cosmetic Act (FFDCA) provides EPA with authority to establish tolerances for pesticides.

FIFRA requires EPA to review registered pesticides every 15 years. To meet this mandate, EPA must review more than 70 pesticide active ingredients annually. Registration review functions as a continuous two-step review process for pesticide tolerances. Where circumstances warrant, pesticides may also be reviewed outside the standard cycle.

If EPA determines that a pesticide tolerance is unsafe under the FFDCA, the tolerance must either be modified or revoked. For example, in 2009, EPA revoked all carbofuran tolerances, after review of the pesticide found extreme neurotoxicity to children. More recently, EPA announced that it anticipates revoking many tolerances for the herbicide carfentrazone-ethyl.

During the review process, EPA first assesses the reliability of pesticide registration data on file. New analyses are conducted as needed.

Evaluation of registration data considers:

- Changes to regulations and policy changes since the pesticide was last reviewed;
- Improved scientific data and capabilities; and
- New data about potential threats to human health and the environment.

The types of data used for the initial tolerance decision affect whether changes in use practices have the potential to raise residue levels in food. Where the initial tolerance decision relied on magnitude of residue studies, current residue levels are unlikely to exceed the anticipated residue levels originally estimated. If, however, the initial tolerance decision relied on actual residue data from monitoring studies and surveillance programs, changes in agricultural and food production practices could result in increases in residues that may require a change in EPA's initial tolerance decision.

Ecological and human health risk assessment will also be considered. Human health risk assessment addresses types of health problems caused by pesticides, exposure levels, and cumulative risk from different pesticides that share a common mechanism of toxicity. Risk assessment analyses include:

- Hazard identification—the extent and type of adverse health effects;
- Dose-response assessment—the exposure levels (doses) at which adverse effects may be seen; and
- Risk characterization—dose response combined with exposure estimates.

A key issue is whether actual or estimated exposure levels for biota, wildlife, consumers, and workers are below those at which no observable effects are seen. EPA may issue a “data call-in” under FIFRA section 3(c)(2)(B) if it finds that new data or information is needed for the review. For example, recent studies suggest that longer exposure periods are appropriate for many of the toxicity tests traditionally used by EPA.

Where new risks of concern are identified, EPA will implement risk mitigation and/or modify tolerances as necessary to protect public health and the environment.

EPA will ultimately revoke a tolerance if it determines that no safe tolerance can be set, however. EPA engages the public throughout registration review. For example, if a new risk assessment is created, it will be available for public comment through a *Federal Register* notice. EPA will then publish for comment the revised risk assessment and solicit comments on proposed mitigation measures. EPA will also publish proposed decisions. These documents and public comments are available through the docket posted at regulations.gov.

Case development follows the comment period. During this time, EPA assesses the state of knowledge on the pesticide and its effects as a result of current practices. The process can take as long as two years. A proposed decision is subject to comment before a final registration review decision is issued. In some cases, EPA issues only an interim decision. This measure is taken when further risk assessment is deemed necessary.

If new or increased risks are identified during review, EPA will weigh the risks against the product's benefits to determine whether or not the risks are unreasonable. If safer alternatives exist for the pesticide under review, the magnitude of the pesticide's benefits may decrease. Thus, recently registered safer alternatives may threaten older pesticides' registrations and tolerances. As a result, pesticide applicators may need to modify application processes to mitigate risk, or identify substitutes for revoked pesticides. These changes could cause crop loss where viable substitutes are not available.

Pesticides can be exempt from tolerance requirements if they are determined under 40 C.F.R. § 180.900 to present no harm to the public health. For example, petroleum oils, pieronyl butoxide, pyrethrins, rotenone or derris or cube roots, and sabadilla are exempt from tolerance requirements when applied to growing crops. This exemption, however, does not extend to use of these pesticides when applied during or after crops harvest.

Tolerances for individual pesticides often differ among crops and application periods. For example, 44

tolerances exist for pyrethrin on post-harvest commodities alone. Pyrethrins are botanical insecticides that alter nerve function to induce paralysis in pests. Pyrethrins are also an example of a pesticide undergoing continued registration scrutiny.

In 2006, EPA issued a reregistration eligibility decision concluding that pyrethrins were eligible for reregistration provided new mitigation measures and label changes were implemented. Nevertheless, pyrethrins have been added to pyrethroid's current review, as pyrethrins can be used as a substitute for pyrethroids. Recent studies identifying a potential link between pyrethrins and asthma/allergies may affect existing pyrethrin tolerances. In fact, in 2010, EPA received voluntary cancellation requests for a large number of pyrethrin registrations.

EPA's review schedule is largely chronological, assessing pesticides with older registrations first. EPA has the discretion, however, to review a pesticide at any time, regardless of when the pesticide was last reviewed. For example, EPA may opt to review a pesticide earlier than anticipated if new data suggest an emerging risk of concern. In addition, EPA will attempt to review pesticide families concurrently where pesticides share related chemical characteristics.

The recent recall of DuPont's herbicide Imprelis may also affect future reviews. According to EPA, significant adverse effects seen after the herbicide's registration were not identified during the products registration. This may heighten oversight of regulations that require registrants to submit data on the pesticide's "adverse effects." Specifically, under FIFRA § 6(a)(2), if registrants discover information on any unreasonable adverse effect of their pesticide after registration, they must report that data to EPA. In the case of Imprelis, EPA launched an investigation after reports alleged the herbicide was harming particular evergreen trees. As a result, EPA is likely to place a greater degree of scrutiny on the adequacy of adverse effects data submitted during the review process of tolerances.

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DTSC GRSP MEETS TO REVIEW REVISED INFORMAL DRAFT SAFER CONSUMER PRODUCTS REGULATIONS

Lynn L. Bergeson

On November 14–15, 2011, the California Department of Toxic Substances Control’s (DTSC) Green Ribbon Science Panel (GRSP) met to review DTSC’s “informal draft” Safer Consumer Products Regulations (SCPR), released on October 31, 2011. Memoranda providing background information are available at <http://www.lawbc.com/regulatory-developments/green-chemistry>. Information about the meeting can be found at <http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/GRSPUpcomingMeetings.cfm>.

During the meeting, DTSC provided an explanation for how the regulations were developed and then set forth questions for discussion on three topics: (1) the chemicals of concern (COC) list; (2) the prioritization of products; and (3) the quality assurance of alternative assessments (AA).

Chemicals of Concern List

DTSC discussed its approach to developing the COC list, which consists of establishing, within 30 days after the effective date of the regulations, a list of approximately 3000 COCs that are included in 22 different lists of chemicals developed by a range of global authoritative bodies or identified by one or more of three sources of “reliable” information. DTSC provided several reasons for its approach, including (1) sending signals to the marketplace of those substances that have been flagged as potential concerns; (2) allowing DTSC to commence work immediately to identify priority products (PP) containing one or more COCs; and (3) using available information on chemicals to save costs and maximize benefits. DTSC also stated that an advantage of a larger list is that it will reduce the incentive for manufacturers immediately to deselect COCs to avoid these regulations but perhaps choose a substitute that is no better or even worse than the listed COC or would be listed later by DTSC.

Some GRSP members found the current approach to be “overreaching” and expressed concern that some of the lists from which the COC list would be derived did not qualify as authoritative bodies or reliable sources. One member noted that while there was an understanding that the COC list would include substances beyond those identified as carcinogenic, mutagenic, or toxic to reproduction (CMR), the COC list will not be credible if DTSC does not use the correct lists developed by indisputable authoritative bodies. Another member suggested that DTSC only consider lists that were developed following public comments and data submissions. One list in particular that several GRSP members commented did not meet the standard of a source of “reliable” information was the Grandjean & Landrigan Identification of Neurotoxicants. Another source in dispute was the Oslo/Paris Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) List of Chemicals for Priority Action.

Other GRSP members found that the sources selected by DTSC were not inclusive enough to capture all chemicals of potential concern. Some members stated, for example, that there were no lists identifying respiratory sensitizers, dermal sensitizers, ambient ozone contributors or ozone depleters, or asthmagens. Members suggested including the Registration, Evaluation, Authorization and Restriction of Chemical’s (REACH) substances of very high concern candidate list and substances that are monitored under California and the Centers for Disease Control and Prevention’s (CDC) biomonitoring program. Another GRSP member suggested that DTSC include not only those chemicals listed in the U.S. Environmental Protection Agency (EPA) toxics release inventory (TRI) as “persistent, bioaccumulative, and toxic chemicals” but also all TRI substances.

Of particular note, one GRSP member raised the question of whether nanomaterials, which are not specifically mentioned in these informal draft regulations, are meant to be excluded. The GRSP member thought that the regulation’s definition of “chemical” may be narrow and that nanomaterials may not fit within the definition.

Priority Products List

DTSC discussed its approach to developing its identification of the first PPs, which will occur after evaluating the potential adverse health and environmental impacts posed by the COCs in each product based on several factors: (1) the potential adverse impacts from the COCs; (2) potential exposures; (3) the “availability of reliable information to substantiate the potential adverse impacts and exposures”; (4) the extent to which other regulatory programs regulate the products; and (5) the existence, if any, of a known “readily available safer alternative, that is functionally acceptable and technologically and economically viable.” DTSC stated that it believed its approach to use this narrative standard was the best way it thought it could achieve its objectives to be forward thinking, take advantage of potential new technologies, and ensure that the standard was one that could grow over time. DTSC stated that it was advised that it would not be legally defensible to list specific products in the regulations. DTSC also stated that it expects the initial list to be quite small, with no more than five PPs, and it will operate as a type of pilot program.

DTSC asked the GRSP to provide comments on what steps might be included to structure the prioritization process so that manufacturers are better able to predict the likelihood of their products being listed as PPs. Several comments addressed issues not directly requested by DTSC, particularly the scope of the notification process. GRSP members also sought clarifications or made suggestions to clarify the regulations so that PP alternatives were not limited to selecting alternative chemicals. GRSP members also expressed concern with the regulation requirement that a company demonstrate that the alternative has no greater significant adverse impacts than those associated with the PP, noting that there should be a higher standard than just exceeding the “floor” of impacts associated with the PP. DTSC noted that if a company performed an AA and did not evaluate or suggest an alternative with impacts that do not go above the “floor,” that company would likely expect a regulatory response from DTSC.

Quality Assurance for AAs

DTSC discussed the two-stage process under which it will require nonexempt “responsible entities” to conduct AAs for its PPs. DTSC noted that the regulations include requirements to ensure quality for the AAs through DTSC audits, creating a certification program for assessors, and posting non-redacted portions of the AAs on DTSC’s Web site for public review. Specifically, after January 1, 2015, AAs must be performed, and reports must be completed by, or under the responsible charge of, an assessor certified by an accreditation body designated by DTSC. This is a significant difference from the initially proposed regulations, which had required third-party verifications of the AAs.

Several members expressed concerns that the third-party certifications were a weakness in the program that might provide too much variability in how companies have their AAs certified. GRSP members made several suggestions to restructure the regulations with regard to certified assessors, including (1) limiting the number of accredited bodies (perhaps to 3–4) and allowing companies to compete to be accredited; (2) establishing a common examination for certification so that everyone is tested the same way; (3) asking for some portion of any fees collected by the certified assessors to be passed back to DTSC; (4) scheduling an annual conference for DTSC and assessors to discuss the accreditation process, how assessors are conducting their reviews, etc.; and (5) requiring assessors to carry professional liability insurance.

While one GRSP member asked DTSC to reconsider the provision prohibiting an entity from seeking accreditation if it has “any economic interest” and instead ensure that organizations do not have significant conflicts of interest which may go beyond financial interests, other members stated that accredited assessors need to be trusted by all parties involved from all different viewpoints.

With regard to other measures in the regulations to ensure quality, GRSP members commented that while DTSC audits were a good idea, DTSC was confronted with significant budget issues and the actual

audits that DTSC conducts may be much less than that which would occur under a well-funded agency. One member suggested that the regulations provide or clarify that DTSC has the authority when conducting audits to require changes or to come to a different conclusion. Regarding the posting of AAs on the Internet with some information redacted, some members commented that this was a necessary step to assist with transparency, although it was noted that knowledge of public disclosure may create incentives for companies to create AAs with very limited information. One member stated that the regulations should specify that the process by which AAs are conducted cannot be claimed as trade secret.

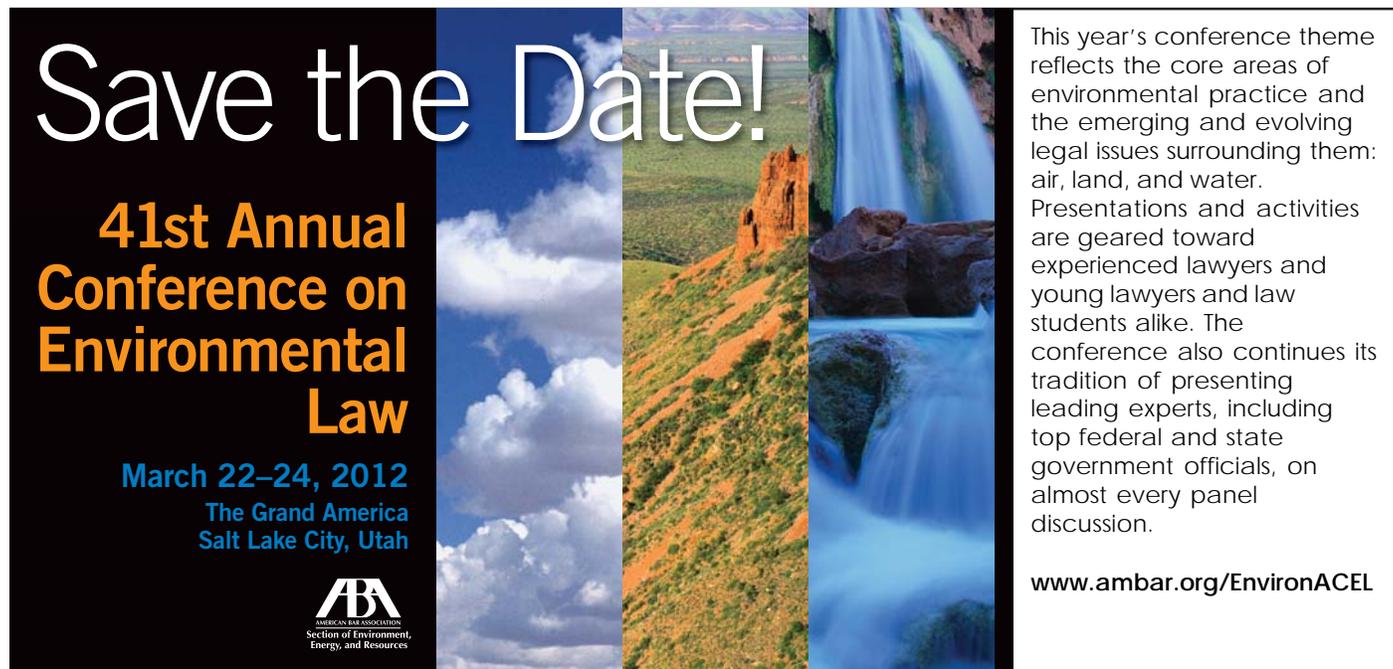
Next Steps

Based on the comments from the GRSP, it appears that most members approved of the general scope and framework of the informal draft regulations and offered comments and suggestions regarding the details of how this framework would be implemented. DTSC does not expect to hold another face-to-face GRSP meeting before the regulations are promulgated. The GRSP may schedule a teleconference sometime during the

process. DTSC convened a workshop on December 5, 2011, to “welcome comments and suggestions from the public to enhance the informal draft regulations to make them more meaningful, practical, technically sound, and legally defensible.” DTSC also accepted comments on the regulations until December 30, 2011.

Stayed tuned and watch for developments in connection with this initiative. It is a game-changing development that will significantly influence domestic and international product manufacturing practices.

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