Texas Environmental Update

BEVERIDGE & DIAMOND PC

January 2011

Texas Office
98 San Jacinto Boulevard
Suite 1420
Austin, TX 78701
(512) 391-8000

Lydia G. Gromatzky
lgromatzky@bdlaw.com

Maddie Kadas
mkadas@bdlaw.com

Laura LaValle
llavalle@bdlaw.com

For more information about our firm, please visit www.bdlaw.com

If you do not wish to receive future issues of Texas Environmental Update, please send an e-mail to: jmilitano@bdlaw.com

Texas Developments

82nd Texas Legislative Session Now Underway

The 82nd Texas Legislative Session is now underway and will run until adjournment on May 30, 2011. To date, more than 1400 bills have been filed. Among the challenging issues to be faced by the Texas Legislature are the state's budget shortfall and the Sunset review of TCEQ, the Texas Water Development Board and the Railroad Commission. The Sunset bills for these regulatory agencies, once filed, will be key measures to monitor. To date, environmental bills of interests include, among many others: (i) House Bill (HB) 125 relating to the inclusion of a draft impact analysis in the notice of rules proposed by TCEQ; (ii) HB 571 relating to the regulation of certain aggregate production operations; (iii) Senate Bill (SB) 332 relating to the vested ownership interest in groundwater beneath the surface and the right to produce that groundwater; (iv) HB 830 relating to the consideration of the cumulative effects of air contaminant emissions in the emissions permitting process; (v) SB 339 relating to disclosure of information related to emissions events and (vi) SB 338 relating to penalty assessment for violations of the Texas Clean Air Act committed by major sources.

EPA Commences Greenhouse Gas Permitting Program in Texas

The U.S. Environmental Protection Agency ("EPA") has initiated a prevention of significant deterioration ("PSD") new source review greenhouse gas ("GHG") emissions permitting program in Texas. Commencement of the program is possible following the U.S. Court of Appeals for the District of Columbia Circuit's January 12, 2011 ruling that lifted an emergency stay that had prohibited EPA from implementing the program. That court granted the stay on December 30, 2010 in response to an emergency motion filed on that date by the Texas Attorney General along with a petition for review seeking to block implementation of an immediately-effective interim final rule published in the December 30th Federal Register (75 Fed. Reg. 82, 430) pursuant to which EPA proposed to promulgate a federal implementation plan "in order to assure that GHG-emitting sources in Texas are able to proceed with plans to construct or expand" when permitting requirements for GHG took effect on January 2, 2011.

In that interim final rule, EPA also proposes to correct its previous full approval of Texas' PSD program into a partial approval and partial disapproval. The correction is based upon EPA's determination that Texas' PSD program is flawed because the state did not address how the program would apply to pollutants that become newly subject to Clean Air Act regulation, including non-National Ambient Air Quality Standard pollutants such as GHGs. In a companion proposed rule published on December 30, 2010, EPA requested comment on the substance of the interim final rule.

At a public hearing held in Dallas on January 14, 2011, EPA accepted comments from the public on the interim final rule, and provided only general information about its implementation of a Texas GHG permitting program. Specific information about the permitting process was not provided beyond referral to the GHG permitting information that EPA has posted on its website (http://www.epa.gov/nsr/ghgpermitting.html), and referral to Jeff Robinson (Chief of EPA Region 6's Air Permits Section) as an initial point of contact for additional information. Development of the Texas permitting program is apparently a work

in progress, with implementation requirements and guidance to be provided as program details are determined.

U.S. Representative Files Joint Resolution To Overturn EPA Disapproval of the Texas Flexible Permit Program

Citing to the Congressional Review Act (the Act), U.S. Representative John Carter (R-Tex) has filed a House Joint Resolution (H.J. Res. 21) to reject EPA's disapproval of the Texas flexible permitting program. The Act allows Congress to review and reject "major" federal rules issued by government agencies by way of joint resolution. A companion resolution must be made by the Senate and the procedural rules of the Act followed for the rejection to take effect. The effect of the disapproval is unclear as it would not constitute approval of the Flexible Permit Program (which would still need to be SIP-approved). As a consequence, the Resolution would not lend more immediate certainty to the status of the flexible permitting program or the permits issued through it. Many companies have already made commitments to "de-flex" in response to EPA's demands. Nonetheless, if passed, the Resolution likely would send a strong message to EPA and could implicate the Agency's posture during subsequent negotiations regarding public notice requirements, the scope of look-back analyses, new permit terms and enforcement. A copy of the Resolution is available at www.bdlaw.com/assets/attachments/HJ%20Res%2021.pdf.

TCEQ Adopts Oil and Gas Permit by Rule and Standard Permit

On January 26, 2011, the TCEQ Commissioners adopted a new permit by rule (PBR) and non-rule standard permit for oil and gas production facilities. This regulatory initiative was the result of the TCEQ's continuing review of air PBRs and standard permits. After extensive public comment on the proposal, the TCEQ Commissioners decided on an approach that limits the measure to Barnett Shale activities to allow the agency to gain real-world experience before it expands the initiative to activities statewide. Since a number of changes were made to the proposal during the TCEQ agenda meeting, the Texas Register version, once published, merits close review.

Texas Groundwater Protection Committee Issues Report to 82nd Legislature

The Texas Groundwater Protection Committee ("Committee") has issued its report to the 82nd Texas Legislature setting forth its groundwater protection recommendations ("Report"). The Committee, an inter-agency group led by TCEQ, requests legislative consideration of three subject areas: (i) strengthening groundwater conservation and water quality protection efforts; (ii) advancing groundwater management and protection through enhanced data collection and availability; and (iii) supporting groundwater research. The Report also details the Committee's activities during the biennium including its implementation of the Texas Groundwater Protection Strategy. A copy of the Report is available at http://www.tceq.state.tx.us/assets/public/comm_exec/pubs/sfr/047_10.pdf.

Texas Water Quality Advisory Workgroup Update

TCEQ staff provided a series of regulatory updates during the Texas Water Quality Advisory Workgroup meeting held in Austin on January 25, 2011. Topics covered included the following: (i) the anticipated July 27, 2011 adoption of the renewal of the storm water multi-sector general permit; (ii) a report on TCEQ-funded watershed protection plans throughout the state; (iii) implementation of EPA's construction effluent guidelines; (iv) a summary of TCEQ's Sanitary Sewer Overflow initiative; and (v) an update on the draft pesticide general permit currently scheduled for TCEQ Commissioner consideration on April 6, 2011. Background documents related to each of these topics are available at http://www.tceq.texas.gov/permitting/water_quality/stakeholders/WQ_advisory_group.html.

BEVERIDGE & DIAMOND PC

TCEQ Issues SO_2 NAAQS Screening Background Concentrations

At the end of December, TCEQ issued interim screening background concentrations for the primary one-hour sulfur dioxide ("SO_2") national ambient air quality standard ("NAAQS") that became effective on August 23, 2010. These county-specific concentrations can be used by facility owners and operators in connection with evaluating whether emissions from a proposed project -- taken together with emissions from already-existing background sources -- will cause or contribute to a NAAQS exceedence. They are conservative background emissions estimates that entities can use in lieu of a project-specific analysis that would include detailed dispersion modeling of sources in the area.

As we reported previously, in August of last year TCEQ issued "Interim NAAQS Guidance on Sulfur Dioxide" addressing implementation of the new NAAQS for SO_2. That document covers numerous topics, among which are monitor source applicability, best available control technology ("BACT"), impacts evaluation, and modeling.

All documents relating to SO_2 NAAQS implementation are available on TCEQ's website at http://www.tceq.texas.gov/permitting/air/memos/interim_guidance_naaqs.html.

Upcoming TCEQ Meetings and Events

- TCEQ is holding ***Dam Safety Workshops*** around the state beginning with an event in Brady on February 22, 2011. Topics to be covered include dam safety laws and regulations, owner responsibilities and liabilities and development and implementation of emergency action plans. Information about these workshops is available at http://www.tceq.state.tx.us/news/releases/1-11DamWorkshops1-4.
- TCEQ's ***Tax Relief for Pollution Control Advisory Committee*** has scheduled a meeting to be held on February 11, 2011 in Austin. Included on the agenda for the meeting are a review of the committee's draft 2010 annual report and consideration of TCEQ staff's request for advice on the draft application and instructions and equipment and categories list issues. Information about this meeting is available at http://www.tceq.state.tx.us/implementation/air/taxrelief/prop2_hottopics.html.

TCEQ Enforcement Orders

TCEQ announcements for enforcement orders adopted in December can be found on the TCEQ website at http://www.tceq.texas.gov/news/releases/commissioners agenda012611.

Recent Texas Rules Updates

For information on recent TCEQ rule developments, please see the TCEQ website at http://www.tceq.state.tx.us/rules/whatsnew.html.

National Developments

EPA Focusing on Chemicals in Articles With Expected PBDEs SNUR

The Environmental Protection Agency (EPA) is preparing to propose to amend a significant new use rule (SNUR) for certain polybrominated diphenyl ethers (PBDEs) that would, unlike the vast majority of SNURs to date, restrict the importation of articles containing the target chemicals. The forthcoming SNUR amendment proposal, along with a test rule to be proposed around the same time, will further commitments made by EPA in its PBDEs chemical action plan issued under the Toxic Substances Control Act (TSCA).[1] While the PBDEs SNUR amendments will have important direct impacts on a number of industry sectors, it is also important as a possible harbinger of a shift by EPA toward greater regulation of chemicals in articles or products.

BEVERIDGE & DIAMOND PC

1. TSCA and Articles

TSCA gives EPA authority to regulate chemical substances, including those contained in articles. TSCA refers specifically to articles in several provisions.[2] (TSCA does not define "article," but EPA has adopted several similar definitions.[3]) Nevertheless, EPA has chosen to adopt administrative exemptions from many of its provisions for chemicals in articles, including general information-gathering rules,[4] export notifications,[5] import notifications,[6] Inventory Update Rule reporting,[7] premanufacture notifications (PMNs),[8] SNURs,[9] and restrictions on use of certain chemicals regulated under section 6.[10] EPA adopted these article exemptions largely due to concerns about the practical difficulties importers would have in finding out what chemical substances are in the articles they import.[11] Nevertheless, EPA does retain the authority to regulate or require reporting on chemical substances in articles.

Much of the recent debate regarding chemicals management in the United States has focused on chemicals in products. For example, when EPA Administrator Lisa Jackson announced the Obama Administration's principles for TSCA reform in 2009, her speech cited chemical additives in cell phones, bisphenol A in baby bottles, phthalates in medical devices, and lead in toys.[12]

Regulation of chemical substances in articles became a heightened topic of interest in 2010 due to the provisions of the two bills introduced to overhaul TSCA. The Senate bill would have redefined the core term "chemical substance" to include "any chemical substance contained in or formed into an article."[13] The apparent purpose was to affirm that chemicals in articles are subject to TSCA. The House bill would have gone further to prohibit administrative exemptions from EPA requirements under sections 4, 5, 6, or 8 of TSCA for chemical substances in articles.[14]

2. Earlier EPA SNUR for PBDEs

PBDEs are a family of chemicals comprising a brominated diphenyl ether molecule attached to one to ten bromine atoms. PBDEs, especially the three commercial PBDE mixtures c-pentaBDE, c-octaBDE, and c-decaBDE, have historically been widely used as flame retardants in electronics, vehicles, furniture, textiles, and a variety of other applications. However, some PBDEs may be persistent, bioaccumulative, and toxic, especially the lower-brominated congeners. Because of the potential risks of PBDEs as shown by animal studies, and the presence of PBDEs in human tissues as shown by biomonitoring studies, a number of countries and international bodies have instituted programs to severely restrict some of these chemicals.[15]

In the United States, manufacture of penta- and octaBDE was phased out in 2004. In 2006, EPA promulgated a SNUR for these chemicals—as well as for tetraBDE, hexaBDE, heptaBDE, and nonaBDE—in order to prevent recommencement of their domestic manufacture or import without prior notice to the Agency.[16] A SNUR requires a manufacturer (including an importer) to notify EPA 90 days in advance of the designated "significant new use," providing EPA with the opportunity to evaluate the intended use and, if necessary, to limit it before it occurs.

The 2006 PBDEs SNUR incorporated the general SNUR provisions, including the standard exemption for chemicals processed or imported only as components of articles (i.e., manufactured products).[17] EPA said that this exemption was necessary because the importation of articles containing PBDEs could be ongoing, and if this were the case, such importation could not be deemed "new" for a SNUR.[18] The 2006 SNUR did not include decaBDE, which is still manufactured in the United States and which EPA believes may break down in the environment to more harmful congeners.

3. PBDEs Chemical Action Plan

Due to lingering concerns regarding decaBDE and other PBDEs in articles, EPA issued a PBDEs chemical action plan in 2009 as part of its efforts to enhance management of existing

chemicals under TSCA. The action plan called for amending the SNUR to address imports of penta- and octaBDE in articles. It also called for continued efforts to phase out decaBDE, and a SNUR for decaBDE, including in articles; an alternatives analysis for decaBDE; and the addition of commercial PBDEs to the Concern List under TSCA section 5(b)(4) as chemicals that present or may present an unreasonable risk of injury to health or the environment.[19] The action plan also called for a test rule for decaBDE under TSCA section 4.[20]

4. Forthcoming Proposed SNUR Amendments

The Office of Management and Budget began its 90-day regulatory review of the SNUR amendments proposal on December 17, 2010, with an indication that EPA plans to publish it in March 2011.[21] The chemical action plan had predicted publication of a proposed SNUR in 2010.

The amendments will need to address the issue of any ongoing importation of articles containing the PBDEs, since a SNUR can only apply to uses that are "new." In promulgating the original SNUR, EPA had considered applying the SNUR to PBDEs in articles, but ultimately decided not to do so, saying:

EPA may not issue a SNUR covering as a significant new use import of the subject PBDEs as a part of articles for any use if that activity is ongoing. EPA received no comments on the proposed rule suggesting import of the subject PBDEs as a part of articles was ongoing. However, comments received from the Polyurethane Foam Association (PFA) after the close of the comment period for the proposed rule indicate the potential for presence of the subject PBDEs in imported articles.[22]

The chemical action plan stated that while "it does not appear that [penta- or octaBDE] treated articles are currently being imported," EPA recognizes that "imported articles treated with c-pentaBDE and c-octaBDE could be a source of human and environmental exposure to these PBDE congeners."[23] According to the chemical action plan, importation of decaBDE-treated articles is even more likely to be ongoing, despite the voluntary phase-out agreed to in December 2009 by its main U.S. manufacturers and importer.[24]

The SNUR amendments are based in part on EPA's belief that that there may be suitable alternatives for all of the major uses of PBDEs. However, concerns have been raised regarding the safety of replacements for PBDEs, especially certain new brominated and chlorinated flame retardants.[25] (PBDEs themselves were replacements for other hazardous flame retardants used in the 1970s.[26])

5. Analysis: EPA Regulation of Chemicals in Products

The PBDEs SNUR amendments exemplify a broadening of EPA's regulatory focus from just industrial chemicals as such to chemicals in consumer products in the United States.

To date, EPA has issued very few SNURs that waive the articles exemption contained in TSCA's general SNUR provisions. These include SNURs for elemental mercury,[27] erionite fiber,[28] and a chemical formerly covered by a SNUR that has been revoked.[29] Thus, the PBDEs SNUR amendments would not be unique in addressing articles, but they would be notable in this regard.

Other chemical action plans also call for regulatory action addressed to chemical substances in articles, including those for long-chain perfluorinated chemicals,[30] benzidine dyes,[31] hexabromocyclododecane,[32] and nonylphenol and nonylphenol ethoxylates.[33]

EPA is not alone in regulating chemicals in articles. For example, the Consumer Product Safety Improvement Act of 2008 (CPSIA) banned the sale of children's toys or child care articles containing more than 0.1% of certain phthalates[34] and children's products containing lead above certain thresholds.[35] The Consumer Product Safety Commission was asked recently to restrict cadmium in children's products,[36] although it decided to recommend a voluntary standard instead.[37] Furthermore, many states are regulating consumer products containing chemicals of concern.

In light of these pressures, the promulgation of SNURs and other rules without the standard TSCA articles exemption may become less of a rarity.

For more information, please contact Mark Duvall at mduvall@bdlaw.com or Alexandra Wyatt at awyatt@bdlaw.com.

---

[1] See Beveridge & Diamond, P.C., "EPA Issues Four Chemical action plans Under TSCA" (Jan. 5, 2010), http://www.bdlaw.com/news-764.html; EPA, Polybrominated Diphenyl Ethers (PBDEs) Action Plan (Dec. 30, 2009), http://www.epa.gov/oppt/existingchemicals/pubs/pbdes_ap_2009_1230_final.pdf.

[2] E.g., TSCA §§ 2(4) (definition of "distribute in commerce"), 5(d)(1)(B) (contents of a PMN), 6(a)(3) and 6(a)(6)(A) (control of unreasonable risks), 7 (imminent hazards), 12(a) (exports), 13(a) (imports), 17(b) (seizure), 18 (preemption).

[3] For example, 40 C.F.R. § 704.3 defines "article" to mean "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article, and that result from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles; except that fluids and particles are not considered articles regardless of shape or design."

[4] 40 C.F.R. § 704.5(a).

[5] 40 C.F.R. § 707.60(b) (other than PCB articles).

[6] 19 C.F.R. § 12.121(b) (unless specifically required by a rule under TSCA).

[7] 40 C.F.R. § 710.50(b).

[8] 40 C.F.R. § 720.22(b)(1) (chemical substances in imported articles).

[9] 40 C.F.R. § 721.45(f) (chemical substances imported or processed as part of an article, unless specifically required by a SNUR).

[10] 40 C.F.R. §§ 747.115(f)(3) (mixed mono and diamides of an organic acid), 747.195(f)(3) (triethanolamine salt of a substituted organic acid), 747.200(f)(3) (triethanolamine salt of tricarboxylic acid).

[11] For example, in adopting the PMN exemption, EPA explained, "[b]ecause it would be enormously difficult for an importer to determine the identity and Inventory status of each chemical substance in imported articles (e.g., automobiles), the rule does not require persons to submit notices on new substances imported as part of articles." 48 Fed. Reg. 21722, 21726 (May 13, 1983).

[12] Administrator Lisa P. Jackson, Remarks to the Commonwealth Club of San Francisco (Sep. 29, 2009), http://yosemite.epa.gov/opa/admpress.nsf/ 12a744ff56dbff8585257590004750b6/fc4e2a8c05343b3285257640007081c5.

[13] The Safe Chemicals Act of 2010, S. 3209, § 4(1)(iv).

[14] The Toxic Chemicals Safety Act of 2010, H.R. 5820, § 13(2).

[15] See generally EPA, supra note 1, at 8-11. One of the most important actions was the listing in 2009 of commercial pentaBDE and octaBDE as targets for elimination under the Stockholm Convention on Persistent Organic Pollutants. See Stockholm Convention, The 9 new POPs under the Stockholm Convention (May 2009), http://chm.pops.int/Programmes/

NewPOPs/The9newPOPs/tabid/672/language/en-US/Default.aspx. In addition, certain PBDEs are restricted in electrical and electronic products under the European Union's Restriction of Hazardous Substances (RoHS) Directive (2002/95/EC).

[16] 71 Fed. Reg. 34015 (Jun. 13, 2006) (adding new 40 C.F.R. § 721.10000).

[17] 40 C.F.R. § 721.10000(b) (incorporating provisions of 40 C.F.R. Part 721, Subpart A); 40 C.F.R. § 721.45(f) (exempting, unless otherwise specified in a particular SNUR, any person who "imports or processes the substance as part of an article").

[18] 71 Fed. Reg. at 34018.

[19] See Beveridge & Diamond, P.C., supra note 1; EPA, supra note 1, at 13-14.

[20] See EPA, supra note 1, at 10. According to available regulatory review information, the proposed test rule will apparently encompass penta- and octaBDE, as well as decaBDE. It is unclear whether importers of these chemicals in articles would be subject to the test rule.

[21] See OIRA, Executive Order Submissions Under Review, http://www.reginfo.gov/public/do/eoReviewSearch (indicating that a draft for Regulation Identifier Number (RIN) 2070-AJ08, "Certain Polybrominated Diphenyl Ethers (PBDEs); Test Rule and Significant New Use Rule (SNUR)" was received by OIRA on December 17, 2010).

[22] 71 Fed. Reg. 34015, 34018 (June 13, 2006).

[23] See EPA, supra note 1 at 1, 12.

[24] Id. at 5.

[25] See, e.g., Linda S. Birnbaum and Åke Bergman, Brominated and Chlorinated Flame Retardants: The San

Antonio Statement, 118 Env. Health Perspectives (Dec. 2010), available at http://ehp03.niehs.nih.gov/article/info:doi/10.1289/ehp.1003088.

[26] Id.

[27] 40 C.F.R. § 721.10068(c)(1).

[28] 40 C.F.R. § 721.2800(b)(1).

[29] SNUR for ethane, 2-chloro-1,1,1,2-tetrafluoro-, former 21 C.F.R. § 721.3180(b)(2), 57 Fed. Reg. 32441 (July 22, 1992), revoked based on receipt of new data, 65 Fed. Reg. 30913 (May 15, 2000).

[30] EPA, Long-Chain Perfluorinated Chemicals (PFCs) Action Plan (Dec. 30, 2009), http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/pfcs_action_plan1230_09.pdf ("For example, the [section 6] rule could address PFAS-containing articles.").

[31] EPA, Dyes Derived From Benzidine and Its Congeners (Aug. 18, 2010), http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/DCB%20Action%20Plan_06232010.noheader.pdf ("Because there is concern for exposure to azo dyes on imported finished textiles, EPA could propose eliminating the article exemption applied to the above SNURs.").

[32] EPA, Hexabromocyclododecane (HBCD) Action Plan (Aug. 18, 2010), http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-AZ10_HBCD%20action%20plan_Final_2010-08-09.pdf ("This Significant New Use Rule (SNUR) also would be proposed to apply to imports of consumer textiles articles containing HBCD.")

[33] EPA, Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs) Action Plan (Aug. 18, 2010), http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/RIN2070-ZA09_NP-NPEs%20Action%20Plan_Final_2010-08-09.pdf ("The proposed SNUR would propose to designate NPEs in detergents and cleaning products as a significant new use").

[34] CPSIA § 108, 15 U.S.C. § 2057c.

[35] CPSIA § 101, 15 U.S.C. § 1278a.

[36] 75 Fed. Reg. 51246 (Aug. 19, 2011).

[37] CPSC letter to Fashion Jewelry and Accessories Trade Association (Oct. 19, 2010), http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelry.pdf.

Prospects for TSCA Legislation in the 112th Congress

The Toxic Substances Control Act (TSCA) has not been amended for over 34 years, but not for lack of critics or legislative effort in recent years. Whether it will be amended in the new Congress, with its Republican majority in the House of Representatives, is unclear. At this early point, there are reasons to think that TSCA legislation may receive serious consideration.

This article assesses the significance of the election for TSCA legislation by distilling some lessons from the legislation introduced in the 111th Congress and addressing the overall prospects for TSCA legislation in the 112th Congress.

1. Why did TSCA Legislation Not Pass in the 111th Congress?

Despite a Democratic President and Democratic majorities in both Houses of Congress, TSCA legislation did not get out of committee, or even go to mark-up, in either House. There are several reasons why the legislation did not get further.

First, other priorities prevented a clear focus on TSCA legislation. The economy, health care, and climate change were higher priorities, thus limiting the time available for TSCA.

Second, it was clear that TSCA is not well understood among the Members of Congress. The original statute was passed decades ago, and no bills to overhaul it significantly had been introduced until 2005 and 2008 (the Kid-Safe Chemicals Act), neither of which went far. Congress had conducted only limited oversight of TSCA implementation before 2009. Thus, much of 2009 and early 2010 was spent educating the Members and their staffs on TSCA.

Third, it is important to recognize that TSCA legislation is likely to be a multi-year effort, and 2009 and 2010 were really the first of several years that may be needed for legislation to pass. The original TSCA legislation was proposed in 1971 and took six years to pass. REACH was debated for six years in the EU before passage.

Fourth, while problems with TSCA had already been identified, there had been no previous

consensus on the provisions of an amended TSCA. During 2009, various stakeholder groups developed their own statements of principles for TSCA legislation. At the 30,000-foot level, these statements are generally consistent with each other. The legislation introduced in 2010 translated those concepts into concrete language, but not in a way that satisfied most industry stakeholders. More work remains to be done on forging a consensus on what an amended TSCA should provide.

Fifth, the 2010 legislation included provisions that attracted considerable opposition. Some of those provisions are discussed below.

2. Lessons From the 2010 Legislation for Future Legislation

The legislation introduced in 2010 failed to win significant industry support. As pointed out in the July 29, 2010 hearing on the House bill, much of industry had an overall concern about potential adverse effects of the legislation on innovation and jobs, two themes likely to resonate in the 112th Congress. Without significant industry support, TSCA legislation is unlikely to move forward in this Congress. The following aspects of the legislation caused significant resistance on the part of industry.

The legislation was perceived by some in industry as fulfillment of NGO wish-lists, with industry viewpoints considered only at the margin. For TSCA legislation to succeed, industry will need to have more influence on the content of the legislation.

The legislation would have followed generally the model of chemical registration used in regulating drugs and pesticides. EPA would evaluate every chemical (regardless of hazard or exposure) on the basis of an extensive database against a very protective safety standard, and impose controls on any chemical not meeting that standard. That model was perceived by many in industry as inappropriate for industrial chemicals, for two reasons. First, that approach was seen as impractical; there are only about a thousand pesticide active ingredients, each of which takes millions of dollars in testing and years to reach approval, but there are tens of thousands of industrial chemicals. EPA does not have the resources to review that many chemicals that intensively, nor is it likely to get the resources necessary to do so. Meanwhile, innovation would be impacted while waiting indefinitely for EPA to review chemicals. Second, the model was perceived by some as overkill. Whereas drugs and pesticides are designed to be biologically active, industrial chemicals are not. Whereas drugs are deliberately used in or on the human body and pesticides are deliberately applied to the environment, industrial chemicals are not. Because there may be potential human and environmental exposure to industrial chemicals, regulation of some kind is seen as appropriate, but not the heightened scrutiny appropriate for drugs and pesticides.

The idea that industry has the burden of proof, a key part of the 2010 legislation, is already present in the current TSCA. Section 2(b) states:

> It is the policy of the United States that-- (1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures ....

The 2010 legislation would have applied that burden of proof idea to all chemicals at once, requiring industry to provide data on tens of thousands of chemicals within just a few years. There would have been no exceptions for low-risk chemicals such as high-molecular-weight polymers or low-volume chemicals. The requirement would have applied to far more chemicals than EPA could possibly review, so that data availability itself became a key requirement, rather than EPA review of that data being the goal. This meant that the legislation would have had high costs and burdens, but with limited regulatory significance. Accordingly, to be successful, future legislation may need to limit data development requirements to those chemicals that EPA is likely to review within a limited time period.

The legislation would have applied requirements for existing chemicals to new chemicals, which raised industry concerns about adverse impacts on innovation. Under the current statute, EPA mostly uses modeling rather than test data to identify the risks of new

chemicals. NGOs and EPA itself questioned the reliability of modeling as a substitute for data on new chemicals, and the legislation would have required development of data on new chemicals for EPA review prior to commercialization. Many in industry regard the new chemicals program at EPA as one of the leading successes of TSCA, although there is some recognition that modeling may be less useful for entirely new materials such as nanomaterials. There is also industry concern about the need to pay for testing on chemicals that have not proven their commercial viability and that have not generated any revenue to pay for the testing. The legislation would also have extended the EPA review period for new chemicals and new uses of chemicals from 90 days to up to 18 months, during which time new chemicals and new uses could not be commercialized. These provisions led to considerable concern about adverse impacts on innovation. Future legislation may need to adopt a different approach for new chemicals and new uses of existing chemicals.

The legislation would have changed the current TSCA rulemaking standard of "unreasonable risk," which has proven to be very difficult for EPA to satisfy, to "reasonable certainty of no harm," which was expected to be very difficult for most chemicals to satisfy. The problems with the current TSCA standard need to be addressed in future legislation, but the legislation may not succeed if it sets an impossibly high standard, one that approaches zero risk.

A problem perceived with the current TSCA is its lack of deadlines for EPA to review existing chemicals. The 2010 legislation would have imposed stringent deadlines for EPA review, which were perceived by many as unrealistic. The legislation would also have imposed burdens on industry if EPA were to miss its deadlines, which burdens were perceived as adversely affecting innovation. Deadlines may be a good thing, but future legislation should tailor them to realistic expectations of what EPA can reasonably achieve.

Another problem with the current TSCA is thought to be its handling of confidential business information, with far too much information considered to be kept from the public. The 2010 legislation would have imposed both procedural restrictions on confidentiality claims, such as up-front substantiation requirements and time limits on approved claims, and substantive restrictions on the ability to keep chemical identities confidential. Many in industry were willing to accept reasonable procedural requirements, but there is no consensus on the appropriate limits for the confidentiality of chemical identities.

Preemption of state laws is a key motivation for industry support for TSCA reform. The 2010 legislation would have removed TSCA's current preemption provision. Democrats generally oppose federal preemption of state legislation, which may complicate negotiations on a new TSCA bill.

Procedural burdens on EPA under the current TSCA were addressed in the 2010 legislation by removing almost all procedural protections. For example, neither bill would have provided for notice and opportunity to comment on EPA bans or controls on chemicals, and the Senate bill would have precluded judicial review of EPA bans. A more balanced set of procedures will be needed for future legislation, since stakeholder comments inform and improve regulations.

A little-recognized aspect of the 2010 legislation was its removal of current TSCA exceptions for small businesses. The legislation would also have imposed equal data obligations on small businesses as on larger ones. This issue could become contentious in future legislation, given Republican concerns for small business.

Several other aspects of the legislation could be addressed as well, such as data compensation and industry funding of TSCA.

3. Prospects for TSCA Reform in the 112th Congress

A. Senate

The Senate in the 111th Congress had 56 Democrats, 2 Independents, and 42 Republicans (an effective 58% Democratic voting share). At the start of the 112th Congress, there were 51 Democrats, 2 Independents, and 47 Republicans (a 6-seat gain for Republicans, for an

effective 53% Democratic voting share).

The Senate committee with jurisdiction over TSCA, the Environment and Public Works Committee, continues to be chaired by Senator Barbara Boxer (D-CA). Senator Boxer is a strong proponent of TSCA reform.

The Senate subcommittee with TSCA jurisdiction, the Subcommittee on Superfund, Toxics, and Environmental Health, will continue to be chaired by Senator Frank Lautenberg, also a strong TSCA reform proponent. He sponsored TSCA legislation in 2005, 2008, and 2010. The ranking member will continue to be Senator James Inhofe (R-OK). Although strongly conservative, he has made several statements cautiously supportive of TSCA reform. For example, on October 26, 2010 he issued a statement for a TSCA hearing saying "I commit today to work with [Senator Lautenberg] to develop legislative solutions to the extent they are needed and according to what the best available science is telling us."

Sen. Lautenberg has scheduled an initial TSCA hearing for the first week of February, 2011. Thus, he is not waiting long to restart the TSCA debate in the Senate.

B. House of Representatives

Before its close, the House of Representatives in the 111th Congress had 255 Democrats and 179 Republicans (for a 59% Democratic voting share, with 1 vacancy). At the start of the 112th Congress there were 193 Democrats and 242 Republicans (a 64-seat gain for Republicans, resulting in a 56% Republican voting share).

The House committee with jurisdiction over TSCA, the Energy and Commerce Committee, is chaired by Representative Fred Upton (R-MI). This choice by the House Republican leadership is a critical factor in the prospects for TSCA legislation in this Congress, as Upton is a member of the moderate Republican Main Street Partnership. His rivals for the post were all more conservative. The previous committee chair, Henry Waxman (D-CA), a strong TSCA reform proponent, is ranking member.

On January 20, 2011, Rep. Upton released an agenda for the Energy and Commerce Committee that included consideration of TSCA, albeit in restrained terms:

> Enacted in 1976, TSCA is the only Federal environmental law that regulates all forms of chemical manufacturing from "cradle to grave." Several public and private interests seek changes to TSCA, but they vigorously disagree on what the problems and solutions are. Robust oversight to understand existing authorities should precede major legislation.

Thus, any consideration of TSCA on the House side is likely to begin with oversight hearings.

The House subcommittee with jurisdiction over TSCA, the new Subcommittee on Environment and Economy, is chaired by Representative John Shimkus (D-IL), who is regarded as more conservative than Rep. Upton. The ranking member is Representative Gene Green (D-TX). The chair of the former Energy and Commerce subcommittee with jurisdiction over TSCA, Representative Bobby Rush (D-IL), will not be a member of this subcommittee. Upon becoming ranking member, Rep. Green declared, "[w]e do need to update the TSCA .... It's not an industry versus environmental issue. [Both sides] want to open it up and bring [the law] up to today's standards."

C. Analysis

There is some chance that TSCA legislation simply will not progress in the 112th Congress. It is clear that TSCA reform is not on the list of first-year priorities for Republicans in the House. That list includes repeal of health care, reining in EPA on greenhouse gases, and addressing other "job-killing" regulations. The House Energy and Commerce Committee, which is responsible for TSCA, also handles those issues. Thus, TSCA will have to compete for attention without a current Republican champion. The committee chair, while generally seen as moderate, appears eager to establish his conservative bona fides. TSCA legislation would also seem to go against the Republican goal of working toward a smaller and less

intrusive federal government.

On the other hand, it may be a mistake to assume that TSCA legislation will not be considered in the 112th Congress. It is noteworthy that Rep. Upton chose to include TSCA in the committee's agenda. TSCA reform is the only environmental legislation being mentioned as possibly being passed by the 112th Congress. One reason is the expectation that over the two years of this Congress, at some point Republicans will want to be "for" something in the environmental area, not just "against" things. Another reason is the support of important industry stakeholders that developed during the 111th Congress.

That industry support arose for several reasons, which mostly continue to apply:

- In 2009, there was a Democratic President and both Houses of Congress were controlled by Democrats. That may have created a sense that TSCA legislation was likely to move, so industry should be part of the process. Now TSCA has become a focus for continuing public policy debate, notwithstanding that the Democratic President is weakened and Republicans control the House. President Obama still has significant power. In the Senate, Democrats still have a small edge, so at least the Senate may propose TSCA legislation.
- A key industry concern is public distrust of chemicals and industry. This distrust probably increased during the 111th Congress, given developments such as publicity about the use of chemical dispersants for the oil spill in the Gulf of Mexico, and public concerns about bisphenol A, phthalates, and other chemicals.
- Another key industry concern is state regulation of chemicals, creating diverse state laws. State regulation of chemicals is also stronger than ever, both of individual chemicals (e.g., seven states passed bisphenol A legislation in 2010) and more broadly (e.g., California's Green Chemistry Initiative). With Jerry Brown as governor of California, the Green Chemistry Initiative is likely to keep moving forward. This movement is gaining strength in the vacuum resulting from a weak TSCA. Even without a preemption provision, an amended TSCA could reduce the drivers for state chemicals regulation requirements.
- REACH is now a reality, showing that modern chemicals management legislation can be implemented. REACH is often perceived by industry as a model of what not to adopt. REACH is now much more of a reality than earlier, with thousands of registrations for chemicals having been submitted by November 30, 2010. Investment in REACH compliance could become a competitive advantage under a modernized TSCA. Data produced under REACH could also make TSCA data requirements more feasible to meet.
- Industry cited changes in technology as a reason for TSCA reform. Increasingly, greener chemicals are replacing older chemicals. Government programs such as the Tox21 project promise high-throughput toxicology screening, vastly increasing testing capabilities, although not until years in the future.

The support of some in industry for TSCA reform may have cooled, given the perceived problems with the 2010 legislation. Others continue to support TSCA reform, but it is unclear if industry will push Republicans to consider TSCA legislation.

With industry support, there could be a window of opportunity to forge the meaningful compromises necessary for TSCA legislation to move forward. Democrats would have the most to give up from the 2010 legislation, but they may be willing to compromise in order to achieve some improvements to TSCA. They have tried the approach of the 2010 legislation and should recognize that that approach is not viable for the 112th Congress. They face possible loss of the Senate in two years (Democrats must defend 23 Senate seats in 2012, Republicans only 10). Accordingly, Democrats may regard the 112th Congress as a better forum for TSCA reform than they are likely to have in the future. The Senate champion of TSCA reform, Senator Lautenberg, will be 90 years old when his term is up in 2014; he may be willing to compromise.

Industry supporters of TSCA reform may want to consider taking these steps:

- Work through trade associations to develop concrete industry proposals.
- Inform Congressional staff and members of both Houses that TSCA reform legislation remains important to industry, and why.
- Provide examples of how TSCA reform can avoid being "job-killing" and promote greener products and the jobs that come with them.
- Bring creative ideas on TSCA reform to Congressional staff for their consideration. While Members of Congress are addressing higher priority issues, the hard work of developing a revised approach to TSCA legislation could proceed behind the scenes.
- Push for a smaller, less-comprehensive bill than the 2010 legislation, which may be easier to pass.

In short, TSCA reform should remain on the table for industry in 2011.

For more information, please contact Mark Duvall, mduvall@bdlaw.com, or Alexandra Wyatt, awyatt@bdlaw.com.

OSHRC Guidance on Repeat Violations and Affiliated Companies

Can the Occupational Safety and Health Administration (OSHA) issue a "repeat" citation to a company based on a previous violation by an affiliate of that company? It depends on whether OSHA may "pierce the corporate veil" and find that the two affiliates are a single employer for OSHA purposes. Until now, the Occupational Safety and Health Review Commission (OSHRC) has provided limited guidance on this topic. At stake are both the pejorative characterization of being a repeat violator and substantially increased penalties -- a "repeat" violation carries a maximum penalty of $70,000, ten times the maximum for a "serious" violation. In a recent decision, *Loretto-Oswego*,[1] the OSHRC laid out clear guidance on this issue for the first time in many years. It also clarified that OSHA bears the burden of proof that the affiliated companies are a single employer.

1. Background

Section 17(a) of the Occupational Safety and Health Act of 1970, as amended (OSH Act), authorizes OSHA to assess a civil penalty of up to $70,000 to "[a]ny employer who ... *repeatedly violates* the requirements of section 5" or a standard under section 6 of the OSH Act.[2] OSHA has summarized the elements for a "repeat" violation in its Field Operations Manual, which provides that "[a]n employer may be cited for a repeated violation if that employer has been cited previously for the same or substantially similar condition or hazard and the citation has become a final order of the Review Commission."[3] Essentially, OSHA must establish: (1) the same employer, (2) an OSHRC final order at the time of the alleged violation, and (3) substantial similarity of the violated requirement.

OSHA also identifies a time element for the previous citation. The 2009 Field Operations Manual provided that the new citation must have been issued within 3 years of the previous citation or within three years of the final abatement date, whichever is later.[4] In 2010, OSHA extended those three-year periods to five years.[5]

The Field Operations Manual does not discuss whether affiliated companies can be considered a single employer for purposes of a "repeat" citation. The leading case on "piercing the corporate veil" for OSHA enforcement purposes is *Advance Specialty Co*. (1976), in which the OSHRC stated:

> It is well settled that corporate entities may be disregarded in order to effectuate a clear legislative purpose .... We find, therefore, that when, as here, two companies share a common worksite such that the employees of both have access to the same hazardous conditions, have interrelated and integrated operations, and share a common president, management, supervision or ownership, the purposes of the Act are best effectuated by the two being treated as one.[6]

Other fact patterns have resulted in different decisions, but little additional clarity, until now. Moreover, those OSHRC decisions did not involve a question of "repeat" citations.[7]

2. Facts

In 2002, OSHA issued five citations to Loretto-Oswego Residential Health Care Facility ("Loretto-Oswego") located in Oswego, New York. These citations were issued in response to two inspections that had been conducted at the facility, and alleged violations of various general industry standards. OSHA classified two of the citations as "repeat" violations. OSHA made this classification based on previous violations that had been found at two affiliated facilities: Loretto-Rest Residential Health Care Facility in Syracuse, New York (Loretto-Rest) and Loretto-Utica Residential Health Care Facility in Utica, New York (Loretto-Utica). The parent company, Loretto Management Company (LMC), was located at the same address as Loretto-Rest. Loretto-Oswego disputed OSHA's characterization of the citations as "repeat" violations, on the basis that it was a separate corporation from its affiliates.

3. ALJ Decision

In 2003, ALJ Schoenfeld determined that Loretto-Oswego, Loretto-Rest, and Loretto-Utica were a single employer and affirmed OSHA's classification of the violations as "repeat" violations.

The ALJ looked for a combination "of most or all" of three factors to determine whether the affiliated entities were a single employer: (1) a common worksite; (2) a common president or management; and (3) close interrelations and integration of operations. These factors were first articulated in *Advance Specialty Co*.

With respect to the first factor, the ALJ concluded that even though the affiliated entities had three different physical addresses, they were nonetheless a common worksite because employees at each of the entities were "exposed to the same or similar types of hazards." Also, he noted that the parent, LMC, and one of the affiliates, Loretto-Rest, shared the same address.

With respect to the second factor, the ALJ concluded that the affiliates had a common president and management, because the affiliates had a common president, chief executive officer, and chief financial officer. The LMC bylaws stated that the parent company "will control, oversee, coordinate, represent and support the interests of all present and future Loretto corporations." The LMC financial statement asserted that "the overall operations of all entities are under the administrative control of the President of the Corporations."

Finally, with respect to the third factor, the ALJ concluded that the affiliates were closely interrelated and integrated because employees with LMC had the authority to settle citations, the affiliates participated in monthly meetings, one of the affiliates operated a central food commissary that provided foods to the affiliates, a common website posted job opportunities for the affiliates, all service and maintenance employees belonged to the same union, and the same insurance agency handled all worker compensation claims. Also, several employees at the parent company had the authority to direct the affiliates and ensure that they followed regulatory requirements.

Finding that each of the factors was present, the ALJ concluded that Loretto-Oswego, Loretto-Rest, and Loretto-Utica were a single employer, and upheld OSHA's citations for "repeat" violations by Loretto-Oswego.

The employer appealed the decision to the OSHRC, which seven years later reversed the ALJ on this issue.

4. OSHRC Decision

In reviewing the ALJ's decision, the OSHRC analyzed the same factors to determine if there was a single employer, but reached a different conclusion.

As for the first factor, a common worksite, the OSHRC found that the affiliates did not share

a common worksite because the facilities were located in three different cities. Thus, it rejected the ALJ's assessment that there was a common worksite because the working conditions were similar at the different locations, and gave no weight to the fact that the parent, LMC, was co-located with Loretto-Rest. This factor makes it more difficult for OSHA to assert that geographically-separate affiliates are the same company for "repeat" citation purposes.

The second factor did favor a finding of a single employer: sharing a common president, management, supervision or ownership. As noted above, the parent and the affiliated companies shared the same president, chief executive officer, and chief financial officer. The OSHRC did not regard this as determinative, however, saying "[t]his outward appearance of a common identity gives way, however, when we consider the extent to which LMC and its affiliates had 'interrelated and integrated operations.'" That factor, discussed below, overrode the significance of a common management structure, which is shared by many affiliated companies.

The critical factor for the OSHRC was the actual interrelationship between the affiliated companies. The OSHRC found that there was little or no interaction between the affiliates. Although there was some involvement on the parent company's part with the Loretto-Oswego operations, on a day-to-day basis, administrative personnel at Loretto-Oswego operated independently of the parent. The OSHRC concluded that "[i]n terms of safety matters, the evidence in the record is particularly weak as to whether LMC and its affiliates were so integrated that they acted as one employer." The OSHRC also commented that even though LMC reviewed an exposure control plan and periodically sent personnel to the facility during inspections or for environmental and maintenance issues, this was "nothing more than resource sharing," and was not "the level of integration necessary to show a single-employer relationship." Thus, separate safety programs among affiliates can be a significant factor in finding that affiliates are not a single employer, despite parent company involvement. In addition, the OSHRC viewed the parent's participation in the OSHA inspection as irrelevant to the issue, in part because it was clear that the Loretto-Oswego personnel, not LMC personnel, were primarily responsible for safety matters at the facility.

Based on this analysis of the factors, the OSHRC concluded that the affiliates were not a single employer and overturned the ALJ's finding of "repeat" violations.

In a footnote, the OSHRC also clarified that the burden of establishing a single-employer relationship when issuing "repeat" citations falls on OSHA. In doing so, it partially overruled its 1981 decision in *Trinity Industries*, where it had ascribed that burden to employers because of their unique knowledge.

5. Conclusion

In Loretto-Oswego, the OSHRC took a careful look at the factors for determining the presence of a single-employer relationship. It concluded that mere affiliate relationships and the sharing of some corporate resources was not enough. Instead, the OSHRC identified critical factors that warranted against treating affiliated companies as a single employer, including little to no interaction among the affiliates; limited involvement among the affiliates and the parent company; independent administrative operations on a day-to-day basis; limited interaction with respect to safety matters; and separate facilities. The OSHRC also shifted the burden of establishing a single-employer relationship back to OSHA, making it more difficult for OSHA to establish a "repeat" violation.

Companies facing possible "repeat" citations based on corporate affiliation may want to review this OSHRC decision carefully.

For more information, please contact Mark Duvall, mduvall@bdlaw.com, or Jayni Lanham, jlanham@bdlaw.com.

---

[1] *Loretto-Oswego Residential Health Care Facility*, OSHRC Docket Nos. 02-1164 & 02-1174 (Rev. Comm'n 2011).

[2] 29 U.S.C. § 666(a) (emphasis added).

[3] OSHA Field Operations Manual, Directive Number CPL 02-00-148, Chap. 4, § VII.A.1 (Nov. 9, 2009) (emphasis

omitted). This description tracks that of the leading OSHRC decision on "repeat" violations, *Potlach Corp.*, OSHRC Docket No. 16183, 7 BNA OSHC 1061, 1063 (OSHRC 1979).

[4] OSHA Field Operations Manual, Chap. 4, § VII.E.1.a.

[5] OSHA Administrative Penalty Information Bulletin (undated, but posted July 2010), http://www.osha.gov/dep/administrative-penalty.html.

[6] *Advance Specialty Co.*, OSHRC Docket No. 2279, 3 BNA OSHC 2072, 2075-75 (OSHRC 1976). See also *C.T. Taylor Co.*, OSHRC Docket No. 94-3241, 20 BNA OSHC 1083, 1086-88 (OSHRC 2003); *Vergona Crane Co.*, OSHRC Docket No. 88-1745, 15 BNA OSHC 1782, 1783 (OSHRC 1992); *Trinity Industries, Inc.,* OSHRC Docket No. 77-3909, 9 BNA OSHC 1515, 1518-19 (OSHRC 1981).

[7] An administrative law judge (ALJ) in 1997 observed that "[t]he Commission ordinarily does not pierce the corporate veil for the purpose of determining whether a company committed a repeat violation," but did so on the facts of that case. His decision is still pending review by the OSHRC. Southern Scrap Materials Co., OSHRC Docket No. 94-3393, 1997 OSAHRC LEXIS 162 (ALJ 1997), petition for review granted (Nov. 24, 1997).

FDA Reopens Comment Period for GRAS Notification Procedure

On December 28, 2010, the Food and Drug Administration ("FDA") reopened the public comment period for a 13-year-old proposal to establish formally a voluntary procedure by which companies may notify FDA of their determination that a substance intended for use in food is "generally recognized as safe" ("GRAS") and FDA may respond.[1] FDA has been accepting GRAS notifications as an interim measure since 1998.

Given the passage of time since FDA first published its proposal on April 17, 1997, the reopened comment period provides manufacturers and other interested parties with an opportunity to raise concerns about FDA's implementation of the notification procedure. FDA is also soliciting further public comment on issues raised by earlier commenters, as well as issues identified in a Government Accountability Office ("GAO") report published last year that urged FDA to strengthen its oversight of GRAS food ingredients.[2]

Comments on the proposed rule are due by March 28, 2011.

1. Background: What is GRAS?

While manufacturers of new food additives must obtain pre-market approval from FDA pursuant to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), GRAS substances are exempt from the premarket approval requirement due to their status.[3]

FDA recognition of GRAS status is not a requirement for being GRAS; however, for commercial reasons, food manufacturers commonly seek FDA recognition. FDA formerly used a GRAS petition process, which was lengthy. Since 1998, FDA has been using the 1997 proposal for a GRAS notification process on an interim basis.

A GRAS determination can be based on either long experience in food (for food ingredients used prior to 1958) or scientific procedures. Critically, such scientific procedures require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. Ordinarily, the scientific procedures must be based on published studies, which may be corroborated by unpublished studies and other data.[4] According to FDA, approximately one-half of the GRAS notices it evaluated during the interim period between 1998 and 2009 included the findings of an "expert panel" specially convened by the notifier to evaluate the data and information that were the basis for the notifier's GRAS determination. In most cases, these findings were included as a report in the GRAS notice but were not published in peer-reviewed journals.[5]

2. The GRAS Affirmation Petition Process

FDA's existing petition process for affirmation of GRAS status is described at 21 C.F.R. § 170.35. This resource-intensive process is no longer used. Under that process, FDA would publish a notice in the Federal Register, request comments on the GRAS petition, comprehensively review the safety of the substance, draft a detailed explanation of why the use is GRAS, and publish that explanation in the Federal Register. Each petition resulted in a rulemaking that allowed public comment, and FDA had to respond to the comments received.

FDA has not used this process since implementing the 1997 proposed rule on an interim basis in 1998. The 1997 notice indicated that "FDA would not continue to commit resources to review of a GRAS affirmation petition" if a GRAS notification is received.[6]

3. The GRAS Notification Process

In its 1997 proposal, FDA sought to:

1. replace its existing voluntary GRAS affirmation petition process with a voluntary notification procedure whereby a manufacturer may notify FDA of its determination that a particular use of a substance in human food or animal feed is GRAS, and

2. clarify the criteria described in its regulations whereby the use of a food additive substance is not subject to the premarket approval requirements of the FFDCA because it is GRAS.

FDA's 1997 proposal described the following major steps in the GRAS notification process:

- A person will submit to FDA a notification that it has concluded that its food ingredient is GRAS. The notification will include information on the chemical identity, manufacturing process, intended use, expected exposure, toxicity information, and comprehensive evidence of general recognition of safety.

- FDA will acknowledge receipt within 30 days and assign a GRAS registry number ("GRN") to the submission.

- FDA will post on its GRAS notification inventory website[7] a notice that review of the GRAS notification is pending. The posting will include the name of the submitter, the identity of the food ingredient, the intended use, and the GRN.

- If FDA has concerns about the notification, it will inform the submitter, who may ask FDA to cease evaluation of the notification or submit additional information.

- The 1997 proposal indicated that FDA's review period would be 90 days, but since 2001 FDA guidance has indicated that FDA will try to address most GRAS notifications within 180 days. According to FDA, since 1998 it has responded to approximately 12% of GRAS notices within 90 days while requiring more than 180 days to respond to more than 31% of GRAS notices.[8]

- If FDA does not object to the notification, FDA will post on its GRAS notification inventory website a letter to the submitter indicating that "FDA has no questions."

- Alternatively, FDA may conclude that the "notice does not provide a basis for a GRAS determination" (e.g., because the notice does not include appropriate data and information or because the available data and information raise questions about the safety of the notified substance), or a notice that the submitter has requested that FDA cease evaluation of the notification.

Although FDA's letter does not represent official approval of a claim of GRAS status, a "no questions" response letter has generally proven sufficient to persuade customers that FDA regards the food ingredient as GRAS. The notification, FDA's response, and other "releasable information" are released pursuant to FDA's implementation of the Freedom of Information Act.[9]

In the proposal, FDA invited interested persons to submit GRAS notifications as described in the proposed rule until FDA publishes a final rule.[10] Thus, FDA has been implementing its proposed rule since 1998 notwithstanding the fact that it still has not yet issued a final regulations.

During that time it has received an average of 26 GRAS notices per year.[11] FDA's on-line inventory of GRAS notifications includes 365 notices submitted since 1998.[12] This inventory provides the name of each notified substance with a link to the text of FDA's corresponding response letter, along with the nature of FDA's response.[13] The inventory also provides

links to information from the notifier's GRAS notification and any additional correspondence FDA has issued regarding the GRAS notice. The FDA website provides guidance about the GRAS notification program.[14]

Recent examples of GRAS notifications include ones for the use of caffeine in alcoholic beverages,[15] for the use of a genetically-modified organism for use as a starter culture in alcoholic beverage fermentation to reduce hydrogen sulfide levels,[16] and for the use of synthetic amorphous silica (silicon dioxide) down to the nanoscale for use as an anticaking agent, defoaming agent, stabilizer, adsorbent, carrier, conditioning agent, chill proofing agent, filter aid, emulsifying agent, viscosity control agent, or anti-settling agent in a variety of food categories.[17]

4. The Newly Reopened Comment Period

The GAO Report concluded that "finalizing the 1997 proposed rule, which FDA considers interim policy, would firmly establish the framework and criteria for FDA's voluntary notification program. It would also reduce the inherent uncertainties for companies of working with an interim policy." GAO noted that FDA had not yet responded to the public comments received on the 1997 proposal.[18] The December 2010 FDA notice is in large part a response to the GAO Report.

In reopening the comment period, FDA is seeking public comments that reflect developments and experience since its original proposal was first published. In addition, the notice addresses GAO's recent report, which recommended that FDA: (1) obtain more information about the use of engineered nanomaterials in food ingredients, (2) strive to minimize the potential for conflict of interest, and (3) issue guidance on how to document GRAS determinations.

Among the 17 specific issues identified by FDA for further comment during the new period are:

1. its proposed use of terms such as "scientific principles," "studies," and "procedures" in describing the "generally available and accepted" information that form the basis of a GRAS determination;

2. whether to include a provision in the final rule expressly allowing a notifier to "incorporate by reference" publically available data that were previously submitted to FDA (FDA notes that, regardless of whether a notifier incorporates such information by reference, the Agency may take into account any relevant data or information that it may have from other sources in making its own determinations);

3. what procedures should apply in connection with the submission of confidential information in a GRAS notice;

4. what information must be submitted to sufficiently identify a notified substance, including – in light of GAO's recent recommendation -- particle size and other chemical and physical properties of engineered nanomaterials that may be used to characterize them; and

5. FDA's proposed requirement that a notifier consider probable consumption of a substance and the cumulative effect of the substance in the diet in a notification submission.

FDA's new request for comments reflects all of this prior experience while providing manufacturers with an important opportunity to identify additional issues for the Agency's consideration before it finally promulgates the notification process.

For more information about FDA's proposed rule or the regulatory status of GRAS substances more generally, please contact Mark Duvall at mduvall@bdlaw.com or (202) 789-6090 or Alan Sachs at asachs@bdlaw.com or (410) 230-1345.

---

1 FDA, "Substances Generally Recognized as Safe: Reopening of the Comment Period," 75 Fed. Reg. 81536 (Dec.

28, 2010). FDA's original proposal was published at 62 Fed. Reg. 18938 (Apr. 17, 1997).

2 GAO, "FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized As Safe" (Feb. 3, 2010) (available at: http://www.gao.gov/new.items/d10246.pdf) ("GAO Report").

3 The FFDCA definition of "food additive" excludes from that definition, and thus from pre-market review requirements for food additives, any food ingredient that is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use." FFDCA § 201(s), 21 U.S.C. § 321(s). In contrast, under FFDCA § 402(a)(2)(C)(i), a food additive is deemed to be adulterated if it has not been affirmatively approved by FDA under FFDCA § 409. 21 U.S.C. §§ 342(a)(2)(C)(i), 348.

4 See 21 C.F.R. § 170.30.

5 FDA's experience with these notices is described in a memorandum dated November 4, 2010. See Document ID No. FDA-1997-N-0020-0016 (available at http://www.regulations.gov, in Docket No. FDA-1997-N-0020) ("Experience Document").

6 62 Fed. Reg. at 18955.

7 The GRAS notification inventory is available at http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing.

8 Experience Document at 24.

9 Experience Document at 27.

10 62 Fed. Reg. at 18954.

[11] A table indicating the specific number of GRAS notices filed by FDA each year is provided in the Experience Document at pages 36-37. FDA also provides statistics on the disposition of every GRAS notice filed each year between 1998 and 2009. Experience Document, at pages 11-12.

[12] See FDA, "GRAS Notice Inventory," available at: http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing.

[13] From 1998 through 2009, 79% of GRAS notices resulted in a "no questions" response, 16% were withdrawn, and 5% were found to provide an insufficient basis for a GRAS determination. Experience Document at 10.

[14] See FDA, "About the GRAS Notification Program," available at: http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASNotificationProgram/default.htm.

[15] GRN 347, withdrawn at the submitter's request. FDA sent the submitter a warning letter about the use of caffeine in the alcoholic drink Four-Loco, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm234023.htm, and issued a consumer update entitled "Serious Concerns Over Alcoholic Beverages With Added Caffeine," http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm233987.htm.

[16] GRN 350 (pending).

[17] GRNs 321 and 298. FDA had no questions. The submitter's notification and FDA's response letter both referred to colloidal silica, which the notification indicated is an aqueous dispersion of discrete amorphous silica particles having diameters of 1 to 100 nm. FDA's letter indicated that the submitter noted that most amorphous silica particles range from 100 nm to 1000 nm and do not exist as easily dispersible nanoparticles.

[18] GAO Report at 17.

EQ Finalizes New NEPA Mitigation Guidance

On January 14, 2011, the White House Council on Environmental Quality ("CEQ") finalized guidance entitled "Appropriate Use of Mitigation and Monitoring and Clarifying the Appropriate Use of Mitigated Findings of No Significant Impact." The guidance is intended to make federal agencies more accountable for mitigation measures that they identify in conducting National Environmental Policy Act ("NEPA") reviews of proposed actions. CEQ issued draft guidance on this topic in February 2010 as part of its modernization of NEPA practices in conjunction with NEPA's 40th anniversary. See http://www.bdlaw.com/news-811.html. The restructured final CEQ guidance expands upon, but overall is consistent with, the earlier draft guidance.

Purpose and Need for the Guidance

Federal agencies, or their cooperating partner agencies, often promise to implement mitigation measures, or, beyond that, represent that such mitigation will successfully reduce otherwise significant impacts to insignificant levels. Perceiving a shortfall in agencies' efforts to ensure such mitigation becomes a reality, CEQ aims to improve agencies' accountability for mitigation commitments made during NEPA reviews. The final guidance places mitigation commitments under the microscope and calls for them to be explicit, clear, verified, and transparent. The central message of the guidance is that "[a]gencies should not commit to mitigation measures considered in an EIS [Environmental Impact Statement] or EA

[Environmental Assessment] absent the authority or expectation of resources to ensure that the mitigation is performed."

Key Features Of The New Mitigation Guidance

The guidance at the outset reaffirms the importance of mitigation in several contexts, including as a component of project design (e.g., best management practices for stormwater) or in the alternatives analysis in a NEPA review document. Importantly, CEQ also validates the use of a "mitigated Finding of No Significant Impact" following an EA. With a "mitigated FONSI," agencies may rely on mitigation to reduce a proposal's environmental effects and avoid preparation of a more detailed EIS. However, CEQ cautions that such mitigation must be "enforceable."

CEQ seeks better implementation of mitigation commitments by making them express, measurable, and viable. According to CEQ, NEPA and decision documents should "carefully specif[y]" any relied-upon mitigation "in terms of measurable performance standards or expected results, so as to establish clear performance expectations." CEQ also asks agencies to disclose and assess potential funding shortfalls upfront in the NEPA analysis and explore adaptive management or specific mitigation alternatives if the selected mitigation does not succeed.

The final guidance stresses a need for creation and disclosure of ongoing mitigation monitoring plans for any agency decision relying on an EIS and for "important" cases relying on an EA/FONSI. Two separate types of monitoring are discussed. Implementation monitoring determines whether mitigation commitments are being performed. Effectiveness monitoring evaluates whether the implemented mitigation is successful. In gauging mitigation effectiveness, the final guidance calls for a baseline analysis of resource conditions before project implementation and sanctions reliance on outside experts and information sources. CEQ defers to individual agency discretion to select the form and method of monitoring, but notes that the selected monitoring method should be incorporated in the agency decision documents and should include a system for reporting results to the public.

The guidance highlights transparency and public involvement in mitigation development and monitoring. CEQ encourages affirmative disclosure of mitigation and monitoring information, particularly via the Internet. Agencies may balance competing confidentiality or privacy concerns, but CEQ opines that environmental monitoring results are rarely considered confidential information.

Consequences Of Mitigation Failure

Finally, CEQ speaks to the consequences of non-implementation or ineffectiveness of mitigation. The appropriate steps to correct such failures depend on the existence of any remaining federal action and any alternative mitigation opportunities. Where no federal action remains, the failure should inform future baselines and NEPA analyses. In other cases, while imposing no hard and fast requirement to restart the NEPA process, CEQ suggests that supplemental NEPA analysis, agency remedial actions to enforce any permit conditions, or securing other funding (or assessing a lack of funding) may be appropriate for the proposed project to proceed.

Implications and Next Steps

The full import of these new guidelines remains to be seen. CEQ's responses to public comments note that the guidance adds no new substantive requirements and is not legally enforceable; yet, compared to the primarily "procedural" elements of NEPA review, the guidance has a distinctly "substantive" focus on the ultimate achievement of mitigation commitments.

CEQ calls for agencies to revise their own NEPA regulations and guidance accordingly and, where applicable, to utilize underlying legal authorities to enforce mitigation as conditions of funding, permitting, or other approvals. CEQ also states that "enforcement clauses, including penalty clauses, should be developed as allowable under the applicable statutory

and regulatory authorities." And, from a practical perspective, it is unclear what effect stressed agency budgets may have on the performance of planned mitigation or the viability of projects incorporating such mitigation measures.

Resources And Other NEPA Developments Of Interest

A link to the final CEQ mitigation guidance can be found at http://ceq.hss.doe.gov/current_developments/docs/Mitigation_and_Monitoring_Guidance_14Jan2011.pdf.

For more information on these mitigation guidelines or their implications for a specific project, please contact James Auslander at (202) 789-6009, jauslander@bdlaw.com; Bill Sinclair at (410) 230-1354, wsinclair@bdlaw.com; or Gus Bauman at (202) 789-6013, gbauman@bdlaw.com.

The release of CEQ's mitigation guidance was not the only NEPA item of interest on January 14. In Pasadena, California, the U.S. Court of Appeals for the Ninth Circuit abandoned its so-called "federal defendant rule," which had barred private parties from intervening as of right on the government's side in NEPA cases. A copy of that decision may be found at www.bdlaw.com/assets/attachments/Wilderness%20Society%20v%20US%20Forest%20Service.pdf. An analysis of that decision can be found at http://www.bdlaw.com/news-1041.html. In addition, the U.S. Environmental Protection Agency ("EPA") has sought to modernize its administrative process for submission and management of EISs. EPA has also solicited public comments on future updates of its EIS filing system. A copy of EPA's Federal Register Notice can be found at www.bdlaw.com/assets/attachments/2011-01-14%20EPA%20FR%20Notice%20re%20EIS%20Filing.PDF.

Please contact us with any questions regarding these or other NEPA developments.

Ninth Circuit Removes Barrier to Intervention in NEPA Cases

In a decision that will facilitate intervention by interested parties in National Environmental Policy Act ("NEPA") cases in Western states, the U.S Court of Appeals for the Ninth Circuit on January 14, 2011 abandoned a rule that had stood as a barrier to intervention for more than two decades. The Ninth Circuit's so-called "federal defendant" rule, which has been in place since 1989, categorically prohibited private parties and state and local governments from intervening of right as defendants to litigate the merits of NEPA challenges brought against federal agencies. In The Wilderness Society v. U.S. Forest Service, No. 09-35200 (9th Cir. Jan. 14, 2011) (available at http://www.bdlaw.com/assets/attachments/Wilderness%20Society%20v%20US%20Forest%20Service.pdf), after weighing the positions of the parties and the 37 groups of amici that filed briefs, the Court did away with the controversial rule.

The Ninth Circuit originally adopted the federal defendant rule after concluding that no parties other than the federal agency defendants in NEPA suits have the "significantly protectable" interest required to intervene of right under Federal Rule of Civil Procedure ("FRCP") 24(a)(2) because NEPA is a procedural statute that binds only the federal government. In abandoning the rule, however, the Court declared that the rule in fact is "at odds with" FRCP 24(a)(2), the standards the Court applies in all other intervention of right cases, and the standards of virtually every other federal Court of Appeals. Slip Op. at 796, 803. The Court explained that such a bright-line rule is inconsistent with the text of FRCP 24(a)(2), which requires only "an interest relating to the property or transaction that is the subject of the action." By categorically providing that private parties lack a significantly protectable interest in NEPA compliance actions, the Court concluded, the federal defendant rule "mistakenly focuses on the underlying legal claim instead of the property or transaction that is the subject of the lawsuit." Slip Op. at 800-01. Such a principle has no support in law, according to the Court.

The Ninth Circuit reasoned that the usual standards applicable in all other cases for intervention of right under Rule 24(a)(2) should apply in NEPA cases as well. To that end, the Court stated that "[t]o determine whether putative intervenors demonstrate the 'significantly protectable' interest necessary for intervention of right in a NEPA case, the

operative inquiry should be 'whether the interest is protectable under some law' and whether 'there is a relationship between the legally protectable interest and the claims at issue.'" Id. at 804. A candidate for intervention generally will satisfy these standards if "it will suffer a practical impairment of its interests as a result of the pending litigation." *Id*.

The Ninth Circuit's abandonment of the federal defendant rule is a welcome development for private parties whose interests are implicated by NEPA litigation in Alaska, Arizona, California, Hawaii, Idaho, Montana, Nevada, Oregon, and Washington. By harmonizing the intervention of right standards in NEPA cases with those in other cases, the Court's ruling makes it easier for private parties in Western states to protect their interests by participating in litigation on the side of federal agencies. In many cases, intervenors will provide important context for the presiding court regarding the interests at stake and the implications of challenges brought under NEPA. In addition, intervening parties will often be more aggressive than the government in defending certain federal agency actions in the face of NEPA challenges.

Also on January 14th, the White House Council on Environmental Quality ("CEQ") issued guidance designed to make federal agencies more accountable for mitigation measures they identify in conducing environmental impact reviews under NEPA. Beveridge & Diamond's analysis of the CEQ guidance can be found at http://www.bdlaw.com/news-1039.html.

For additional information about the Ninth Circuit's recent decision or related issues, please contact Dan Krainin (dkrainin@bdlaw.com or (212) 702-5417) or Parker Moore (pmoore@bdlaw.com or (202) 789-6028).

Firm News & Events

Beveridge & Diamond, P.C. Welcomes a Diverse Class of Principals into the Firm

Beveridge & Diamond, P.C., is pleased to announce that Nadira Clarke, Nessa Horewitch, Peter Schaumberg and Katherine Eller Wesley in our Washington, D.C. office and Lily Chinn and Laura Duncan in our San Francisco office have been elected Principals of the Firm. Of our six accomplished new Principals, five are women, and two of these women are minorities. To read more about these talented attorneys, please go to http://www.bdlaw.com/assets/attachments/2011-01-25%20BD%20Press%20Release%20-%20BD%20Welcomes%20Diverse%20Group%20of%20Principals%20into%20the%20Firm.pdf.

Fred Wagner Appointed Chief Counsel of the Federal Highway Administration

Beveridge & Diamond, P.C. is pleased to announce the appointment of Fred Wagner as Chief Counsel of the Federal Highway Administration by President Obama. The Firm congratulates him on his appointment.

Mr. Wagner was Principal in Beveridge & Diamond's Washington, DC office, and had been an attorney with the Firm since 1991. His practice while with Beveridge & Diamond involved counseling and litigation in a wide variety of land use, environmental impact analysis and public lands matters, focusing on the National Environmental Policy Act (NEPA) and related federal natural resources statutes. He chaired Beveridge & Diamond's Land Use Practice Group for the past six years.

Benjamin F. Wilson, Beveridge & Diamond's Managing Principal, said "I thank Fred for his service and sincerely appreciate his tireless efforts on behalf of the firm and its clients. Over the years, he has played a critical role in shaping the Land Use Practice of Beveridge & Diamond, and he will be missed. We wish him nothing but the very best in his new position."

Fred was sworn into his new position at the Federal Highway Administration on Tuesday, January 18, 2011. For more information, please contact Mr. Wilson at bwilson@bdlaw.com.

Office Locations:

Washington, DC

Maryland

New York

Massachusetts

New Jersey

Texas

California