FROM THE CHAIR

Martha Marrapese

In so many ways, 2012 marks a standout year of growth and recognition for the Pesticides, Chemical Regulation, and Right-to-Know Committee. PCRRTK was recognized at the 20th Section Fall Meeting with the 2011–2012 Best Newsletter Award for Environmental Committees. Our membership recruitment efforts are being rewarded—we end 2012 with a total of 230 PCRRTK members across the country.

PCRRTK sponsored or cosponsored several well-received webinars and breakfast briefings in 2012, as well as a Fall Meeting session on hydraulic fracturing. Our contribution to the 2012 Environment, Energy, and Resources Law Year-in-Review will double in length over prior years. We also are fortunate now to have full participation in the PCRRTK leadership ranks, with the recent addition of vice chairs for social media and nonprofit membership, respectively.

I would like to extend a tremendous thank-you to PCRRTK’s immediate past 2011–2012 chair, Charles Franklin at Akin Gump, to all those who served as vice chairs during that period, and to other members who organized and participated in these events and milestones. Congratulate yourselves on another stellar PCRRTK year!

In 2013, let’s continue to pay particular attention to our committee’s strengths: timely and thoughtful writing for this newsletter, PCRRTK’s quality programming, and young lawyer recruitment. For example, do you have an idea and a couple hours to help organize a webinar on pesticide or right-to-know topics? If so, please drop us a line.

In recent monthly calls, other areas of activity we might consider have been raised. For example, we want at least one PCRRTK face-to-face event or meeting in 2013 in a west coast location. Are you interested in hosting such a meeting? Would you like to develop a proposal addressed to the SEER Congressional Relations Task Force on how PCRRTK members can be a resource for Capitol Hill? Have you thought about a moderating role for PCRRTK in the debate on legal standards of review for Toxic Substances Control Act reform? Is a task force to explore synergies with our SEER Science and Technology Committee colleagues of interest over the coming months? We welcome your experience and insight.

In the end—as our practices can attest—we are all just an e-mail away. With that in mind, contact information for your final 2013 PCRRTK leadership roster is presented below. Please accept my very best wishes for a successful 2013.

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Committee Newsletter
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continued on page 3
In this issue:

From the Chair
Martha Marrapese ............................... 1

Draft Mold Policy Raises Questions for Treated Article Manufacturers
Charles L. Franklin .............................. 4

EPA’s New Cadmium in Consumer Products Reporting Rule
Lawrence E. Culleen, Shailesh Sahay, and Jonathan Elsasser ............................. 5

TSCA, FIFRA, and Perhaps EPCRA Likely to Play Featured Roles in the Piecemeal Development of Federal Fracking Regulation
Katherine Ghilain and Shailesh Sahay ............................................. 7

EPA Weighing the Use of FIFRA as a New Regulatory Tool to Address Concerns with Fracking
W. Ryan Stephens and Catherine M. Wilmarth ................................. 9

EPA Announces Availability of Draft Chemical Risk Assessments
Lynn L. Bergeson .................................. 11

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continued from page 1

**Committee Newsletter (continued)**

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www.ambar.org/EnvironSpring
On December 12, 2012, the U.S. Environmental Protection Agency (EPA) released the draft “Guidance for Antimicrobial Pesticide Products with Mold-Related Label Claims” (Mold Claim Policy). The Mold Claim Policy, which was issued in the form of a pesticide registration notice (PRN), purports to clarify EPA’s evolving thinking regarding when products claiming to inhibit or destroy mold should be regulated as public health pesticides versus non-public health pesticides, and establishes new labeling policies for products that have not submitted efficacy data to EPA for premarket review. The policy reflects EPA’s belief that human exposure to various fungal molds may pose greater risks to public health than previously believed, requiring the agency to tighten its oversight of mold claims generally, and less stringent claims in particular. As currently proposed, however, the Mold Claim Policy could also clash with EPA’s long-standing policy on treated articles.

The mold PRN would apply to “antimicrobial pesticides that bear a label claim to inhibit or destroy mold or mildew growth on hard, nonporous and porous surfaces in indoor environments.” Substances or mixtures purporting to “[destroy] fungi (including yeasts) and/or fungal spores pathogenic to man or other animals in the inanimate environment” would be regulated as “fungicides,” requiring manufacturers to submit efficacy data as for premarket review during the registration process. Substances or mixtures purporting to “[inhibit] the growth of fungi in the inanimate environment . . . for aesthetic or cosmetic (non-public health) purposes only” or (2) delete all mold claims from the label. Mold PRN at 8.

EPA has long held that pesticides and pesticide products claiming to protect humans from public health pests should be held to a higher standard of review and performance than pesticides and products claiming to provide offering other types of pest-control benefits. See, e.g., 40 C.F.R. section 161.640 FN1 (waiving all requirements to submit efficacy data “unless the pesticide product claims to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user”). Consistent with that policy, EPA already distinguishes between public health claims and non-public health claims involving mold, mildew, and other sources of fungal contamination.

But while the regulatory distinction between public health pesticides and non-public health pesticides is well established, the mold PRN goes further, categorizing all mold claims into one of two groups: fungicidal or fungistatic claims. This binary analysis ignores both the complexity of the marketplace and EPA’s own precedent. For example, EPA cites a 2009 draft product performance test guideline for its interpretation of the terms “fungistat” and “fungicide.” PRN at 1, FN1 (citing “OPPTS 810.2000: General Consideration for Public Health Uses of Antimicrobial Agents” (Nov. 5, 2009 (Draft), issued in final as OPPTS 810.2010 in Mar. 2012)) (General Considerations Guidance). Unlike the proposed Mold Claim Policy, the General Considerations Guidance recognizes “treated article” claims as its own distinct category.

Treated articles or substances are treated with a registered pesticide for the limited purpose of protecting the treated article or substance itself from decay, odor, stains, or other microbial damage caused by microbial contamination, including contamination from mold and mildew. 40 C.F.R. § 152.125. The primary source of guidance on the scope, applicability, and labeling requirements for treated articles is PRN 2000-1, entitled “Applicability of the Treated Articles Exemption to Antimicrobial Pesticides” (Treated
Articles PRN). The Treated Articles PRN offers numerous examples of acceptable claims referencing a treated product’s ability to “inhibit the growth of microorganisms which may cause odors or to inhibit the growth of mold and mildew.” Id. at 2, 5–7.

This raises a challenge for the regulated community. By its omission of any reference to treated articles, EPA’s proposed Mold Claim Policy could be read to lump treated article claims in with traditional fungistatic claims or to exclude them in their entirety. Given the impact that the additional labeling requirements would have on commercial, industrial, and consumer product manufacturers that incorporate antimicrobial pesticides into treated articles, the ambiguity creates a significant challenge for the regulated community and for other pesticide stakeholders. Rather than roll the dice on how EPA may interpret its policy down the road, interested parties should review and weigh in now.

EPA is accepting comments through February 11, 2013. The notice, draft PRN, and supporting documentation are available under Docket No. EPA-HQ-OPP-2010-0539 at www.regulations.gov.

Charles L. Franklin is an attorney with Akin Gump Strauss Hauer & Feld LLP in Washington, D.C.

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**EPA’S NEW CADMIUM IN CONSUMER PRODUCTS REPORTING RULE**

Lawrence E. Culleen, Shailesh Sahay, and Jonathan Elsasser

To close out 2012, the U.S. Environmental Protection Agency (EPA) issued and subsequently announced the withdrawal of a final rule under the Toxic Substances Control Act (TSCA) section 8(d). Notwithstanding the false start, the action demonstrates EPA’s continued willingness to use TSCA to regulate consumer products based on their chemical composition. See original publication at 77 Fed. Reg. 71,561 (Dec. 3, 2012) and notice of withdrawal at 77 Fed. Reg. 76,419 (Dec. 28, 2012). The withdrawn rule would have required manufacturers of cadmium or cadmium compounds, or companies that import consumer products containing cadmium compounds, to report certain unpublished health and safety studies to EPA. EPA’s rulemaking is notable not only because it would have affected the chemicals industry, but also because it demonstrates EPA’s continued willingness to regulate consumer products on the basis of chemical content.

If established, the new reporting requirements would have applied to manufacturers or importers of cadmium or cadmium compounds (defined as chemicals that contain any cadmium in their chemical structure) when the compounds have been or are reasonably likely to be incorporated into consumer products. Further, the reporting requirements also would have applied to entities manufacturing or importing “articles” (i.e., products) that contain cadmium compounds, as long as those articles have been or are reasonably likely to be incorporated into consumer products. EPA provided several examples of companies that could be affected by the final rule, including entities such as manufacturers of basic organic chemicals, manufacturers and importers of inorganic dyes and pigments, producers or refiners of nonferrous metals (except copper and aluminum), wholesalers of toy and hobby goods, discount department stores, and warehouse clubs and supercenters. EPA also announced its intent to propose to extend the rule to processors and distributors of cadmium and cadmium compounds and articles.
containing those compounds. The notice of withdrawal did not indicate that EPA is backing away from such a future action.

The withdrawn rule would have required manufacturers and importers to report unpublished studies related to human and environmental effects of cadmium and cadmium compounds. Entities would have had to submit studies on a variety of topics relating to human health effects, ecological and environmental effects, human and environmental exposure, and monitoring data. Relevant studies also would include those involving “measurable content of cadmium or cadmium compounds in consumer products.” Section 8(d) rules do not obligate companies to initiate new studies, but do require reporting any initiated or completed studies that fall within this scope.

The origin of EPA’s rulemaking dates to 2010, when EPA announced that it would issue a proposed TSCA reporting rule in response to a petition by the Sierra Club and other groups. See http://www.cpsc.gov/library/foia/foia10/petition/cadmiumdenial.pdf. In the petition, these groups sought several actions by EPA and the Consumer Product Safety Commission (CPSC) to regulate more strictly cadmium compounds in children’s products. EPA had indicated that it would likely review information received pursuant to the section 8(d) rule before pursuing further restrictive actions concerning cadmium under TSCA section 6. CPSC recently announced that a new and revised ASTM standard will adequately address the risks of cadmium; thus, it appears that the commission will not likely pursue additional rules at this time.

The agency withdrew the section 8(d) rule based on comments and questions it received raising concerns about the scope and interpretation of the immediate final rule. Citing “significant confusion and uncertainty about the final rule in certain industrial sectors,” EPA concluded there was “good cause” to withdraw the rule. The section 8(d) rule had a very broad scope and would have affected many companies within industry sectors not typically subject to TSCA section 8(d) reporting requirements.

EPA’s path forward is unclear. The agency is expected to review the questions and comments it has received, but did not specifically commit to issuing an updated section 8(d) rule. EPA plans to continue to collaborate with CPSC to address safety concerns related to cadmium in consumer products.

One potential implication of the cadmium section 8(d) reporting rule was the possibility that EPA could allege that violations of TSCA section 8(e) had occurred in the past. TSCA section 8(e) requires manufacturers, processors, and distributors of a chemical substance or mixture to “immediately” report information to EPA that reasonably supports the conclusion that the substance or mixture presents a substantial risk of injury to health or the environment. The reporting rule, therefore, would have created a risk for entities that might submit copies of unpublished health and safety studies if the agency were to interpret those studies also to have been reportable pursuant to TSCA section 8(e).

Lawrence E. Culleen and Shailesh Sahay are members of the Environmental Practice Group in the Washington, D.C., offices of Arnold & Porter LLP (A&P). Jonathan Elsasser also contributed to this article.

Judges Needed for the 2013 National Environmental Law Moot Court Competition

The 2013 Competition will be held February 21-23 on the White Plains campus. Over 70 schools are registered to participate in this preeminent moot centered on current, and often controversial, environmental issues. Attorneys who are admitted to the bar are invited to judge the preliminary rounds of oral arguments on February 21 and 22. Two NYS CLE practice credits may be earned per round of judging.

Additionally, we are also offering three separate environmental CLE programs in connection with the competition: a one-credit environmental ethics CLE on Thursday, February 21, and two environmental CLEs (one practice credit for each) on Friday, February 22. These programs will inform on a number of practical and ethical concerns pertinent to environmental lawyers and are FREE for all attorneys who also judge the competition. For more information, visit www.law.pace.edu/nelmcc or e-mail Leslie Crincoli at nelmcc@law.pace.edu.
TSCA, FIFRA, AND PERHAPS EPCRA LIKELY TO PLAY FEATURED ROLES IN THE PIECemeAL DEVELOPMENT OF FEDERAL FRACKING REGULATION
Katherine Ghilain and Shailesh Sahay

Hydraulic fracturing, or “fracking,” has emerged as a central issue in American energy, economic, and environmental policy. Technological advances, infrastructure development, and increasing demand have prompted a boom in natural gas production in shale formations across the United States. Fracking involves the injection of fluid at high pressure to force open cracks within shale formations and release the natural gas trapped inside. The fluid is a mixture of water, a proppant (often sand) used to keep fractures open, and chemical substances used to help facilitate the process. These chemicals typically include substances designed to reduce friction, eliminate bacterial growth, and prevent well pipe corrosion. States in which fracking is already occurring have created a patchwork of laws and regulations, but federal regulatory involvement is still a work in progress.

According to a September 2012 Government Accountability Office (GAO) report, parts of the following eight federal environmental and public health laws apply to unconventional oil and gas development:

- Safe Drinking Water Act (SDWA);
- Clean Water Act (CWA);
- Clean Air Act (CAA);
- Resource Conservation and Recovery Act (RCRA);
- Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA);
- Emergency Planning and Community Right-to-Know Act (EPCRA);
- Toxic Substances Control Act (TSCA); and
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

The oil and gas industry has enjoyed long-standing exemptions or limitations in coverage related to the first six of these statutes, id., which places limitations on federal authority absent new legislation. As a result, the U.S. Environmental Protection Agency (EPA) is in the process of evaluating its existing statutory authority to regulate fracking and may end up taking a piecemeal approach, adding further complexity to the already complicated legal landscape.

In November of 2011, EPA announced that it plans to propose rules under TSCA to collect and subsequently disclose information on the composition and potential health and environmental effects of chemical substances used in the fracking process—an effort prompted by a petition filed by Earthjustice and more than 100 other environmental groups. Letter from Stephen A. Owens, Assistant Administrator, Environmental Protection Agency, to Deborah Goldberg, Earthjustice (Nov. 23, 2011), available at http://www.epa.gov/oppt/chemtest/pubs/EPA_Letter_to_Earthjustice_on_TSCA_Petition.pdf.

EPA is still weighing a 2010 petition from the Natural Resources Defense Council asking the agency to reconsider the exemption of exploration and production wastes from hazardous waste regulation under subtitle C of RCRA. According to the GAO report, narrowing this exemption would require congressional approval. More recently, EPA has made apparent it also is considering its authority to oversee certain aspects of fracking operations under FIFRA, as biocides used in fracting fluid may be characterized as pesticides, and FIFRA contains no exemptions for extraction operations. Bridget DiCosmo, EPA Eyes Novel Use of FIFRA to Address Fracking, Prompting New Concern, Inside EPA (Oct. 22, 2012). Finally, an October 24, 2012, petition by another group of environmental organizations has asked EPA to add the oil and gas extraction industry to the list of industry sectors already regulated under EPCRA section 313(b)(1)(B), that would require the industry to report chemical releases from drilling and other phases of production and processing to the

Toxics Release Inventory (TRI). Letter from Eric Schaeffer, Executive Director, Environmental Integrity Project, and Adam Kron, Attorney, Environmental Integrity Project, to Hon. Lisa Jackson, Administrator, U.S. Environmental Protection Agency (Oct. 24, 2012), available at http://www.environmentalintegrity.org/news_reports/documents/2012_10_24TRIPetitionFINALSIGNEd.pdf. This request follows an earlier decision by the Department of Interior (DOI), through the Bureau of Land Management (BLM), to propose revisions to existing regulations that would require public disclosure of chemicals used in fracking operations on federal and Indian lands. 77 Fed. Reg. 27,691 (May 11, 2012). The BLM has authority to regulate fracking on federal and Indian lands pursuant to the Federal Land Policy and Management Act, the Mineral Leasing Act, the Mineral Leasing Act for Acquired Lands, and the Indian Mineral Leasing Act. See 43 C.F.R. § 3160.0-3. Current BLM regulations applicable to fracking are found at 43 C.F.R. § 3162.3-2.

In addition to considering regulation under these environmental laws, EPA has already taken several steps to regulate fracking. Earlier this year, EPA issued a final rule under the CAA to require fracking operators to reduce air emissions at new or modified natural gas wells. 77 Fed. Reg. 49,490 (Aug. 16, 2012). The agency also initiated a rulemaking to develop CWA effluent guidelines to control the discharge of wastewater produced by fracking operations. 76 Fed. Reg. 66,286 (Oct. 26, 2011). EPA has also issued draft guidance to clarify permitting requirements for using diesel fuels during fracking operations under the SDWA. 77 Fed. Reg. 27,451 (May 10, 2012).

The extent to which EPA will seek to regulate fracking under these and the other applicable environmental laws remains to be seen and may be determined in part by the agency’s multi-year study of fracking’s potential impacts on drinking water. Stakeholders will need to monitor EPA’s activities closely and engage with the agency to ensure that any proposed rules take into consideration existing state requirements and other federal requirements.

Katherine Ghilain and Shailesh Sahay are members of the Environmental Practice Group in the New York and Washington, D.C., offices of Arnold & Porter LLP.

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**Call for Nominations**

ABA Section of Environment, Energy, and Resources

**2013 Award for Distinguished Achievement in Environmental Law and Policy**

The ABA Award for Distinguished Achievement in Environmental Law and Policy will be given in recognition of individuals or organizations who have distinguished themselves in environmental law and policy, contributing significant leadership in improving the substance, process or understanding of environmental protection and sustainable development. Eligible individuals must be lawyers and may include academics, policymakers, legislators, practitioners, members of the judiciary, or journalists.

**Environment, Energy, and Resources Dedication to Diversity and Justice**

The Environment, Energy, and Resources Dedication to Diversity and Justice Award recognizes and honors the accomplishments of a person, entities, or organizations that have made significant accomplishments or demonstrated recognized leadership in the areas of environmental justice and/or a commitment to gender, racial, and ethnic diversity in the environment, energy, and natural resources legal area. Accomplishments in promoting access to environment/energy/resources rule of law and to justice can also be recognized via this award.

**Nomination deadline: May 13, 2013**

These awards will be presented at the ABA Annual Meeting in San Francisco in August 2013.

[www.ambar.org/EnvironAwards](http://www.ambar.org/EnvironAwards)
EPA WEIGHING THE USE OF FIFRA AS A NEW REGULATORY TOOL TO ADDRESS CONCERNS WITH FRACKING
W. Ryan Stephens and Catherine M. Wilmarth

Introduction

To address environmental concerns associated with natural gas extraction by hydraulic fracturing, the U.S. Environmental Protection Agency (EPA) is investigating its regulatory authority under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Currently hamstrung by gas and oil production exemptions in environmental statutes such as the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA), FIFRA could provide EPA with a regulatory avenue to monitor hydraulic fracturing, commonly referred to as “fracking.”

Background

The risks and rewards of fracking are fiercely debated, but one thing is certain: the practice of fracking has surged recently. Currently, it is used in approximately nine out of ten onshore oil and gas wells in the United States. Experts estimate that 11,400 new wells are fractured each year.

As a result, fracking continues to grow as a hot topic in the nation’s energy dialogue. Proponents tout the benefits of the cleaner fuel, including the importance of a safe domestic energy supply and its use as a bridge between our current reliance on fossil fuels and a future driven largely by renewable energy sources. The thought is that a transition away from conventional fossil fuels toward natural gas would provide environmental benefits while minimizing effects on the nation’s energy infrastructure, while alternative sources are further researched. When burned, natural gas emits half as much carbon dioxide as coal, and does not release sulfur dioxide, mercury, or particulates.

Critics highlight the stories of fracking gone wrong: flammable tap water, methane leaks, earthquakes, and area residents complaining of illness. Among the concerns is the use of chemical additives in the fracking fluid. Mixtures vary within the industry, but water generally makes up 90 percent of the fracking cocktail, sand or glass beads used as “proppants” to keep the fissures open equate to about 9 percent, and the remaining 1 percent consists of chemical additives. Each chemical additive has a particular purpose. Chemicals commonly used include acids to dissolve minerals and help initiate fissures in the rock, friction reducers to minimize resistance between the fluid and pipes, and biocides to eliminate bacteria in the water that may lead to corrosion. It is this use of biocides that may open the door to EPA regulation through FIFRA.

Other Federal Statutes

A recent Government Accountability Office (GAO) report listed eight federal environmental and public health laws that apply to “unconventional oil and gas development.” Six of the eight laws contain exemptions to regulatory coverage: (1) Safe Drinking Water Act, (2) CWA, (3) Clean Air Act, (4) RCRA, (5) Comprehensive Environmental Response, Compensation, and Liability Act, and (6) Emergency Planning and Community Right-to-Know Act. The two not containing such exemptions are FIFRA and the Toxic Substances Control Act (TSCA).

Potential Regulation Under FIFRA

EPA has been searching for a way to regulate fracking through existing statutory authority. The agency’s regulatory power is greatly curtailed by the previously mentioned oil and gas production exemptions in many environmental statutes. Most chemicals used fall within TSCA’s scope. Biocides, however, are pesticides, and fall under FIFRA. According to the GAO report, FIFRA “mandates that EPA administer pesticide registration requirements and authorizes EPA to regulate the use, sale, and distribution of pesticides to protect human health and preserve the environment.”

EPA’s research into potential FIFRA regulatory authority over fracking focuses on the antimicrobial chemicals, or biocides. Biocides are used in small quantities to limit the growth of algae and other microbials in the fissures, as such growth could potentially inhibit the extraction process.
While many of these biocides have been registered by EPA as required under FIFRA, industry use in fracking may account for a “new use.” If the utilization in fracking constitutes a new use, EPA’s regulatory powers become less clear.

The registration requirement requires significant detail and it does not encompass all possible uses of a chemical. Industry officials suggest that current biocide registrations do not properly list the use of fracking—a potential impediment to EPA regulatory power that would require labeling modifications under FIFRA to resolve. EPA’s Office of Pesticide Programs (OPP) is currently investigating to determine if the agency properly accounted for the risks presented by these biocides.

**Consequences of Potential FIFRA Regulation and Proactive Measures**

EPA’s use of FIFRA as a regulatory tool has raised a number of questions within industry. Industry concerns include what obligations there would be under FIFRA; what labeling requirements and responsibilities would be mandated; and what the liabilities would be for end users that fail to meet FIFRA requirements.

One solution for industry may be to file a special local need (SLN) registration under FIFRA. Such a registration would protect users from EPA enforcement. These state-specific needs are filed under FIFRA section 24(c), requiring EPA approval and they would only be applicable within the specific state. Montana has taken steps to collaborate with industry to ensure these local need registrations are filed in accordance with FIFRA.

For more information, please see the GAO report on *Unconventional Oil and Gas Development: Key Environmental and Public Health Requirements*, GAO-12-874 (Sept. 2012), available at http://www.gao.gov/assets/650/647782.pdf.

*R. Ryan Stephens* and *Catherine M. Wilmarth* are law fellows with the U.S. Environmental Protection Agency’s Office of Enforcement and Compliance Assurance.
The U.S. Environmental Protection Agency (EPA) announced on January 9, 2013, the availability of the first draft risk assessments developed under the Toxic Substances Control Act (TSCA) Work Plan. 78 Fed. Reg. 1856. The draft risk assessments are for particular uses of five chemicals found in household products: methylene chloride or dichloromethane (DCM) and N-methylpyrrolidone (NMP) in paint stripper products; trichloroethylene (TCE) as a degreaser and in consumer products used by individuals in the arts/crafts field. Given the range of end points (cancer; non-cancer, including potential effects on the developing fetus), the susceptible populations addressed are children and adults of all ages (including pregnant women). Thus, the draft assessment focuses on all human life stages.

For TCE, EPA is asking for nominations of peer reviewers who are experts in the following areas: toxicology of TCE (developmental cardiotoxicity, immunotoxicology, reproductive toxicology, and cancer biology), expertise in physiologically based pharmaco-kinetics (PBPK) modeling for TCE, exposure of volatile organics, experts on use of volatiles as solvent degreasers and in the arts/crafts field, chemical/environmental risk assessment experts, and experts familiar with environmental release data and associated modeling/interpretation.

EPA will forward the nominations to the independent peer review contractor setting up the individual peer review panels. EPA states the draft assessments focus either on human health or ecological hazards for specific uses that are subject to TSCA regulation. Three of the draft risk assessments—DCM, NMP, and TCE—indicate a potential concern for human health under specific exposure scenarios for particular uses. The draft assessments for ATO and HHCB indicate a low concern for ecological risks. If EPA concludes in the final risk assessments that there is a potential for concern, EPA states that it will take appropriate action to address possible risks.

The Federal Register notice includes the following information on the draft risk assessments:

- **HHCB**: HHCB is a synthetic polycyclic musk used as an ingredient in a wide range of consumer products, including perfumes, cosmetics, shampoos, lotions, detergents, fabric softeners, and cleaning agents. The draft assessment focuses on environmental risk due to release of HHCB to the aquatic and terrestrial environment from all combined uses. Human health risks have been evaluated previously and are summarized in the draft assessment.

For HHCB, EPA is asking for nominations of peer reviewers who are experts in the following areas: aquatic ecotoxicology, terrestrial ecotoxicology, fate and biodegradation, fate and bioaccumulation, environmental risk assessment (aquatic and terrestrial), and analytical chemistry of organic waste water contaminants.

- **TCE**: The draft assessment focuses on uses of TCE as a degreaser and in consumer products used by individuals in the arts/crafts field. Given the range of end points (cancer; non-cancer, including potential effects on the developing fetus), the susceptible populations addressed are children and adults of all ages (including pregnant women). Thus, the draft assessment focuses on all human life stages.

For TCE, EPA is asking for nominations of peer reviewers who are experts in the following areas: toxicology of TCE (developmental cardiotoxicity, immunotoxicology, reproductive toxicology, and cancer biology), expertise in physiologically based pharmaco-kinetics (PBPK) modeling for TCE, exposure of volatile organics, experts on use of volatiles as solvent degreasers and in the arts/crafts field, chemical/environmental risk assessment experts, and experts familiar with environmental release data and associated modeling/interpretation.

- **ATO**: The draft assessment focuses on the ecological hazards that may be associated with ATO use in flame retardants. Human health risks for the flame retardant use have been
evaluated previously and are summarized in this draft assessment. Because ATO use in plastics was previously evaluated for human health and the environment, that use scenario is not evaluated.

For ATO, EPA is asking for nominations of peer reviewers who are experts in the following areas: exposure modeling, aquatic ecotoxicology, terrestrial ecotoxicology, inorganic chemistry addressing water and sediment issues, and groundwater.

- **DCM and NMP**: The related draft assessments focus on the use of DCM and NMP in paint stripping and will be addressed by the same peer review panel. With regard to DCM, the draft assessment focuses on inhalation exposure to consumers and workers, and addresses human health concerns for both cancer and non-cancer effects. The low concern for environmental effects of DCM is discussed in the draft assessment. With regard to NMP, the draft assessment focuses on acute and chronic inhalation and dermal exposure to consumers and workers in the paint stripping use and the end point of concern is developmental toxicity. The low concern for environmental effects of NMP is discussed in the draft assessment.

For DCM and NMP, EPA is asking for nominations of peer reviewers who are experts in the following areas: inhalation toxicology, toxicokinetics/PBPK modeling, dermal toxicology, neurotoxicology, immunotoxicology, developmental and reproductive toxicology, cancer biology, expertise in U.S. consumer modeling (inhalation and dermal), and expertise in occupational exposure assessment (inhalation and dermal), especially as related to volatile organic chemicals.

EPA states that the draft risk assessments on the two remaining chemicals from the initial group of seven work plan chemicals scheduled to begin assessment in 2012—the long- and medium-chain chlorinated paraffins—are on a different schedule for completion. EPA will make the draft risk assessments available for public comment through another Federal Register notice issued on a later date.

**Next Steps**

EPA states that it will publish the list of candidate peer reviewers, which will include those nominated by the public and those identified by a contractor, in the Federal Register for public comment. After a 30-day comment period, informed by any comments, the contractor will select the peer reviewers for these “influential” risk assessments. The detailed peer review plans for the draft assessments are accessible through the EPA’s Peer Review Agenda Web site at http://cfpub.epa.gov/si/si_public_pr_agenda.cfm. EPA will consider comments received from the public and the subsequent peer review when preparing the final individual chemical risk assessments and will describe in a written report how it addressed public and reviewer comments in the final assessments. EPA will issue another Federal Register notice to announce the availability of the final risk assessments.

**Interesting Issues Raised**

Based on a quick skim, the human health risk assessments seem to be clearly and carefully presented. They also seem to be quite conservative in the approaches applied and the conclusions obtained. One could argue that such conservatism, while appropriate for a preliminary or screening-level risk assessment, may inappropriately overstate the risk conclusions and their significance given that these assessments are intended to be followed by “appropriate risk reduction actions” if potential risks of concern are determined to exist. Because of the detail provided, the bases for EPA’s health risk conclusions are clearly set forth. This level of detail may also be seen to provide multiple “handholds” for raising issues with and contesting EPA’s judgments as it constructed its assessments and outlined its conclusions. While EPA seems to have done a good job of identifying and discussing the uncertainties in its assessments, as noted above it also seems to have consistently opted for
conservative, worst-case assumptions and approaches. The results of the peer review and its reaction to EPA’s approach will be an important development to watch, both for purposes of these assessments and for signaling whether a more refined and realistic approach is suggested for future work plan risk assessments.

Overall, this would appear to be the next step in the continued “TSCA revitalization” effort of the current Office of Chemical Safety and Pollution Prevention (OCSPP) leadership, especially as articulated by Jim Jones, acting assistant administrator. These assessments, while conservative, will place a marker in terms of what the Office of Pollution Prevention and Toxics (OPPT) believes to be is the best risk assessment estimate given the state of knowledge it has about hazard and exposure. Should an interested party claim that the risk estimates are unreasonable overestimates, it will be its burden to supplement the current record so that OPPT can revise its assessments and perhaps reach a different conclusion.

This is intended, in part, to improve on past practices where often incomplete or missing information was identified and then any follow-up was left to an uncertain fate. Separately, it will remain to be seen whether any new approach can result in more meaningful generation of additional data or enhance regulatory conclusions made by the program.

Another issue that has been raised concerns the adequacy of the peer review that EPA plans to conduct on what it believes to be “influential” draft risk assessments. On December 21, 2012, Senator James Inhofe (R-OK), ranking member of the Senate Environment and Public Works Committee, and committee members Senators Lamar Alexander (R-TN), Mike Crapo (R-ID), and David Vitter (R-LA) requested that EPA classify the risk assessments prepared under the TSCA Work Plan as “highly influential.” Because EPA chose to classify them as “influential,” the senators noted that they would be subject to a less rigorous peer review. The senators cite the Office of Management and Budget (OMB) 2004 “Final Information Quality Bulletin for Peer Review” and EPA’s Peer Review Handbook, which state that highly influential scientific assessments are those that are “novel, controversial, or precedent-setting” or that have significant interagency interest.

The senators recommended that, to ensure a “robust body of reviewers,” EPA encourage the public to nominate peer review candidates. In addition, consistent with the best practices of the National Academies and EPA’s Science Advisory Board, EPA should allow the public to comment on the specific peer reviewers under consideration. The senators also criticized EPA’s plan to conduct the peer reviews by teleconference, and encouraged EPA to respond to public comments in writing.

While EPA will solicit nominations from the public for peer review candidates and allow comment on specific peer reviewers, it appears that EPA does not intend to follow all the senators’ recommendations. Based on language in the draft risk assessments, it seems EPA has decided to continue to classify the risk assessments as “influential” scientific assessments and not to conduct any peer review sessions in person. Each draft risk assessment states: “A peer review panel is being arranged for this influential workplan assessment product based upon need and following Agency peer review guidance. The format will be a teleconference of an ad hoc panel meeting consisting of independent experts.” How this aspect plays out will also be very telling regarding EPA’s future approach to work plan risk assessments.

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