

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

Vol. 14, No. 1

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FROM THE CHAIR

Martha Marrapese

As I write this column as chair of the Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) Committee, I do so with great optimism and continuity in mind. Not too many years ago, a bright summer associate candidate, when asked if she had any questions, responded by asking if I thought environmental law was dead. My response: not if you can adapt. Today more than ever, we practice in a growing and dynamic area of the law. PCRRTK has played a pivotal role in educating our members on cutting-edge areas of our practice that have a direct or indirect impact on more conventional practice areas. We are fortunate to have the strong leadership and support of the American Bar Association (ABA) and Section of Environment, Energy, and Resources (SEER) as our field continues to grow and evolve.

PCRRTK traditionally covers legal, legislative, and global regulatory developments associated with our primary statutes (Toxic Substances Control Act (TSCA), Federal Insecticide, Fungicide, and Rodenticide Act, Emergency Planning and Community Right-to-Know Act, the Integrated Risk Information System, Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH), and beyond). In recent years, we have taken on discussions of developments associated with nanotechnologies related to chemical control, pesticides, and community right-to-know. This year, we have more “front burner” topics before us,

including legal developments associated with green chemistry/biobased chemistry, requirements associated with hydraulic fracturing and chemical disclosure, TSCA reform, and legal trends affecting genetically engineered crops/genetically engineered technologies, both for food production and for alternative energy generation.

The critical importance of these new technological developments—and the legal and regulatory issues they raise—fit under our committee, and are not being addressed anywhere else by SEER (or other sections). To remain faithful to PCRRTK’s commitment to keep on top of the latest developments in its programs and publications, our vice chairs plan to offer excellent programming and coverage in our *SEER Year in Review* chapter on these topics.

With the help of ABA and SEER leadership, PCRRTK will continue to make good on its efforts to increase its cultural, professional, and regional diversity in several ways. We enlist your help to spread the word about PCRRTK as an ongoing legal resource. Check out the PCRRTK webpage—<http://apps.americanbar.org/dch/committee.cfm?com=NR351500>—a standout that offers many useful resources to practitioners. In addition, we plan to continue to offer more face-to-face PCRRTK networking opportunities in and outside of Washington, D.C. Contact regional membership vice chair Lori Warner if you are interested in planning and hosting one of these networking events. Ensuring a

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Vol. 14, No. 1, November 2012
Lynn L. Bergeson, Editor

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**AMERICAN BAR ASSOCIATION
SECTION OF ENVIRONMENT,
ENERGY, AND RESOURCES**

CALENDAR OF SECTION EVENTS

November 15, 2012
11th Annual Energy Litigation Conference
Primary Sponsor: Institute for Energy Law
Houston, TX

November 15, 2012
Environmental Law and Hurricane Sandy
Quick Teleconference

January 25-27, 2013
ABA SEER Winter Council Meeting
La Concha Resort
San Juan, PR

February 6-12, 2013
ABA Midyear Meeting
Dallas, TX

February 26, 2013
Key Environmental Issues in US EPA Region 4
Atlanta, GA

March 21-23, 2013
42nd Spring Conference
Grand America Hotel
Salt Lake City, UT

April 11-12, 2013
ABA Petroleum Marketing Attorneys' Meeting
Washington, DC

April 18, 2013
ABA Public Lands and Resources Law Symposium
Missoula, MT

April 19-21, 2013
ABA SEER Spring Council Meeting
Greenough, MT

June 5-7, 2013
31st Annual Water Law Conference
Las Vegas, NV

**For full details, please visit
www.ambar.org/EnvironCalendar**

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range of viewpoints, backgrounds, and professional affiliations represented in the committee in these ways will only increase its value and relevance going forward.

In closing, the people who volunteer their time as vice chairs, as planners and as participants for programs and special projects, and as sounding boards and implementers for new ideas, are what make this committee a success. I look forward to working with our new and continuing vice chairs and participating members in the coming months ahead as PCRRTK continues to reflect the changing landscape of pesticide and chemical law and policy.

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FTC'S REVISED GREEN GUIDES: HELP STILL WANTED FOR REAL MARKETING SOLUTIONS

Charles L. Franklin

After 14 years, including more than four years of public consultation, consumer research, and internal analysis, the Federal Trade Commission (FTC) has finally updated its “Guides for the Use of Environmental Marketing Claims,” widely known as the “Green Guides.” 16 C.F.R. pt. 260. The revised Green Guides, released October 1, 2012, refine FTC’s position on many long-regulated types of claims, establish FTC positions on a variety of more recent environmental claims and scenarios, and provide generally applicable principles for developing, substantiating, and qualifying such claims.

As reflected in the name, the Green Guides provide guidance—not binding standards—on FTC’s approach to enforcing false, deceptive, and misleading environmental claims under section 5 of the Federal Trade Commission Act. 15 U.S.C. § 45(a). FTC regulates environmental claims on a case-by-case basis using the Green Guides as a reference point in assessing the legality of specific marketing claims during enforcement proceedings. *See* 16 C.F.R. pt. 260. Though lacking the force of law, the Green Guides offer an important guidepost to FTC and the regulated community by identifying presumptive prohibitions and safe harbors with respect to marketing practices.

At the broadest level, the guides establish general principles applicable to all environmental marketing.

- **Express and Implied Claims:** Marketers are accountable for all claims that a marketing statement or advertisement reasonably conveys, whether express or implied, and whether intended or not. *Id.* § 260.2.
- **Substantiation:** Marketers must be able to substantiate claims, both express and implied, under a “reasonable basis” test. *Id.* § 260.2.
- **Qualification:** Marketers must qualify and limit claims where the purported claim would otherwise expressly or impliedly overstate the attribute or benefit. *Id.* § 260.3.
- **Product vs. Package vs. Service:** Marketers must limit claims to the relevant portion(s) of the product, package, or service. *Id.*

- **Negligible vs. Significant Benefits:** Marketers should not make express or implied claims for environmental attributes with a negligible net benefit. *Id.*
- **Special Care with Comparative Statements:** Where marketing materials make explicit or implicit comparisons between the environmental attributes of different products or processes, the materials should make the basis for the comparison sufficiently clear to avoid consumer deception. *Id.*
- **Prominent Display of Qualifying Language:** Any qualification or disclosure should be sufficiently clear, prominent, and understandable to prevent deception. *Id.*
- **Qualification of General Environmental Claims:** General environmental claims like “environmentally friendly,” “environmentally preferable,” “earth-smart,” “essentially non-toxic,” etc., may be easily misunderstood by consumers due to their ambiguity and lack of precision. To avoid deception, marketers should use clear and prominent qualifying language that limits the claim to a specific benefit or benefits. *Id.* § 260.4.
- **Cautious Recognition of Certifications and Seals of Approval:** Marketers can reference certifications and seals of approval, but must include language conveying that the mark refers to limited or specific benefits. Marketers have an independent responsibility to substantiate any claims made through a certificate or seal, and must disclose any material relationship between the product and the certifying body. *Id.* § 260.6.

As a general matter, the revised guides cover a good deal of ground in a relatively compact set of principles, and FTC has taken extra care to provide supporting materials on its Web site to distill key principles and themes using summaries, a detailed “Statement of Basis” document, and even a video featuring Laura Koss, the program’s key legal architect.

At a more granular level, the guides walk through a long list of specific terms and claims subject to scrutiny, including claims that a product or service is compostable; degradable; “free-of” one or more substances; non-toxic; ozone-safe or ozone-friendly; recyclable; made with recycled content; refillable;

made with renewable energy; made with renewable materials; or formulated or repackaged to reduce waste or toxicity. In each case, the guides discuss potential sources of consumer confusion and offer examples of compliant and noncompliant claims.

But, while the guides are thorough from a regulatory standpoint, they do not necessarily reflect the realities that product and service companies face in the marketplace. Whereas FTC’s safe harbor examples often recommend lengthy qualifications one to two sentences long, regulatory counsel typically face intense pressure from brand managers and advertising experts to minimize verbiage, especially on product labeling and packaging itself. For regulatory counsel advising a company on a compliant environmental marketing strategy, providing helpful advice will require more than a simple recitation of the safe harbor examples in the guides. Counsel must be able to understand the risk tolerance of the company, the needs, goals, and merits of the proposed marketing strategy, the basis and substantiation for the claims, and the potential areas of greatest consumer confusion with respect to both express and reasonably implied claims. With this understanding of the client’s needs and constraints in mind, regulatory counsel will need to translate the concepts underlying the safe harbor examples into shorter and simpler forms tailored to the product and label. In short, regulatory counsel must find a way to balance regulatory compliance with commercial salesmanship.

The revised guides provide useful insight into FTC’s regulatory mind-set and certainly help flag some of the more obvious no-no’s in the advertising context. For practitioners advising clients on viable marketing language, however, the bureaucratic language suggested by FTC is unlikely to survive a pitch meeting. As the cliché goes, the marketer’s mission is to sell the “sizzle,” not just the steak. For regulatory practitioners advising companies on environmental marketing policies, the trick is to keep a focus on the sizzle, without turning the product into bologna.

Information on the revised Green Guides is available at <http://business.ftc.gov/advertising-and-marketing/environmental-marketing>.

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WILL RECENT ACTION IN THE SENATE FORCE A FLOOR VOTE ON THE SAFE CHEMICALS ACT?

Larry Culleen and Jonathan Elsasser

Recent efforts on the part of Senator Lautenberg have made it conceivable that there could be a floor vote in the Senate on the Safe Chemicals Act (S. 847). If so, the Safe Chemicals Act would become the first comprehensive Toxic Substances Control Act (TSCA) reform bill to be voted on by a least one legislative chamber during the nearly 36 years since the statute was signed by Gerald Ford in 1976. It is no coincidence that these recent events and TSCA's enactment both occurred in election years.

Background

Representatives of both political parties, environmental groups, and trade associations all agree that TSCA is in need of modernization. Industry groups have argued that reform of TSCA will reassure consumers of the safety of their products and streamline complicated webs of state and local regulations, while environmentalists articulate a need to fundamentally strengthen the law to ensure the safety of consumers and the environment more generally.

During the past seven years, New Jersey Senator Frank Lautenberg has championed the reform effort by introducing numerous such bills and garnering support for updating the statute. In 2012, the senator has pushed the effort even further in the course of hearings and by holding out the possibility that there could be partisan work on a compromise bill. On July 9, Senator Lautenberg sent a letter to the U.S. Environmental Protection Agency (EPA) Administrator Lisa Jackson co-signed by 25 senators of both political parties in an effort to engage EPA more actively in his attempts to move forward with TSCA reform. As the legislative session comes to a close, however, the two sides are still unprepared to come to an agreement.

The Current Bill and Proposals

Currently, TSCA does not require chemical manufacturers affirmatively to demonstrate the “safety”

of a chemical substance before it is brought to the market, nor to sustain it in the marketplace. To take an action to restrict or limit uses of a substance, the agency must find that a substance presents “an unreasonable risk of injury to health or the environment.” Agency regulatory actions are expected to be undertaken only after EPA has considered the costs and benefits of the action and the comparative burden that different possible actions might impose. Inaction by EPA, and a growing “chemical-phobia” within certain sectors of the public, have contributed to increased scrutiny from consumers and health advocates alike of the effectiveness of TSCA.

Senator Lautenberg's current proposal would establish a new safety standard requiring that chemical substances be considered acceptable only upon a showing that there is “a reasonable certainty of no harm” resulting from its production, use, and disposal. The legislation seeks to enforce that standard by increasing the amount of information chemical manufacturers and processors would be required to provide to EPA. For example, manufacturers would be required to provide a “minimum information set” to the agency for most substances in commerce within deadlines to be imposed following enactment of the Safe Chemicals Act. EPA would be granted expanded authority to require additional testing of any chemical substance, new or existing, by administrative order. The burden of this testing would fall on the manufacturer to prove that the chemical substance meets the new safety standard. The bill considerably expands EPA capacity to swiftly impose restrictions or to ban substances in commerce, including those being considered for market entry.

While environment and health advocates applaud these reform measures, chemical manufacturers, trade organizations, and GOP leaders have significant concerns about the numerous changes. Many cite the significant burden the changes would place on producers, especially how such measures would potentially discourage innovation and hamper the entry of new products into commerce. In an effort to address these complaints and gain credibility for his bill, Senator Lautenberg recently introduced amendments intended to relax certain provisions.

Senate Environment and Public Works Committee Votes

Failing to get bipartisan reform efforts off the ground, Senate Democrats scheduled a markup of S. 847 in the Senate Environment and Public Works Committee on July 25, 2012. The amended legislation passed in party-line vote amidst criticism from Republicans.

Republicans argued that the manager's mark effectively abandoned the bipartisan efforts pursued over the past year while Democrats countered that the vote was necessary to put Republican senators on the record as opposing moderated legislation. Importantly, the Environment and Public Works Committee vote effectively allows Senate Democrats to introduce the legislation on the Senate floor and potentially force a vote before the end of the legislative cycle.

While a favorable Senate vote on the Lautenberg legislation is unlikely to cause the bill to be considered seriously in the House of Representatives, many expect that Democratic senators nevertheless might call a vote to make a political statement if not before the November elections, then during a lame duck session, perhaps even more firmly announcing Democratic support for TSCA reform. As the legislative session comes to a close without a vote scheduled during the closing days of September 2012, it seems more likely that the presidential election results will be the single greatest factor in determining whether Democrats consider it more important to force a vote during the lame duck session or try to rekindle bipartisan negotiations with an eye toward the next Congress.

Lawrence E. Culleen and *Jonathan Elsasser* are members of the environmental practice group in the Washington, D.C., offices of Arnold & Porter LLP.



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EPA AND UMASS REACH A SETTLEMENT FOR THE REMOVAL OF PCBs

Tom Ahmadifar

In June 2012, the U.S. Environmental Protection Agency (EPA) reached a consent agreement with the University of Massachusetts (UMass) that should serve as a preemptive warning to all colleges and universities across the country. This article focuses on a recent EPA action of which the academic community, and the lawyers representing it, should be aware.

UMass was in the midst of renovations of the Lederle Graduate Research Center on its Amherst campus in 2009 when it voluntarily conducted tests for asbestos-containing materials, lead in paint, polychlorinated biphenyls (PCBs), and other hazardous building materials. The test revealed that the window glazing compound used on windows throughout the building contained PCBs at concentrations well above 50 parts per million (ppm). The federal regulations for PCBs under the Toxic Substances Control Act (TSCA) prohibit the use of PCBs at concentrations at or above 50 ppm. Because of the design of the windows and the location of the window glazing compound, UMass must remove the windows to ensure the elimination of the PCBs and must do so in a manner that complies with the regulations on removing PCB bulk product waste, a project of significant cost due to the 900 windows in the campus building.

UMass notified EPA and the two sides began working toward a settlement, the second of its kind after EPA reached a settlement with the New York City public schools regarding PCBs and caulk in school buildings. Consistent with EPA's *Current Best Practices for PCBs in Caulk*^{3/4}*Interim Measures for Assessing Risk and Taking Action to Reduce Exposures, October 2009* and EPA's PCB regulations, UMass and EPA worked out a two-phased consent agreement with interim measures for containing the PCBs in the window glazing compound and a final plan for removal of the 900 windows. Ultimately, UMass must remove and replace all windows and PCB-contaminated window-glazing compound within 15 years of the consent agreement. In the interim, UMass must (1)

vacuum and clean the window units and surrounding surfaces using a HEPA vacuum; (2) encapsulate the PCB-containing window glazing compound by applying an overlying barrier system made of aluminum foil tape and silicone caulking; (3) conduct visual inspections and wipe sampling; (4) record a deed notice; (5) perform annual long-term monitoring of the windows; (5) take corrective measures, which might consist of re-encapsulation or blocking off contaminated rooms, at least annually to address any PCBs that exceed 10,000 µg/100 cm²; (6) provide general awareness training to staff; and (7) submit an annual report to EPA and make it public. By UMass completing the interim measures, EPA will deem that there is no unreasonable risk of PCB exposure to human health or the environment, which is the TSCA statutory safety standard.

Because TSCA does not give EPA administrative order power but rather penalty authority, UMass must pay a \$75,000 penalty if it does not timely comply with the consent agreement. If UMass complies timely, the penalty will remit.

The UMass circumstances are a possible warning for many colleges and universities throughout the United States. Many university buildings, like the contaminated building at UMass, were built in the 1960s and early 1970s to accommodate the swell of baby boomers attending college. The 1960s and early 1970s are also in the period when PCBs were being used in building materials such as window-glazing compound and caulk, placing many universities potentially in the same position as UMass. Even though TSCA does not have a requirement to test for prohibited substances like PCBs, once a test is conducted and contaminated materials are found, the institution has an obligation to address the situation. Despite the lack of obligation to

test, to the extent that EPA might mitigate the ultimate penalties, the UMass case might better be seen as a call to action for other universities to reassess their compliance efforts. The UMass case might also serve as motivation for universities to preemptively identify any possible violations.

Although the use of PCBs was prohibited in 1978, PCBs continue to present a risk to the public through their prevalence prior to 1978 and their long-lasting life cycles. With UMass as the example, universities should be mindful of the widespread use of PCBs in building materials prior to the implementation of broad PCB regulatory restrictions. With PCBs possibly in materials found in university buildings, students and staff are potentially at risk for the health effects of PCB exposure such as cancer, and effects on the immune system, reproductive system, nervous system, and endocrine system. PCBs can transport from their original locations through deterioration or weathering over time. As university buildings built in the 1960s and 1970s age, the risk of exposure to PCBs is likely to increase and, along with it, potential legal liability arising under TSCA, and, potentially, private actions brought by campus inhabitants. Even without an obligation to test for PCBs, now might be a good time to test for America's universities.

Other Sources

CURRENT BEST PRACTICES FOR PCBs IN CAULK FACT SHEET, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (Oct. 2009), <http://www.epa.gov/pcbsincaulk/caulkinterim.pdf>.

Tom Ahmadifar is a second-year student at American University Washington College of Law.



The Section has undertaken a five-year project with the goal of planting a million trees by 2014. ABA members are encouraged to get involved in hands-on tree planting activities in their communities. If you have participated in a tree planting project or have planted a tree on your own, please report this information as we want to count the trees you planted towards our goal. If you can't plant a tree in person, please consider making a contribution to one of the Section's partner tree organizations. The Section's One Million Trees Project will get credit for one tree planted for every dollar donated through the Section website.

To report a tree planting event or donate to one of our project partners, please visit www.ambar.org/EnvironTrees

TSCA AND THE REGULATION OF RENEWABLE CHEMICALS

Lynn L. Bergeson

The dual national goals of reducing America's dependence on foreign oil and greening the economy converge in biobased chemicals, the promising and rapidly evolving technology of producing commercial chemicals from renewable feedstocks. Although biobased chemicals have a history longer than most would appreciate, continued and increasing sensitivity to reliance upon nonrenewable feedstocks and the environmental impacts of petroleum-derived chemicals have hastened the commercialization of biobased chemicals, and today they are in production as never before.

The enthusiasm that supports the rapid commercialization of biobased chemicals has eclipsed a solid understanding of the application of the Toxic Substances Control Act (TSCA) to them and the commercial consequences of the application of TSCA's premanufacture review requirements to biobased chemicals deemed "new" chemicals. While there is no doubt TSCA applies, a lack of awareness as to how TSCA applies, and the commercial and regulatory consequences thereof, can invite business disruption and other unpleasant commercial consequences.

My colleagues, Charles Auer of Charles Auer & Associates, LLC, and Dr. R. David Peveler of Bergeson & Campbell, P.C., recently published an article appearing in the October issue of *Industrial Biotechnology*. The article provides background on biobased chemicals, explains TSCA's application to these commercial products, discusses some of the anomalies derivative of the application of TSCA to biobased chemicals, and suggests strategies for industry stakeholders to assure the successful introduction and marketing of biobased chemical products.

Of relevance to committee members is the discussion in the article on TSCA section 8(b)(1), which directs the U.S. Environmental Protection Agency (EPA) to

compile and keep current a list, commonly referred to as the TSCA Chemical Substance Inventory, of each chemical substance that is domestically manufactured or imported into the United States. The initial Inventory allowed "existing" chemical substances already in commerce to be "grandfathered" onto the Inventory. These chemicals were included on the TSCA Inventory automatically, side-stepping any EPA review of them at the time of the listing. Thus, under TSCA, EPA has less authority over existing (as opposed to new) chemical substances.

Given the late 1970s' timing for creation of the TSCA Inventory, the organic chemicals listed on it are reflective of the commercial chemistry of that time, which was largely petroleum based. This can be seen in the large number of petroleum-based feedstocks listed on the original Inventory. EPA has identified almost 600 "petroleum process streams" for purposes of partially exempting these substances from reporting under TSCA section 8 Chemical Data Reporting (CDR) rule obligations. Many of these chemicals are named in ways that make explicit their petroleum sourcing (i.e., the term "petroleum" is included in many of the names). While biobased chemicals were present on the original TSCA Inventory, their number and variety were limited in comparison to petroleum-based substances with the result that many biobased chemicals will be considered "new chemicals" subject to TSCA section 5 notification.

Our article describes in detail a key nomenclature issue of special relevance to biobased chemicals involving "naturally occurring" substances. For purposes of the TSCA Inventory, a naturally occurring substance is a "combination that occurs in nature, is a chemical substance and not a mixture." Under EPA's regulations, certain naturally occurring chemical substances are automatically included on the TSCA Inventory. These include chemical substances that are naturally occurring and that are unprocessed or processed only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or that are extracted from air by any means. EPA provides examples of such substances, including raw agricultural commodities such as corn

and soy; water, air, natural gas, and crude oil; and rocks, ores, and minerals.

Because naturally occurring substances are automatically included on the TSCA Inventory, they are considered “existing” substances and are thus exempt from premanufacture notification (PMN) requirements. EPA’s treatment of naturally occurring substances reflects a general EPA view that a certain amount of minimal processing does not materially alter a substance such that the substance is naturally occurring for Inventory purposes. For example, the act of mechanically isolating a substance from nature does not alter its status as “naturally occurring” or make it subject to PMN requirements.

In contrast, chemical substances that are chemically extracted or produced from naturally occurring substances by chemical treatment are not considered naturally occurring for TSCA Inventory purposes. These substances are subject to PMN requirements if they are not already included on the TSCA Inventory.

While the U.S. government recognizes the issues associated with chemicals based on nonrenewable feedstocks, such as petroleum, and encourages the development of biobased products as a matter of policy, TSCA legal requirements for the chemicals must be satisfied as part of the commercialization process. Thus, a tension can exist between meeting the policy goal and satisfying the legal requirements for biobased chemicals.

Given the way that the TSCA Chemical Inventory was constructed historically with its prevalence of petroleum-based substances, a number of anomalous situations arise. While EPA is generally supportive of new chemistries that can replace older, nonrenewable petroleum-based chemistries, EPA takes its new chemical review responsibilities seriously, and biobased chemical introductions are and will continue to be the subject of regulatory scrutiny by EPA as “new” chemicals. This can lead to a disproportionate amount of regulatory scrutiny at the point of commercial introduction when these new, presumptively greener chemicals are attempting to break into the market and compete with established nonrenewable chemicals that

as Inventory-listed substances escape such regulatory scrutiny under TSCA. The article explores these issues in detail.

This delicate balancing act illustrates the importance of emphasizing, in new chemical notifications, the benefits, broadly speaking, of a biobased new chemical. The PMN form requests information on the “pollution prevention” aspects of a new chemical. This often under-utilized section of the PMN form can and should be used to discuss the benefits of a biobased new chemical. In developing the points to include, it may be helpful to think of the task as one of essentially “making the case” for a new biobased chemical introduction and including as appropriate points establishing renewable sourcing; pollution prevention or risk reduction benefits (these could include reduced pollution, role of or contribution to recycling (e.g., uses agricultural waste), use of safer processes or products, avoidance of toxic intermediates, reduced or less toxic waste generation, energy efficiency, relatively safer or less polluting than competing existing chemicals, and related considerations); and cost or performance benefits (these could include improved product performance, lower costs, more energy efficient production, processing or use, and related factors). The article also identifies practical pointers to help ensure TSCA regulatory challenges do not impede commercial start-up operations. In summary, these include

Ensure TSCA Compliance Is a Core Element of the Business Plan: Know the TSCA requirements, understand the regulatory responsibilities, and be prepared to meet both the requirements and the responsibilities as a part of a business development plan for the biobased chemical.

Understand the Relevance of Chemical Naming Conventions: It is critically important to recognize and understand the importance of how a chemical is named and identified, and how that can affect new chemical responsibilities. If this core competency does not exist within the company’s staff, find competent professionals who can guide this important process.

Know the Fundamentals of the TSCA Review

Process: A basic understanding of EPA's review process and regulatory approach is essential. While EPA works off of the information included in the PMN, it also considers information on other "related" cases, applies (quantitative) structure activity relationships ((Q)SAR) analysis when hazard test data are not available, and, inter alia, will use assumptions about likely exposures and releases if information is not provided in the PMN. EPA also has a number of policy drivers that can affect new chemicals, including its use of "categories" of PMNs, the Persistent, Bioaccumulative, and Toxic (PBT) policy, and the exposure-based policy for new chemicals.

Consider Testing in Advance of PMN

Notification: If EPA is likely to impose testing requirements on a biobased new chemical, consider the benefits of either doing the testing in advance of the notification (and thus avoiding that issue), or, if future commercialization plans involve additional structurally similar new chemicals, whether it might make sense to develop a testing strategy that would attempt to encompass and account for the range of new chemicals likely to be introduced. While such a strategy could be implemented by a single company, if other firms are known to be active in this area of new chemical development, there might be significant cost saving and advocacy opportunities for organizing consortia to share the costs and responsibility of testing. EPA is also more likely to be receptive to a consortium's regulatory advocacy as opposed to a single company's efforts to influence new chemicals policy.

Work with EPA: Regardless of the approach taken, it is always wise to consult with EPA before embarking on chemical-specific testing or developing and implementing a testing strategy to ensure an understanding of EPA's views on and obtain its receptivity to the approach proposed.

Advocate, Advocate, Advocate: As a final thought, understand and advocate the benefits of a biobased new chemical. This should involve careful preparation of the points that can be made on the optional pollution prevention section of the PMN notice. Beyond that, there may be value in recognizing and advocating the

bigger picture policy benefits of biobased chemicals to ensure that the EPA new chemical reviewers are aware of and appropriately consider and value those aspects. While EPA at the higher management levels is likely aware of U.S. government policy drivers (such as the 2012 National Bioeconomy Blueprint), this awareness may or may not have reached the scientists and other career EPA staff levels actually reviewing PMNs.

For a copy of the article, *TSCA and the Regulation of Renewable Chemicals*, please e-mail Chad Howlin at chad.howlin@lawbc.com.

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Trends can be found in a new electronic format at www.ambar.org/EnvironTrends.

GREEN CHEMISTRY'S CALL FOR ALTERNATIVES ASSESSMENTS

Sheila A. Millar and Eric P. Gotting

With efforts to reform the Toxic Substances Control Act (TSCA) and modernize chemical control at the federal level still ongoing, some states have taken the initiative to fill perceived gaps in chemical regulation by adopting “green chemistry” initiatives. The policies underlying such laws are laudable—to identify potentially hazardous substances in consumer products and reduce exposures by, in part, considering safer alternatives. These initiatives, however, have come under increasing criticism, as product manufacturers point to a growing patchwork of differing requirements and obligations across states, thus increasing the cost and effort needed to ensure compliance.

While it is not surprising that interested parties have focused most of their attention on the regulatory aspects of these programs, there is yet another area that deserves further consideration—the impact of green chemistry initiatives on product liability litigation. On the one hand, the process of evaluating the use of chemicals in consumer products and, in particular, identifying safer alternatives through what are known as “alternatives assessments” (AA), tracks on some level a similar type of analysis that is undertaken by courts in product liability cases. On the other hand, while green chemistry programs address policy concerns regarding the general public’s exposure to chemicals, product liability claims focus on individual plaintiffs. Thus, in many respects, each approach is designed to answer very different questions regarding issues of whether a chemical, in fact, poses a health risk, what exposure levels are of concern, and to what extent, if any, a manufacturer has a duty to address potential safety issues.

This article briefly discusses this important distinction and identifies several points of interest that manufacturers and product liability attorneys should keep in mind as states begin to implement the AA process.

Green Chemistry: A Brief Overview

To date, green chemistry programs have been adopted in California (CAL. HEALTH & SAFETY CODE § 25251 et seq.), Connecticut (CONN. GEN. STAT. § 21a-335 et seq.), Maine (ME. REV. STAT. tit. 38, § 1691 et seq.), Michigan (Executive Directive No. 2006-6, “Promotion of Green Chemistry for Sustainable Economic Development and Protection of Public Health,” *available at* http://www.michigan.gov/granolm/0,1607,7-168-36898_40426-153806_00.html), Minnesota (MINN. STAT. § 116.9401 et seq.), and Washington (WASH. REV. CODE § 70.240.010 et seq.). The programs differ in terms of scope and requirements, but they share the same underlying goals of identifying and evaluating potentially hazardous chemicals and using this information to minimize or eliminate the risk of consumer harm. To these ends, the green chemistry programs typically require that:

- the state identify and prioritize lists of potentially toxic chemicals;
- manufacturers of regulated consumer products report the presence of listed chemicals in covered products; and
- manufacturers, at least in some states, perform an AA that evaluates potentially “safer” alternatives to listed chemicals used in the products (referred to in this article as “target” chemicals) and report their findings to the state.

The AA Requirement

Although only a few states have adopted or proposed detailed AA requirements as part of their green chemistry initiatives, it is already apparent that manufacturers will have to develop considerable amounts of information regarding target chemicals used in their products and any “safer” alternatives. An “alternative” might include not only a replacement chemical that may pose fewer health or environmental risks, but also non-chemical substitutes, product redesign, new manufacturing processes, or the removal of the target chemical from the product. Manufacturers

and/or state agencies will then use these data to compare the chemical and alternatives to determine whether it is possible to reduce or eliminate any hazards associated with the product.

There are three AA programs currently in various stages of enforcement or development. Maine's program has taken effect and currently applies to children's products containing bisphenol A (BPA) and nonylphenols (06-096 ME. CODE R. ch. 880 (general), ch. 882 (BPA), ch. 883 (nonylphenols)). California has proposed several versions of draft regulations, the latest issued in July 2012, which cover a broad range of consumer products (*see* Proposed CAL. CODE REGS. tit. 22, § 69501 et seq., *available at* <http://www.dtsc.ca.gov/upload/SCPPProposedRegulationsNoUnderlineJuly2012.pdf>). Washington's law applies to children's products, but includes a greater number of chemicals than the Maine program. Washington does not currently have a mandatory AA program, but is encouraging manufacturers to conduct voluntarily AAs using guidance materials now being developed by the state (*see* Alternatives Assessment Guidance Document, *available at* <http://www.ecy.wa.gov/programs/hwtr/ChemAlternatives/altAssessment.html>). While these programs differ in some respects, all three require information that will be of interest to plaintiffs in product liability cases.

With regard to target chemicals, such information includes the:

- nature of the chemical and the amount used in each regulated product;
- function of the chemical in the product;
- likelihood of exposure through product use and exposure pathways; and
- human health and environmental risks posed by the chemical.

As for potential alternatives, relevant information includes the:

- availability, costs, and product performance of each identified alternative;
- present commercialization of the alternatives or barriers to marketplace entry;
- potential exposure levels to replacement chemicals and exposure pathways; and
- human health and environmental risks associated with the alternatives.

In Maine, a manufacturer must produce an AA report, but is not required to indicate as part of the AA whether it will adopt an alternative or continue using the target chemical, at least as a general principle (*see* 06-096 ME. CODE R. ch. 880(5)), although BPA is subject to special and different treatment. (Maine has also implemented a ban on children's reusable food or beverage containers that contain intentionally added BPA. Manufacturers of regulated products must report to Maine whether they intend to comply by discontinuing product sales or by substituting a "safer" alternative for BPA. 06-096 ME. CODE R. ch. 882(5). This example highlights how seemingly innocuous AA requirements may expand to become substance-specific bans.) California's proposed regulations take a slightly different approach, requiring the manufacturer, as part of the AA, to actually select an alternative or indicate that no changes to the product will be made (*see* Proposed CAL. CODE REGS. tit. 22, § 69505.4(c)). Both programs, however, require that information submitted as part of the AA process, including the AA reports, be made publicly available subject to trade secret or confidentiality claims (*see* 06-096 ME. CODE R. ch. 880(5)(F); Proposed CAL. CODE REGS. tit. 22, § 69505.5(a)(6)).

Implications for Product Liability

There are several aspects of the AA process that could be relevant in the product liability context. In putative design defect actions, arguments to support that a product's design is defective will often include evidence that foreseeable risks of harm, such as those associated with chemical exposures, could have been reduced or avoided through a reasonable alternative

design (*see, e.g., Soproni v. Polygon Apt. Partners*, 971 P.2d 500, 504–05 (Wash. 1999); *Stanley v. Schiavi Mobile Homes, Inc.*, 462 A.2d 1144, 1148 (Me. 1983); *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 431–32 (Cal. 1978)). Under this “risk-utility” approach, the product and potential alternatives are compared. Various factors are typically considered, including cost, technical feasibility, functionality, and relative risks or hazards to human health (*see, e.g., Barker*, 20 Cal. 3d at 431). This looks much like the AA process and, thus, parties in a product liability suit will likely battle over whether the AA report should come into evidence.

In failure to warn claims, moreover, a design defect may be established in many states by showing that foreseeable risks of harm could have been reduced or avoided by adequate instructions or warnings (*see, e.g., Bouchard v. Am. Orthodontics*, 661 A.2d 1143, 1145 (Me. 1995); *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 999–1000 (Cal. 1991); WASH. REV. CODE § 7.72.030). In particular, courts will ask if the manufacturer knew or should have known of the hazards at the time of manufacture (*id.*). Similarly, AA provisions ask manufacturers to provide information regarding the potential risks of a target chemical. For instance, in Maine and under California’s proposed rules, the AA report must identify the human health and environmental hazards of the target chemical, including information like toxicological endpoints (e.g., skin irritation, reproductive effects, cancer) and pathways of exposure (e.g., inhalation, dermal, ingestion) (*see* 06-096 ME. CODE R. ch. 880(5)(B); CAL. CODE REGS. tit. 22, § 69505.4). An AA report, therefore, might also be viewed as relevant to this type of claim.

In addition, information regarding potential chemical exposures may be pertinent to claims like fear of disease or medical monitoring, at least where those causes of action are recognized under state law. For example, in states that have already adopted green chemistry statutes, courts have allowed fear of disease claims where the plaintiff has been exposed to a chemical and the resulting fear is deemed reasonable (*see, e.g., Potter v. Firestone Tire and Rubber Co.*, 863 P.2d 795, 816 (Cal. 1993) (allowing California

claim where plaintiff proves fear stems from knowledge that it is more likely than not that cancer will develop in the future due to toxic exposure); *In re Moorenovich*, 634 F. Supp. 634, 637 (D. Me. 1986) (permitting Maine claim where there is exposure and alleged anxiety is reasonable); *Wilson v. Key Tronic Corp.*, 701 P.2d 518, 524 (Ct. App. Wash. 1985) (finding Washington claim reasonable where there was actual exposure to toxic chemicals)). Similarly, at least in California, medical monitoring costs may be recovered as damages in a negligence action where, through reliable expert testimony, the need for future monitoring is deemed reasonable and necessary (*Potter*, 863 P.2d at 824–25). Given the broad scope of information that will be contained in AA reports, including data regarding public exposures, AA analyses could become a focus in these types of suits as well.

It is important to note that, depending on the information and conclusions contained in an AA report, the AA process may be helpful to either plaintiffs or defendants in a product liability suit. For instance, once an AA report concludes that safer alternatives exist, the redesigned product as envisioned during the AA process may become the alleged industry standard that plaintiffs will point to when establishing a *prima facie* case. Conversely, an AA report may conclude that there are no “safer” alternatives and the product as designed is representative of industry standards, thus aiding in a manufacturer’s defense. The same could be true for failure to warn claims. The AA report might point to potential hazards that had not been previously disclosed by the defendant or provide conclusive evidence that the manufacturer has adequately warned against known risks.

Limitations of an AA Report

While an AA report, in certain cases, will go a long way in helping at least one side litigate a product liability claim, the AA process will not address other types of information that will be relevant to the suit. Simply showing that a product *contains* a target chemical will not be enough for a plaintiff to win a case. Central to any chemical exposure claim is the notion that “the dose makes the poison.” Specifically, a plaintiff must demonstrate that (1) the target chemical

can cause the alleged disease and at what dose; and (2) he/she was exposed to the chemical at or above such dose so one may draw the inference that the chemical, in fact, caused the individual's disease. In other words, the plaintiff must submit evidence establishing a "dose-response" relationship (FED. JUDICIAL CTR., REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 603, 609, 638 (3d ed. 2011)).

An AA report, however, will not contain all of this information, and will have virtually nothing to do with any scientifically supportable dose-response analysis. Courts and litigants should be particularly sensitive to this distinction, as chemicals are often used in products in only trace amounts or are encapsulated in the product thus minimizing the chance of exposure.

Nothing in an AA report, moreover, will speak to an individual plaintiff's actual level of exposure to a target chemical, thus leaving the parties with significant proof issues to fight over notwithstanding the AA process.

Conclusion

Regulatory requirements associated with green chemistry initiatives are not the only issues on which manufacturers should focus. Broader considerations are at play, especially with regard to product liability litigation, when considering the overall impact of the AA process.

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The poster features a green header with the ABA logo and the text "Section of Environment, Energy, and Resources". Below the header, the text "SAVE THE DATE" is written in large green letters, followed by "MARCH 21-23, 2013". The central graphic is a footprint composed of several green leaves of various sizes and shades. Below the footprint, the text "42ND" is centered between two horizontal lines. Underneath, "SPRING CONFERENCE" is written in large, bold green letters. Below that, "Environment, Energy, and Resources Law" is written in smaller green text. The location "GRAND AMERICA HOTEL SALT LAKE CITY, UT" is listed in black text. At the bottom, the website "www.ambar.org/EnvironSpring" is provided in green text.