Massachusetts Environmental and Land Use Alert

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Massachusetts Environmental Developments

MassDEP Issues New Solid Waste Master Plan

The Massachusetts Department of Environmental Protection has released a revised Solid Waste Master Plan, setting forth agency planning goals for solid waste management through 2020. *(full article)*

Public Water System Manager Found Guilty of Tampering with Drinking Water Samples After Trial

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In a major development for the agricultural biotechnology industry, the U.S. Court of Appeals

for the Ninth Circuit has upheld the decision of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service to deregulate Monsanto's Roundup-Ready Alfalfa (RR Alfalfa). *(full article)*

Bipartisan TSCA Modernization Bill, Chemical Safety Improvement Act, Introduced in Senate

In a major breakthrough, bipartisan and broadly supported legislation to modernize the Toxic Substances Control Act (TSCA) has been introduced in the Senate. *(full article)*

The Impacts of New EPA Vapor Intrusion Guidance

EPA recently issued two draft guidance documents on vapor intrusion and will accept comments on them through May 24, 2013. *(full article)*

Court Upholds EPA Authority to Retroactively Veto CWA Section 404 Permits

In a closely watched case of first impression, the D.C. Circuit Court of Appeals ruled on April 23, 2013 that Clean Water Act Section 404(c) "expressly and unambiguously" authorizes the U.S. Environmental Protection Agency ("EPA") to withdraw previously-approved disposal sites specified in a Section 404 permit issued by the U. S Army Corps of Engineers, after the permit has been finalized. *(full article)*

Safe Cosmetics and Personal Care Products Act of 2013 Mirrors TSCA Proposals, Would Greatly Expand FDA Authority Over Cosmetics

Representative Janice Schakowsky (D-IL), with fifteen co-sponsors, has introduced legislation in the House of Representatives to dramatically increase Food and Drug Administration (FDA) oversight of chemicals in cosmetics and other personal care products. *(full article)*

Firm News and Events

Beveridge & Diamond Named to National Law Journal's "Midsize Hot List" for Third Consecutive Year

The National Law Journal has again included Beveridge & Diamond on its "Midsize Hot List." The list recognizes 20 law firms of between 50 and 200 lawyers who stand out from their peers and from larger firms with unique business strategies and practice success. 2013 marks the third consecutive year that Beveridge & Diamond has been so honored. *(full article)*

Chambers USA 2013 Ranks Beveridge & Diamond, P.C. Among Leading Law Firms

The Chambers USA Guide to the Legal Profession has again ranked Beveridge & Diamond, P.C. as a leading environmental law practice, both nationally and regionally. In addition to firm-level rankings, individual lawyers from the Firm's regional offices are ranked. *(full article)*

Legal 500 US Ranks Beveridge & Diamond, P.C. Among Leaders in Environmental Litigation, Transactional, and Regulatory Matters

The Legal 500 United States has again ranked Beveridge & Diamond, P.C. as a leading national environmental law practice, noting the Firm's Environmental litigation capabilities as well as its transactional and regulatory capabilities. *(full article)*

Back to Top

Massachusetts Environmental Developments

MassDEP Issues New Solid Waste Master Plan

The Massachusetts Department of Environmental Protection (MassDEP) has released a revised Solid Waste Master Plan, setting forth agency planning goals for solid waste management through 2020. The new plan indicates MassDEP intends to continue pursuing aggressive recycling goals and also plans to increase enforcement of current bans on disposal of recyclable materials. The plan also modifies a long-standing moratorium on new combustion facilities by allowing development of waste to fuel facilities.

MassDEP is required by statute to produce a comprehensive statewide master plan for solid waste disposal, containing both short-term and long-term programs planning goals. M.G.L. c. 16, § 21. The last time the plan was revised was in 2006. The agency is currently mid-way through a ten-year planning cycle, which it describes as a pathway to zero waste. The current plan actually seeks a more modest goal than achieving zero waste, and instead calls for a 30% reduction in waste disposal over 12 years, from 6,550,000 tons of waste in 2008 to 4,550,000 tons of waste in 2020. The plan also suggests a long-term goal of 80% reduction by 2050.

MassDEP has identified three general goals: (i) reducing waste and maximizing recycling, (ii) improving solid waste facility performance, and (iii) developing integrated waste management systems. The specific strategies identified by MassDEP to accomplish these goals include the following:

- *Increase Residential, Business, and Institutional Recycling and Composting.*
  MassDEP plans to provide technical assistance, aggressively enforce generator and hauler waste ban requirements, and focus on efforts on increasing recycling of paper and organic waste streams.

- *Strengthen Incentives Through Producer Responsibility.*
  MassDEP plans to work for legislative changes to promote producer responsibility requirements and an expanded bottle bill.

- *Stimulate Greater Reuse of Materials and Products*.
  MassDEP intends to develop a regional materials exchange.

- *Commonwealth Leading by Example.*
  MassDEP will attempt to get state agencies to improve purchasing efficiencies, maximize recycling and minimize disposal.

- *Eliminate Barriers to Siting Anaerobic Digestion, Recycling, and Composting Facilities.*
  MassDEP hopes to mitigate or eliminate barriers to siting organics and recycling facilities.

- *Modify the Moratorium on Municipal Solid Waste (MSW) Combustion.*
  MassDEP wishes to encourage innovative and alternative technologies (e.g., gasification or pyrolysis) for converting MSW to energy or fuel. The moratorium will remain in place for new capacity for traditional MSW combustion but MassDEP intends to allow capacity development of up to 350,000 additional tons per year for gasification or pyrolysis of MSW, including expressing a major commitment to the development of anaerobic digestion facilities.

- *Increase Stringency of Facility Waste Ban Requirements.*
  MassDEP intends to include more stringent requirements in facility waste ban plans to increase the amount of banned material that is diverted from disposal.

Upon issuance of the revised master plan, MassDEP immediately encountered some resistance. First, some environmental organizations attacked the agency for lifting the

Back to Top

incineration moratorium, which has been a hotly contested issue for many years. One group called on the MassDEP commissioner to sign a pledge to maintain the moratorium and to increase compliance with current waste bans. The agency has announced plans to hire three additional employees whose sole job will be to inspect disposal facilities for waste ban compliance.

Second, the first anaerobic digester to be considered in Massachusetts since the issuance of the revised master plan hit a major road block. In the Town of Franklin, which is considering the development of a digester, the Planning Board voted not to recommend a zoning change to authorize the construction of a facility on a town-owned parcel, and the Town Council then tabled a proposal to consider the zoning amendment. Thus, in spite of a MassDEP commitment to help promote this developing technology, it is clear that there are significant obstacles yet to be overcome.

For more information about the MassDEP's Solid Waste Master Plan, please contact Stephen Richmond at srichmond@bdlaw.com.

Public Water System Manager Found Guilty of Tampering with Drinking Water Samples After Trial

After a four-day trial in May 2013, a Superior Court judge found Henry Papuga guilty of tampering with drinking water samples and making false statements. He was sentenced to one year in jail, suspended for five years, and 250 hours of community service. Papuga was the manager of the Milford Water Company.

The incident arose from efforts in August 2008 to terminate a boil-water order issued by the Massachusetts Department of Environmental Protection (MassDEP) due to the presence of E. coli in the public water system serving Milford. To ensure "clean" results, Papuga tampered with six drinking water samples by adding chlorine and falsely certified the integrity of the samples on the chain-of-custody form submitted to the lab. When the lab tested the samples, the samples apparently turned unexpected colors. In order to determine why this occurred, the lab tested the samples for chlorine. The chlorine levels were 700 times the acceptable level for drinking water. The lab contacted MassDEP, which launched an investigation, ultimately resulting in this conviction.

For further information regarding criminal environmental enforcement, please contact Jeanine Grachuk at jgrachuk@bdlaw.com or Steve Richmond at srichmond@bdlaw.com.

Revised MEPA Regulations Codify Review of Project Greenhouse Gas Emissions

The regulations implementing the Massachusetts Environmental Policy Act (MEPA) were recently revised, effective May 10, 2013, to codify the MEPA office's existing practice of evaluating greenhouse gas emissions associated with projects undergoing its review.

Generally speaking, MEPA's jurisdiction over private projects extends to those receiving financial assistance, land transfers or a permit, license, certificate, variance, approval or other entitlement for use from a state agency. Whether and what level of review is required for a project within MEPA's jurisdiction depends on which, if any, of the regulatory review thresholds a project triggers. Depending on the threshold triggered, projects proponents must prepare either an environmental notification form (ENF) or an ENF and environmental impact report (EIR).

Since 2007, the MEPA office has addressed greenhouse gas (GHG) emissions in accordance with its Greenhouse Gas Policy and Protocol, last revised in 2010. This required proponents of projects requiring an EIR to: (i) identify a project baseline; (ii) calculate estimated GHG emissions from the project baseline condition; and (iii) calculate estimated emissions reductions based on mitigation measures by comparing project alternatives to the baseline. The GHG Policy remains an important guidance document that includes direction on methodologies for quantifying emissions and suggestions for mitigation projects. More information about the policy is available at http://www.bdlaw.com/news-878.html.

Back to Top

The revisions to the MEPA regulations, 310 CMR 11.00 et seq., create new thresholds for GHG emissions that are equivalent to permitting requirements recently established by the U.S. Environmental Protection Agency under the Clean Air Act. Proposed projects that trigger either of the following thresholds will be required to prepare both an ENF and EIR:

- Construction of a New Stationary Source with federal potential emissions, after construction and the imposition of required controls, of 100,000 tons per year of GHGs based on CO2 equivalent.

- Modification of an existing Stationary Source with federal potential emissions that collectively will result, after construction and the imposition of required controls, of 75,000 tons per year of GHGs based on CO2 equivalent.

These and other thresholds in the MEPA regulations are intended to identify categories or aspects of projects that, by their nature, size or location, are likely to directly or indirectly cause "Damage to the Environment," the definition of which has been expanded to reflect additional climate change impacts, including reduction of groundwater levels, impairment of water quality and increases in flooding or stormwater flows.

The revised regulations also incorporate aspects of the Massachusetts Global Warming Solutions Act of 2008, for instance, providing that "the reasonably foreseeable climate change impacts of a project, including its additional GHG emissions, and effects, such as predicted sea level rise, are within the subject matter of any required permit, land transfer or financial assistance."

Going forward, the next significant revisions to the MEPA regulations will likely relate to the implementation of either (i) the Massachusetts Ocean Management Plan, for which the Office of Coastal Zone Management issued proposed regulations earlier this year that would implement the Plan largely through MEPA and other existing permitting processes; or (ii) the Massachusetts Department of Environmental Protection's streamlining regulatory initiatives. For more information on MEPA, please contact Aladdine Joroff at ajoroff@bdlaw.com or Marc J. Goldstein at mgoldstein@bdlaw.com.

Railway Agrees to Pay over $49,000 Penalty and Change Practices to Resolve Solid Waste Claims in Settlement with MassDEP

Pan Am Railways and its subsidiary Boston & Maine Corporation (the Railway Companies) entered into an Administrative Order on Consent with Penalty (ACOP) to resolve allegations by the Massachusetts Department of Environmental Protection (MassDEP) of improper storage of solid waste near railroad tracks. Without admitting liability, in March 2013, the Railway Companies agreed to pay a penalty of $49,746.50 and to improve their rail tie storage practices.

MassDEP alleged that the Railway Companies had discarded creosote treated railroad ties along railroads tracks in several Massachusetts communities, in one case causing a brush fire to become more dangerous and difficult to extinguish. MassDEP claimed that this disposal violated a number of solid waste requirements, including the requirement to obtain a solid waste facility site assignment.

The ACOP requires the Railway Companies to cease permanent disposal of railroad ties along their rail corridors, and provides a series of management requirements for railroad ties that allows for temporary storage of such ties near railroad tracks including for purposes of determining which are scrap and which may be reused, as long as various management requirements are met.

For further information regarding solid waste issues, please contact Jeanine Grachuk at jgrachuk@bdlaw.com or Steve Richmond at srichmond@bdlaw.com.

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Back to Top

Massachusetts Land Use Developments

Supreme Court Backs Landowner in Major Takings Case

The Supreme Court expanded private property rights in a major takings case that arose from the Florida state courts. The Court held in *Koontz v. St. Johns River Water Management District* that not only does the Constitution's Takings Clause apply to situations where a project is approved with "extortionate" conditions but it also applies where a project is denied because the owner refuses to accede to coercive property demands of the government.

And the Court further held that the Takings Clause protection applies to monetary exactions as well as real property exactions.

Koontz had sought permission to develop a small portion of a 15-acre tract in the Orlando area. Because of wetlands on the site, Koontz offered to convey 11 of his acres as a conservation easement over to the District. In the back-and-forth negotiation, the District made clear it would only approve the project if Koontz also paid to enhance a 50-acre wetland owned by the District several miles away.

Believing the government's mitigation demands excessive given the environmental impact of his building proposal, Koontz filed suit in state court. He claimed a taking under the Supreme Court's *Nollan* (1987) and *Dolan* (1994) decisions. In those cases, however, the Court was dealing with project approvals, not denials, in which conditions that went "too far" were attached to the approvals. And the conditions involved real property easements; they did not also involve monetary exactions. The *Nollan/Dolan* rule basically says that a condition attached to a project approval must have an essential "nexus" and "rough proportionality" between the government's demand and the project's impact on the public.

The Supreme Court has now extended the *Nollan/Dolan per se* takings rule to cover projects that are turned aside because an owner refuses to be forced to accept unconstitutional conditions in order to receive its applied for land use approval. And the Court has made clear that property is property, be it real estate or money. After all, in the real world, a land use exaction is a land use exaction regardless of the form it takes.

The author of this alert was deeply involved in the *Nollan* case on behalf of the owners at the Supreme Court level. It has taken 26 years for the Court to say what many thought back in 1987, and now the lower courts have clear direction as to the proper application of the Constitution's Takings Clause in the land use exactions context.

For more information, please contact Gus Bauman at gbauman@bdlaw.com or Brian Levey at blevey@bdlaw.com.

Massachusetts Appeals Court Reaffirms Local Control Over Nonconforming Uses

Zoning amendments that expand the grounds upon which nonconforming status may be lost apply to structures and uses otherwise protected under Mass. General Laws 40A, § 6. The Massachusetts Appeals Court in *Plainville Asphalt Corp. v. Town of Plainville*, 83 Mass. App. Ct. 710 (2013), makes plain that the manner of discontinuing the protections of § 6 is not forever determined by the terms of the local zoning regulation in effect on the date that either the nonconforming use began or the nonconforming structure was built.

In 1965, Plainville Asphalt's predecessor manufactured bituminous concrete at a facility in Plainville. A 1967 zoning amendment prohibited this use, but the manufacturing operation continued to function as a nonconforming use. The zoning bylaw then in effect also provided that the existing use was "`grandfathered' as a nonconforming use, subject to loss only by abandonment." However, a zoning amendment in 1983 provided

Back to Top

that nonconforming uses could be extinguished by either abandonment (which includes an intent to shutter or close a business) or mere nonuse. When Plainville Asphalt sold certain assets and liabilities in 2002, it entered into a noncompete agreement that resulted in the closure of the plant from 2003 to 2009. Plainville subsequently claimed that the plant could not reopen for manufacturing operations because it had lost its status as a nonconforming use due to nonuse. The company filed suit. The Land Court granted summary judgment in favor of Town and the Appeals Court affirmed.

Reviewing the judgment, the Appeals Court rejected Plainville Asphalt's "strained and incorrect" argument that the grandfathering of the manufacturing use was governed by the terms of the "abandonment" provision in place at the time the use began in the 1960's or when the use became nonconforming in 1967. Instead, the Court opined that the Town was free to rely upon either the "abandonment" or "nonuse" approach adopted in 1983's zoning amendment as a means of discontinuing the use. The Court held that because the third paragraph of section 6 of chapter 40A "gives cities and towns the explicit authority to regulate nonconforming uses and structures which are unused (for the nonconforming purpose) for two years or more, the plain language of the statute… compels the conclusion that the 1983 bylaw amendment applies here." Notably, both parties agreed that the minimum two year period in § 6 for establishing abandonment or nonuse superseded the Town's 1983 bylaw requiring only one year of nonuse before extinguishment.

For further information regarding land use and zoning issues, please contact Brian C. Levey at blevey@bdlaw.com or Marc J. Goldstein at mgoldstein@bdlaw.com. Special thanks to Benjamin Apple, a summer associate in Beveridge & Diamond's Washington D.C. office, for his assistance.

National Developments

Genetically Engineered Crop Prevails Again in Court

In a major development for the agricultural biotechnology industry, the U.S. Court of Appeals for the Ninth Circuit has upheld the decision of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service to deregulate Monsanto's Roundup-Ready Alfalfa (RR Alfalfa). *See Center for Food Safety v. Vilsack*, No. 12-15052 (9th Cir. May 17, 2013). The Court rejected all of plaintiffs' claims and affirmed in all respects the decision of the U.S. District Court for the Northern District of California. (Click here for a copy of the earlier decision and our summary of it).

The Ninth Circuit's decision is the latest in this long-running litigation that has attracted close attention in many circles throughout the country. APHIS initially granted non-regulated status to RR Alfalfa and supported its decision with an environmental assessment (EA) under the National Environmental Policy Act (NEPA). After that decision was reversed in litigation, APHIS prepared a more detailed environmental impact statement (EIS) under NEPA and again deregulated RR Alfalfa. Plaintiffs challenged the new deregulation decision and EIS on the same grounds, alleging violations of NEPA, the Plant Protection Act (PPA), and the Endangered Species Act (ESA).

The Ninth Circuit's 31-page decision dismissed each of these claims and agreed with APHIS' determinations. First, the Court found that the PPA requires analysis of only the "plant pest" risks identified by the statute and regulations, not a broader set of extrinsic concerns favored by plaintiffs. Second, the Court found that because RR Alfalfa is not a plant pest, APHIS had no jurisdiction to continue regulating the crop, and thus there remained no discretionary agency action to trigger consultation under the ESA. Finally, the Court upheld APHIS' revised NEPA analysis, including APHIS' rejection of "partial deregulation" alternatives after a finding of no plant pest risk.

This important decision has implications beyond RR Alfalfa. Special interest groups, including the plaintiffs in the RR Alfalfa litigation, have filed similar arguments in

Back to Top

response to pending petitions for deregulation of other genetically engineered crops. APHIS and the industry can now draw confidence from the Ninth Circuit's ruling in responding to such comments. Moreover, by refocusing the deregulation analysis on whether a new trait presents a "plant pest risk" as defined by statute and APHIS' regulations, the Court's decision has the potential to simplify and expedite agency decisions on genetically engineered crops going forward.

It is possible that the plaintiffs will seek to appeal this decision to the U.S. Supreme Court, which previously heard aspects of the prior challenge to APHIS' first RR Alfalfa deregulation decision. APHIS has also been considering proposed revisions to its rules governing deregulation and commercialization of genetically engineered crops. These issues continue to warrant careful monitoring.

For more information on developments in this case and other agricultural biotechnology litigation, please contact Kathy Szmuszkovicz at kes@bdlaw.com or (202) 789-6037, Jamie Auslander at jauslander@bdlaw.com or (202) 789-6009, or Sean Roberts at sroberts@bdlaw.com or (202) 789-6017.

Bipartisan TSCA Modernization Bill, Chemical Safety Improvement Act, Introduced in Senate

In a major breakthrough, bipartisan and broadly supported legislation to modernize the Toxic Substances Control Act (TSCA) has been introduced in the Senate. The Chemical Safety Improvement Act (CSIA), S. 1009,[1] was announced on May 22, 2013[2] by its chief Democratic and Republican sponsors, Senator Frank Lautenberg (D-NJ) and Senator David Vitter (R-LA). This client alert provides the political context for this remarkable development, and then explains the key provisions of the bill. It concludes with comments on the prospects for passage.

Political Context

Just weeks ago, Senator Lautenberg, a longtime champion of TSCA reform, had reintroduced his own comprehensive chemical safety bill, the Safe Chemicals Act (SCA), as described in our previous report.[3] The SCA targets many of the same aspects of TSCA as the CSIA does, but applies different, often more complex approaches. The SCA has obtained support only from the Democratic caucus, with 26 Democratic and 2 Independent co-sponsors. This one-sided support left the SCA with few prospects for passage by the Republican-majority House of Representatives, even assuming that the Democratic majority in the Senate could pass it.

Now, with Senator Lautenberg's retirement next year lending more urgency to his quest for a viable TSCA modernization bill, the long-sought goal of bipartisan support has been achieved. As of this writing, the CSIA has been co-sponsored not only by a number of Democratic senators who had co-sponsored the SCA,[4] but also by eight Republicans,[5] as well as three more conservative Democratic senators who had not signed on to the SCA.[6] Since the original introduction, three more Democrats and one more Republican have co-sponsored the bill,[7] for a total of 19 co-sponsors (10 Democrats and 9 Republicans).

Initial reactions to the CSIA have been generally been very favorable, by both industry groups[8] and some NGOs.[9] Other NGOs have already announced their opposition, however.[10]

EPA has not commented publicly on the bill, although two former EPA officials in the TSCA office, Steve Owens and Charlie Auer, issued statements of support.[11]

There is no guarantee of passage, but never before have the prospects for TSCA modernization been more favorable.

Back to Top

Key Provisions

1. Overview

The CSIA would mandate that EPA determine, on a prioritized basis, whether chemical substances meet a safety standard under the intended conditions of use. If they are found not to meet the safety standard, EPA would have to regulate them. The CSIA would establish a prioritization mechanism; set a safety standard; require EPA to determine whether chemical substances meet that safety standard under the intended conditions of use, by deadlines set by EPA; authorize EPA to require testing when additional information is needed in order to complete that determination; and direct EPA to select risk management measures by taking costs and benefits into account, but not by requiring use of the least burdensome alternative.

In addition to these core provisions, the bill would make limited changes to the new chemical provisions; require reporting by processors; lead to identification of chemical substances that are actively manufactured or processed; revise confidentiality protections, including protection for chemical identities; expand preemption of state and local restrictions of chemicals; and update export and import reporting requirements.

2. Prioritization

The prioritization mechanism would classify a chemical substance as being a high priority or a low priority for a safety assessment and safety determination. With few exceptions, only chemicals classified as active (see below) would be considered for prioritization. Only high-priority chemical substances would continue on to safety assessments and determinations.

For the most part, there would be no statutory deadlines for completing the prioritization process, but EPA would have to make every effort to complete the prioritization of all active substances in a timely manner. A state governor or agency could recommend chemical substances for prioritization; EPA would have to complete its prioritization of those substances within 180 days. If EPA were to need additional information before prioritizing a chemical substance, it could ask the public to submit existing data, but it could not require testing. Lists of high- and low-priority substances would be made public.

3. Safety Assessments and Safety Determinations

EPA would conduct a safety assessment and then a safety determination of each high-priority substance. The safety assessment would be based solely on considerations of risks to health and the environment. EPA would have to establish a methodology for conducting safety assessments and would have to rely on the best available science. The methodology would have to be reviewed every five years and updated as necessary.

Upon completing a safety assessment, EPA would make a safety determination, i.e., determine whether or not the chemical substance meets the safety standard under the intended conditions of use, taking into account factors such as the range of exposure, the weight of the evidence, and the magnitude of the risk.

EPA could require testing if necessary for it to complete either a safety assessment or a safety determination.

There would be no statutory deadlines, but EPA would have to set its own deadlines for completing each safety assessment and safety determination. Those deadlines could vary for different chemical substances. If EPA found that it could not meet a deadline, it would have to explain publicly the reasons for extending the deadline. This innovative approach would subject EPA to deadlines that are likely to be realistic (since it would set them itself), but would avoid the sue-and-settle litigation over failure to meet statutory deadlines that has proven problematic under some other environmental statutes.

Back to Top

Proposed safety assessments and safety determinations would be available for public comment. Final versions would also be made public. Safety determinations would be subject to judicial review.

4. Safety Standard

The safety standard used for safety determinations would be a standard that ensures that no unreasonable risk of harm to human health or the environment will result from exposure to the chemical substance. Compliance with the safety standard would be assessed in light of the intended conditions of use, meaning the circumstances under which a chemical substance is intended or reasonably anticipated to be manufactured, processed, distributed in commerce, used, or disposed of.

This “unreasonable risk” standard would differ from the “unreasonable risk” standard currently in TSCA. That one mandates a weighing of costs and benefits of regulation, the chemical substance, and its alternatives. The CSIA “unreasonable risk” standard would not be a weighing of competing economic and social factors, but rather a judgment after evaluation of various aspects of risk to health and the environment. Among the factors that EPA would consider would be the subpopulations that would be exposed, the degree of exposure, and the protections provided by the intended conditions of use (such as use of engineering controls, protective clothing, or warnings). For example, presumably EPA could find that a chemical substance meets the safety standard under the intended conditions of use for occupational exposure but not for exposure to children.

5. Risk Management

If EPA were to find that a chemical substance did not meet the safety standard under the intended conditions of use, it would have to adopt risk management measures through rulemaking. EPA could consider a wide variety of options, such as labeling, quantity or use restrictions, or even phase-outs or bans, if appropriate. Unlike under current TSCA, EPA would not be constrained to select the least burdensome option.

EPA would evaluate the different risk management options in terms of costs and benefits. It would have to consider whether technically and economically feasible alternatives exist; the risks of those alternatives as compared to the risks of the chemical substance under the intended conditions of use; the economic and social costs and benefits of the preferred regulatory option and other options considered; and the economic and social costs and benefits of the chemical substance and its alternatives.

6. New Chemicals and Significant New Uses of Existing Chemicals

Under the CSIA, the current approach for premanufacture notifications (PMNs) for new chemicals, and for significant new use rules (SNURs) and significant new use notices (SNUNs) for new uses of existing chemicals, would continue. The bill would codify some of EPA’s current administrative practices for review of PMNs and SNUNs. The authority for the current PMN exemptions, such as those for R&D, polymers, and low volume, would remain unchanged.

In evaluating PMNs and SNUNs, EPA would determine whether or not the new chemicals and significant new uses were likely to meet the safety standard under the intended conditions of use. If so, EPA would allow the review period to end and the PMN submitter to submit a notice of commencement of commercial manufacture or import (NOC). If EPA were to determine that a new chemical substance or significant new use would not be likely to meet the safety standard, it would have to impose restrictions in a manner similar to section 5(e) consent orders under current TSCA.

If EPA were to determine that it needed more information in order to make a determination about likelihood of meeting the safety standard, it could require the submitter to develop the information through testing. However, rather than require test results to be submitted before manufacture or the significant new use could commence, EPA could allow the submitter to file an NOC, begin commercial manufacture or the

Back to Top

significant new use, and thereby generate income to pay for the testing. If the test results later created concerns for EPA, it could prioritize the chemical substance as a high-priority substance.

7. Testing

Unlike the SCA, the CSIA would have no requirements for submission of minimum information sets in specified circumstances. Instead, under the CSIA, EPA could require testing where it found that it needed additional data in order to complete a safety assessment or a safety determination, or to make a determination of likelihood of meeting the safety standard for a new chemical substance or a significant new use. It could also require testing to meet agency needs under another federal law.

EPA would have to explain its need for testing, including an explanation of why existing information could not be extrapolated to meet the need. Testing requirements would have to be tiered. There would be provisions to encourage alternatives to animal testing.

It would generally be easier for EPA to require testing under the CSIA than under current TSCA. EPA would not have to establish that a chemical substance may pose an unreasonable risk or meets certain volume or exposure levels, and it would not have to proceed by rulemaking. Instead, it could issue an order or enter into a consent agreement to require testing.

8. Reporting and Recordkeeping

EPA currently has authority to require processors to report information, but it rarely exercises that authority. The CSIA would require EPA to adopt reporting requirements for processors, although the requirements could differ from those for manufacturers.

The CSIA would address some of issues of nomenclature used for naming chemical substances on the TSCA Inventory. For example, individual members of statutory mixtures listed on the Inventory would be declared to be on the Inventory. EPA would be directed to continue using its Class 2 and carbon chain length nomenclature.

EPA would have to identify those chemical substances on the Inventory that are active, i.e., have been manufactured or processed within the past five years. It would do so by establishing a candidate list of proposed active substances, then requiring manufacturers and processors to report either the candidate list substances or other substances on the Inventory that they have manufactured or processed in the past five years. For chemical substances on the confidential Inventory, manufacturers and processors would have to reaffirm (but not resubstantiate) that the identities continue to be confidential. If no one were to reaffirm that a chemical substance on the confidential Inventory was still confidential, EPA could make that identity public. EPA would publish the list of active substances (or generic names of confidential active substances). With few exceptions, EPA would prioritize only active substances.

9. Confidential Business Information (CBI)

CBI would be protected from disclosure if certain requirements were met. Like the SCA, the CSIA would identify categories of information likely to be eligible for CBI protection or likely not to be eligible for CBI protection. New CBI claims would have to be substantiated. In most cases, previous CBI claims would not need to be resubstantiated.

Chemical identities could be protected as CBI, even if present in health and safety studies. Additional substantiation would be required, and a structurally-descriptive generic name would have to be made public. Chemical identities could be disclosed under prescribed circumstances, such as in a medical emergency.

Instead of setting fixed time periods for CBI protection, as under the SCA, the CSIA would allow CBI to be protected for the time period requested by the submitter, except where the submitter either withdrew the CBI claim or EPA otherwise learned that the claim could no longer be substantiated. In most cases, before releasing CBI publicly,

Back to Top

EPA would have to notify the submitter and afford an opportunity to seek a court order barring release.

10. Preemption

Whereas the SCA would have allowed for virtually no preemption of state or local requirements, the CSIA would expand the preemptive effect of EPA actions as compared with current TSCA.

EPA testing requirements would continue to preempt new or existing state or local testing requirements. With limited exceptions, EPA rules, orders, and consent agreements under sections 5 or 6 for a chemical substance would preempt new or existing state or local restrictions or bans on the manufacture, processing, distribution in commerce, or use of that substance, as would a completed safety determination for the substance.

New state or local restrictions on the manufacture, processing, distribution in commerce, or use of a chemical substance would be preempted by EPA's classification of a chemical substance as a high-priority substance or a low-priority substance.

State and local provisions relating to disposal of chemical substances, such as environmental monitoring requirements, generally would not be preempted.

A state or locality could seek a waiver of preemption if it could meet prescribed criteria. Waiver applications would be subject to notice and opportunity for comment, and waivers could be appealed to the D.C. Circuit.

11. Exports and Imports

Export notifications would only be required for chemical substances that EPA found under section 5 not to be likely to meet the safety standard under the intended conditions of use, or that a safety determination had found not to meet the safety standard under the intended conditions of use, or for which the U.S. was required by treaty to provide export notification. The latter provision refers to treaties which the U.S. has not yet ratified, such as the PIC and POPs Conventions.

Import certifications would be similar to those today, but would also require notification that an imported chemical substance was a high-priority substance or a substance for which the U.S. was required by treaty to provide export notification.

Prospects for Passage

No hearings on the CSIA have been announced, nor has a schedule for consideration been established. These are early days; some senators may still be evaluating the bill (for example, the Chair of the Environment and Public Works Committee, Senator Barbara Boxer, has not yet indicated whether she will support the bill).

Still, this bipartisan bill has fundamentally changed the prospects for passage of TSCA legislation in this Congress, which had been dim. It has effectively stopped any consideration of the SCA as a viable bill, although the SCA will serve as a touchstone for Democrats in evaluating whether to support amendments to the CSIA.

The House of Representatives remains unlikely to initiate its own TSCA legislation. However, if the Senate were to pass the CSIA with a large majority, including many Republicans, the House leadership would be likely to bring a companion bill up for consideration.

Some NGOs (e.g., the Environmental Working Group) have already announced their opposition to the bill, although others are taking a pragmatic approach of considering the CSIA as the best bill that has a realistic chance of passage.

Some Democrats are likely to seek to amend the CSIA, such as by adding statutory

Back to Top

deadlines. Some Republicans may also want changes. Given that less than six months of the 113th Congress have passed, there is time for the Senate to consider the bill thoroughly, pass it or an amended version, and still have the House agree to what the Senate had passed. Another scenario, less likely but still possible with this breakthrough, is that both Houses would consider and pass the legislation within a short time. That is what happened with the Consumer Product Safety Improvement Act of 2008 and the Food Quality Protection Act of 1996. One thing is certain: it is important to stay tuned, because TSCA has suddenly become a hot topic on Capitol Hill.

This client alert was prepared by Mark Duvall, mduvall@bdlaw.com, and Andie Wyatt, awyatt@bdlaw.com.

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[1] Chemical Safety Improvement Act, available at www.bdlaw.com/assets/attachments/Chemical%20Safety%20Improvement%20Act.PDF.

[2] Senate Environment and Public Works Committee, Press Release, "Senators Lautenberg And Vitter Reach Groundbreaking Agreement To Reform Nation's Chemical Laws; Bipartisan Legislation Would Protect Americans From Risks Posed By Exposure To Chemicals" (May 22, 2013), http://www.epw.senate.gov/public/index.cfm?FuseAction=Minority.PressReleases&ContentRecord_id=ccf8cd45-e41f-28bd-0252-9984333f7335.

[3] Beveridge & Diamond, P.C., "'Safe Chemicals Act,' First TSCA Reform Bill of 113th Congress, Reintroduced" (Apr. 16, 2013), http://www.bdlaw.com/news-1462.html; see also Beveridge & Diamond, P.C., "TSCA Modernization Proposals in Congress: Recent History and Prospects" (Feb. 25, 2013), http://www.bdlaw.com/news-1447.html.

[4] Senator Lautenberg is listed as the sponsor. Democratic co-sponsors include Senators Kirsten Gillibrand (D-NY), Richard Durbin (D-IL), Charles Schumer (D-NY), Tom Udall (D-NM), Robert Menendez (D-NJ), Tom Harkin (D-IA), and Patty Murray (D-WA).

[5] Senator Vitter is listed as a co-sponsor. Other Republican co-sponsors include Senators Mike Crapo (R-ID), Lamar Alexander (R-TN), James Inhofe (R-OK), Susan Collins (R-ME), Marco Rubio (R-FL), John Boozman (R-AR), John Hoeven (R-ND), and Lisa Murkowski (R-AK).

[6] Senators Mary Landrieu (D-LA), Joe Manchin (D-WV), and Mark Begich (D-AK).

[7] Democratic Senators Begich, Harkin, and Murray, and Republican Senator Murkowski.

[8] E.g., American Chemistry Council, Press Release, "ACC Commends Senators Lautenberg and Vitter for Bipartisan Leadership to Reform TSCA" (May 22, 2013), http://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACC-Commends-Senators-Lautenberg-and-Vitter-for-Bipartisan-Leadership-to-Reform-TSCA.html/; American Cleaning Institute, Press Release, "Introduction of the Chemical Safety Improvement Act" (May 22, 2013), http://www.reuters.com/article/2013/05/22/aci-safety-act-reax-idUSnPNDC19227+1e0+PRN20130522.

[9] Environmental Defense Fund, Press Release, "A bipartisan path forward to reform U.S. chemical safety law; Hard-fought compromise legislation would better protect American families" (May 22, 2013), http://www.edf.org/news/bipartisan-path-forward-reform-us-chemical-safety-law. For a variety of NGO viewpoints, see Safer Chemicals Healthy Families blog, "Reactions to the bi-partisan Chemical Safety Improvement Act" (May 23, 2013), http://www.microsofttranslator.com/BV.aspx?ref=IE8Activity&a=http%3A%2F%2Fblog.saferchemicals.org%2F2013%2F05%2Finitial-reactions-to-the-bipartisan-chemical-improvement-safety-act.html.

[10] E.g., Environmental Working Group press release, "EWG President Ken Cook Weighs In On Senate Chemical Policy Reform Bill" (May 23, 2013), http://www.ewg.org/release/ewg-president-ken-cook-weighs-senate-chemical-policy-reform-bill.

[11] Senate Environment and Public Works Committee, "Top EPA Toxics Officials Under Obama & Bush Admins Hail Lautenberg-Vitter Bill to Reform Nation's Chemical Laws" (May 23, 2013), http://www.epw.senate.gov/public/index.cfm?FuseAction=Minority.PressReleases&ContentRecord_id=d2553c0f-beb5-e270-2971-ff2b84a06e88&Region_id=&Issue_id=.

The Impacts of New EPA Vapor Intrusion Guidance

EPA recently issued two draft guidance documents on vapor intrusion and will accept comments on them through May 24, 2013. If finalized in current form, these guidance documents would formalize and enhance EPA's existing practice of prioritizing vapor intrusion as a central issue in environmental remediation and could result in increases in the expense and effort required from responsible parties to achieve compliance for cleanup of contaminated sites conducted under federal authorities such as CERCLA or RCRA. They could also be highly influential in clean-ups overseen by state regulators.

Back to Top

Lastly, while intended for use in the regulatory context, recommendations in these guidance documents may be used to establish a standard of care in litigation involving vapor intrusion (e.g., RCRA citizen suits or common law toxic tort litigation).

Vapor intrusion is the migration of hazardous vapor from contaminated soil or groundwater into an overlying building. It is considered potentially harmful to human health, creates risks in real estate transactions and financing due to potentially diminished property values and environmental liability, increases exposure in toxic tort litigation, and, in the federal regulatory context, is considered a pathway of possible exposure that must be evaluated as part of the evaluation and selection of a site remediation plan.

The first of these two guidance documents was prepared by EPA's Office of Solid Waste and Emergency Response (OSWER) and is a comprehensive set of technical and policy recommendations regarding indoor air contamination arising from subsurface-source vapor intrusion attributable to all classes of volatile, or vapor-forming, chemicals (VI Guidance).[1] The VI Guidance modifies and expands draft guidance on vapor intrusion issued by the agency in 2002 (2002 Draft VI Guidance), which provided general direction for evaluating the potential for vapor intrusion pathways at cleanup sites but omitted any measures for delineation and mitigation of potential risks.[2] In a 2009 report, EPA's Office of the Inspector General (OIG) recommended that EPA update the 2002 Draft VI Guidance to reflect the numerous technical and policy advancements made since that time in both the public and private sectors.

The second guidance document was prepared by EPA's Office of Underground Storage Tanks (OUST) and is focused on investigations and assessments at petroleum contaminated sites where vapor intrusion by petroleum hydrocarbons may occur (Petroleum VI Guidance).[3]

VI Guidance

The VI Guidance presents a step-by-step vapor intrusion assessment plan, beginning with gathering and evaluating data for an initial conceptual site model, through collecting and evaluating additional data from various sources, and culminating in a risk assessment. According to EPA, the VI Guidance addresses the recommendations made in the OIG's 2009 report and takes into consideration more recent guidance developed by states and other technical working groups. Some of the elements in this document may well trigger an increase in expense in addressing VI risks and lengthen the site evaluation process.

- *Superfund Five-Year Reviews:* At Superfund sites that require five-year reviews,[4] EPA will gather data on vapor intrusion pathways and assess the sufficiency of the selected remedy for follow up in the five-year review report. Therefore, according to the VI Guidance and related Directive 9200.2-84,[5] the five-year review process could result in the re-opening of established Superfund remedies to address vapor intrusion, "even if vapor intrusion was not addressed as part of the original remedial action."[6]

- *Preemptive Mitigation/Early Action:* EPA recommends consideration of engineered methods to reduce vapor in buildings (e.g., by installing a radon-type detection system or vapor barriers), even in the absence of all pertinent lines of evidence necessary to characterize the vapor intrusion pathway. Any such measure would be an early effort to cut off exposure before completing investigations, but would not address the subsurface vapor source. The agency's rationale is that installation of engineered exposure controls in buildings is typically more cost-effective and less disruptive than conventional vapor intrusion investigations and subsurface characterization. Once preemptive mitigation measures are installed, however, that may conclude only an initial step rather than complete remediation. In the context of brownfields programs, treating preemptive mitigation now as only an interim solution may affect long term redevelopment plans.

Back to Top

- *Aggregate Noncancer Health Risk:* Even when the exposure level for each contaminant at a site is below screening levels and it is assumed that each "acts independently (i.e., there are no synergistic or antagonistic toxicity interactions among the chemicals)", the VI Guidance nevertheless proposes that a risk manager aggregate the individual noncancer health risks associated with each contaminant exposure to determine whether a response is warranted. The aggregated risk is reflected in a "noncancer hazard quotient" that would ultimately drive the response. This approach could be overly precautionary if the aggregated sum overstates the actual risks presented by the individual constituents. Furthermore, the VI Guidance recommends use of multiple lines of evidence in calculating and evaluating these risks, a process that may prolong response decisions and negatively affect situations where quick resolution of VI issues is paramount (e.g., brownfield redevelopment projects). On the other hand, evaluation of multiple lines of evidence may be more advantageous to the extent it provides for a more informed view of likely risk.

- *Background Levels:* Time-integrated sampling of volatile chemicals (as opposed to short-duration, or "grab" sampling) at multiple locations in and around a site is, in EPA's view, necessary to distinguish among potential sources of these chemicals (i.e., ambient sources, indoor sources, or vapor intrusion). In the past, generic values of historic background concentrations have been used to characterize ambient or indoor source concentrations. However, EPA now recommends against the use of these generic values, even those from peer-reviewed sources, and instead asserts that only site-specific data (e.g., sub-slab, indoor air, and ambient air sampling data) should be used. This recommendation will likely lead to improved accuracy and better understanding of site conditions, while at the same time increasing the time and cost related to characterization efforts.

Petroleum VI Guidance

The 2009 OIG report expressed concern that EPA's 2002 Draft VI Guidance did not address petroleum vapor intrusion at UST sites. The proposed Petroleum VI Guidance seeks to address that concern for UST sites and RCRA-driven activities undertaken by private UST owners and operators. In addition to the traditional chemicals found in petroleum products (such as benzene), the Petroleum VI Guidance would require consideration of vapor risks associated with gasoline additives (such as MTBE) and chemicals that develop from biodegradation of petroleum in soil and groundwater (such as methane).

As proposed, at least two parts of the Petroleum VI Guidance may, in comparison with past experience, result in increased response costs and delays for responsible parties.[7] First, the Petroleum VI Guidance rejects the notion that a single sampling event is a sufficient basis to conclude that further vapor intrusion investigation is unnecessary because "periodic monitoring and sampling over more than one annual cycle is generally needed" to address fluctuations in groundwater levels and contaminant plumes over time. Second, the Petroleum VI Guidance includes a number of recommendations that suggest EPA seeks to reduce reliance on models. Specifically, when modeling requires the use of literature values due to the unavailability of site-specific data, EPA "recommends that an uncertainty analysis be conducted to provide error bounds on predictions of the computer model," and that the results of any modeling exercise be verified with field data.

Considerations for Both Guidance Documents

In conclusion, both of these proposed guidance documents signal an increased focus on vapor intrusion within EPA. As they are amended and finalized, there is a limited opportunity to comment on them to try to encourage a final guidance that is workable and effective for remediation of sites with vapor intrusion issues. There may be ways to improve the guidance by clarifying where there is site-specific flexibility and where the guidance is overly prescriptive.

Back to Top

Notably, these guidance documents may help define the standard of care in the context of RCRA citizen suits or common law toxic tort litigation. Clarifying key assumptions in the guidance may buffer some of that impact.

Even though these guidance documents are in draft form and will likely be subject to considerable comment, EPA regions and states can be expected to consult and employ them during what may be a long interval before they are finalized. To the extent EPA or a state regulatory agency does so and an affected party disagrees with aspects of the guidance at issue, parties should be aware that the draft guidances are non-binding on their face. The documents state that they do "not impose any requirements or obligations on the [EPA], the states, or the regulated community." Accordingly, parties should be free to suggest alternative, technically sound approaches to regulators. Moreover, because these documents are solely drafts and have not been tested by external expertise that will be provided in public comment, reliance on them in their current state is arguably premature.

Given the potential long term impact on cleanup requirements, interested parties should evaluate the guidance and strongly consider submitting comments to EPA by May 24, 2013. In light of the complex technical issues involved, interested parties may also wish to request that EPA extend the comment period.

For more information please contact Karl Bourdeau at (202) 789-6019, kbourdeau@bdlaw.com, Pam Marks at (410) 230-1315, pmarks@bdlaw.com, Steve Jawetz at (202) 789-6045, sjawetz@bdlaw.com, or Geoff Goode at (202) 789-6031, ggoode@bdlaw.com.

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[1] EPA OSWER, "Final Guidance for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Sources to Indoor Air" (Apr. 11, 2013)

[2] EPA OSWER, "Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils" (Nov. 29, 2002). This draft document was never finalized.

[3] EPA OUST, "Guidance for Addressing Petroleum Vapor Intrusion at Leaking Underground Storage Tank Sites" (Apr. 9, 2013).

[4] Section 121 of CERCLA (42 U.S.C. § 9621) requires that remedial actions that result in any hazardous substances, pollutants, or contaminants remaining at the site be re-evaluated every five years to ensure that the remedy is and will continue to be protective of human health and the environment.

[5] "Assessing Protectiveness at Sites for Vapor Intrusion: Supplement to the 'Comprehensive Five-Year Review Guidance'" (Nov. 14, 2012).

[6] In a related context, EPA officials have already acknowledged that later discovery of vapor intrusion at Superfund sites may trigger parties to litigate over whether site remedies provided for in consent decrees should be revisited under the reopener provisions in those decrees. See InsideEPA, "EPA Official Says Vapor Intrusion May Drive Suits To Reopen Cleanup Pacts" (May 3, 2013), available at http://insideepa.com/201305032433234/EPA-Daily-News/Daily-News/epa-official-says-vapor-intrusion-may-drive-suits-to-reopen-cleanup-pacts/menu-id-95.html?s=mu.

[7] These issues may also be relevant in scenarios involving vapor intrusion from sources other than those covered by the Petroleum VI Guidance. However, because these points were emphasized in that guidance document, we highlight them here.

Court Upholds EPA Authority to Retroactively Veto CWA Section 404 Permits

In a closely watched case of first impression, the D.C. Circuit Court of Appeals ruled on April 23, 2013 that Clean Water Act Section 404(c) "expressly and unambiguously" authorizes the U.S. Environmental Protection Agency ("EPA") to withdraw previously-approved disposal sites specified in a Section 404 permit issued by the U. S Army Corps of Engineers, after the permit has been finalized. *Mingo Logan Coal Co. v. USEPA*, No. 12-5150 (D.C. Cir. April 23, 2013).

Accordingly, the Court reversed the district court's prior ruling that EPA had exceeded its authority in retroactively vetoing specified disposal sites for a mountaintop mining operation that had been authorized in a Corps 404 permit. The Court did not reach the merits of whether EPA's withdrawal of certain specified disposal sites was arbitrary and

Back to Top

capricious or otherwise not in accordance with law, and remanded the matter to the district court for further review of that issue.

At stake in *Mingo Logan* was the scope of EPA's authority to "veto" Section 404 wetlands permits issued by the Corps of Engineers. Under the CWA, the Corps has primary authority to issue Section 404 permits to allow dredge and fill material to be placed in waters of the U.S. 33 U.S.C. § 1311(a). However, Section 404(c) of the Act gives EPA a lead role in determining environmental impacts from proposed Section 404 activities. EPA had in past permit proceedings invoked the "veto" powers of Section 404(c) to prevent the issuance of a permit by the Corps when the Agency determined the proposed discharge would have unacceptable environmental effects. EPA had not, prior to the *Mingo Logan* Section 404 permit, used that authority to revoke portions or all of a previously approved and finalized 404 permit.

With regard to the *Mingo Logan* Section 404 permit, during the Corps Section 404 permitting process EPA had expressed concern about certain potential adverse environmental impacts from the proposed activities, but had not formally objected to or prohibited the issuance of the permit. Indeed, the administrative record for the permit indicated EPA had communicated to the Corps that the Agency had "no intention of taking our Spruce Mine concerns any further from a Section 404 standpoint." Subsequent to issuance of the 404 permit in 2007, EPA asked the Corps to use its discretionary authority under 33 C.F.R. § 325.7 to revoke or modify the permit to eliminate discharges to certain waters, asserting there was "new information and circumstances" justifying such action. After the Corps did not accede to EPA's request, EPA proceeded with a notice and comment action to withdraw certain specified disposal sites from the permit, effectively amending the 404 permit. The permit holder challenged EPA's action and prevailed in federal district court on its claim that EPA lacked authority to retroactively veto Corps-issued Section 404 permits. *Mingo Logan Coal Co. v. USEPA*, 850 F.Supp.2d 133 (D.D.C. 2012).

The Circuit Court's analysis began and ended with the statutory text of Section 404(c). In particular, the Court deemed Section 404(c) unambiguous in expressly authorizing EPA not only to "prohibit" the specification of disposal sites, e.g., by prohibiting the issuance of a Section 404 permit or the inclusion of prohibited disposal sites in the first instance, but also to "withdraw" previously approved specifications. The text of Section 404(c) ties this authority to the phrase "whenever [the EPA Administrator] determines" such action is necessary to avoid "unacceptable adverse effects" on specified types of potential environmental harm (namely, municipal water supplies, shellfish beds and fishery areas, wildlife and recreational areas). 33 U.S.C. § 1344(c). The Court characterized EPA's authority as "a broad environmental 'backstop'" and concluded that Section 404 imposed "no temporal limit" on the withdrawal authority. In the Court's view, the use of the "expansive conjunction 'whenever'" in Section 404(c) demonstrated that Congress gave EPA the ability to "prohibit/deny/restrict/withdraw a specification at any time."

The Court further rejected the permittee's arguments that EPA's veto powers could operate only pre-permit, finding such a reading contradicted by the express authorization noted above (and noting that EPA's interpretation was longstanding, having been first articulated in 1979 guidance). The Court also found that the CWA permit shield provision of Section 404(p) was not at odds with retroactive withdrawal of specified disposal sites since such action effectively amends a permit "so that discharges at the previously specified sites are no longer in '[c]ompliance with' the permit…." Also unavailing was the permittee's argument that Section 404(q), which requires the Corps and EPA to cooperate in issuing Section 404 permits, placed limits on the express "withdrawal" language in Section 404(c). The Court also rejected the argument that contrary legislative history could override the unambiguous language used in the statute. As noted, the Court remanded the matter back to the district court for review of the permittee's challenge that EPA's withdrawal was improper under the Administrative Procedures Act.

The *Mingo Logan* case is important as it is the first time a federal court has determined

Back to Top

that EPA may exercise CWA Section 404(c) "veto" authority after a valid Corps permit has been issued in final form. The remand for analysis of whether EPA's withdrawal on the specific facts of this case was proper will be important to watch, both because of the Agency's post-permit flip-flop of the position it took with the Corps during the permit process, and because the Section 404(c) authority is on its face limited to certain types of adverse environmental impacts, and the record may or may not support EPA's findings of adverse impact. Whatever the result on remand, however, this case represents a new phase of dramatic uncertainty for Section 404 permit holders who understandably rely on the authorizations in a finally issued permit to plan and conduct business operations consistent with their CWA permit.

For more information about this important CWA development, please contact Karen Hansen (khansen@bdlaw.com) or Parker Moore (pmoore@bdlaw.com).

Safe Cosmetics and Personal Care Products Act of 2013 Mirrors TSCA Proposals, Would Greatly Expand FDA Authority Over Cosmetics

Representative Janice Schakowsky (D-IL), with fifteen co-sponsors, has introduced legislation in the House of Representatives to dramatically increase Food and Drug Administration (FDA) oversight of chemicals in cosmetics and other personal care products.[1] The Safe Cosmetics and Personal Care Products Act of 2013, H.R. 1385,[2] includes a number of provisions also included in the Safe Chemicals Act of 2013, S. 696, a bill to modernize the Toxic Substances Control Act (TSCA).[3] The bill would fundamentally transform the regulation of cosmetics and their ingredients. It expands on prior proposals in a number of respects.[4] The bill, introduced March 21, 2013, has been referred to the House Committee on Energy and Commerce and to the Committee on Education and the Workforce.

The bill would add a major new subchapter to the Federal Food, Drug, and Cosmetic Act (FFDCA) chapter on cosmetics.[5] This new subchapter would impose significant new obligations on FDA and on "brand owners," the entities responsible for bringing a cosmetic to market, whether domestic or foreign establishments. Obligations would also be imposed on ingredient manufacturers and suppliers. The key provisions are as follows:

Labeling

- FDA currently requires cosmetic ingredients to be listed on a label, except that a flavor or fragrance may be listed as such, and trade secret ingredients may be listed as "other ingredients." Incidental ingredients present at insignificant levels and without technical or functional effect do not have to be listed.[6]
- The bill would require all ingredients to be listed by name. Contaminants would have to be listed if present at more than 1 part per billion (or lower in some circumstances).
- Like the Safe Chemicals Act of 2013, there would be no trade secret protection for ingredient names. There would be trade secret protection for the concentration of cosmetic ingredients used in a finished cosmetic.
- Nanomaterials would have to be identified as "nano-scale," using standard of 1% of particles having at least 1 dimension of 100 nanometers or less.
- Vendors of cosmetics sold over the Internet would have to include the ingredient list on their websites.

Safety Standard

- Currently, FDA requires manufacturers to establish the safety of each ingredient and finished cosmetic prior to marketing, and to label any cosmetic whose safety has not been established with a warning.[7] FDA itself does not routinely review cosmetics or their ingredients for safety.
- Like the Safe Chemicals Act of 2013, the bill would establish a "reasonable

Back to Top

certainty of no harm" standard. Under this standard, FDA would have to evaluate whether a cosmetic or an ingredient in a cosmetic would be reasonably certain to cause no harm to members of the general population or any vulnerable population (including pregnant women, children, salon and spa workers, and cosmetic manufacturing plant workers) by aggregate exposure to the cosmetic or ingredient, taking into account possible harmful effects from low-dose exposures (a reference to endocrine effects), additive effects from repeated exposure over time, and cumulative exposures from all sources.[8]

- The bill would require FDA to ensure that the likely exposure to all sources of the ingredient or cosmetic, including environmental sources, would result in either "not more than a 1 in a million risk for any adverse health effect in any vulnerable population at the lower 95th percentile confidence interval," or exposure in a concentration "shown to produce no adverse health effects, incorporating a margin of safety of at least 1,000 and considering the impact of cumulative exposure from all sources."

Safety Determinations

- FDA would have to review and evaluate the safety of all cosmetics and ingredients, taking into account information submitted by brand owners as well as "authoritative sources" including the Environmental Protection Agency, the International Agency for Research on Cancer, the National Toxicology Program, the California Environmental Protection Agency, and "any other authoritative international, Federal, and State entity," as determined by FDA.
- FDA would have to place an ingredient on a list of ingredients that are prohibited or restricted in light of the safety standard, or a list of ingredients that are safe without limits or restrictions (at any concentration), or a list of priority for which additional information is needed. FDA would have to place at least 300 chemicals on one of those lists within 2 years of enactment, and at least 100 per year thereafter. Where needed, FDA would have to specify restrictions on concentration or use necessary for an ingredient to satisfy the safety standard. Manufacturers would have to comply with prohibitions or restrictions within 1 year of listing. Cosmetics containing ingredients on the prohibited list would be considered adulterated.
- For an ingredient on the list of priority chemicals, within 2 years of listing, FDA would have to determine whether the ingredient qualifies for either of the other two lists. If there were to be insufficient information, FDA would have to prescribe minimum data requirements. Brand owners would have to either supply the information or eliminate the ingredient within 18 months of the insufficient information determination. If FDA were to fail to classify a priority chemical as either meeting the safety standard or not meeting the safety standard within 5 years of listing as a priority chemical, the ingredient could not be used in cosmetics.
- FDA would have to annually publish a list of "contaminants of concern" linked to severe acute reactions or long-term adverse health effects.
- Any person could petition FDA for prioritization, listing or delisting of ingredients, or listing of contaminants of concern. FDA would have to respond within 6 months of any "reasonable" petition, as determined by FDA rules.

Reporting

- A brand owner would have to submit to FDA "all data and information that the brand owner can access" regarding the safety of the cosmetic and of its ingredients. The required information would span a wide range of chemical identity, hazard, risk, and use information. The information would have to be updated annually or within 60 days of receiving information on adverse effects suspected to be caused by an ingredient or a cosmetic.
- If a brand owner were to request that a supplier or manufacturer of an ingredient

Back to Top

provide any of the information required to be submitted to FDA, the supplier or manufacturer would have to provide it to the brand owner within 90 days of the request.

- A provision would be added for mandatory reporting by brand owners of any serious adverse event associated with the use of a brand owner's cosmetic, similar to FDA's current reporting requirements for drugs and medical devices.
- FDA would have to maintain a database of all non-confidential information received under the above requirements.
- Brand owners would have to submit to FDA a cosmetic and ingredient statement providing product use and ingredient information and any warnings and directions for use from the cosmetic label or insert. Failure to submit this statement would render all cosmetics sold by the brand owner misbranded.
- As under the Safe Chemicals Act of 2013, chemical identity could not be claimed confidential business information.

Testing

- FDA would be authorized to require any brand owner to conduct testing to demonstrate that a cosmetic meets the safety standard.
- Suppliers could also be required to conduct testing regarding listed "contaminants of concern."
- FDA would have to require alternative testing methods where practicable and would have to encourage other means to minimize the use of animal testing of ingredients and cosmetics. FDA would have to publish a list of the alternative testing methods every three years.

Establishment Registration and Cosmetic Listing

- FDA currently encourages voluntary registration of cosmetic manufacturing establishments and filing of finished cosmetic ingredient composition statements.[9]
- The bill would require annual registration of domestic and foreign establishments manufacturing cosmetics for the U.S. market, along with annual fees. Microbusinesses (those with annual sales from cosmetics of less than $2 million) would be exempt from this requirement. Registration information would include the gross receipts or sales by the establishment from cosmetics, but would not be subject to the Freedom of Information Act. FDA would have to maintain a list of registered establishments.
- Each brand owner would be required to report annually to FDA information about each cosmetic that it markets, including a list of ingredients.

Other Requirements

- New enforcement provisions would be added regarding random annual product sample audits, notification of adulterated or misbranded cosmetics, and orders to recall or cease distribution. FDA could require information about, and from, the supply chain.
- FDA would have to issue guidance prescribing good manufacturing practices for cosmetics and ingredients.[10]
- An Interagency Council on Cosmetic Safety would be established among FDA, the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, the Occupational Safety and Health Administration, and EPA.
- There would be no preemption of differing state or local regulations.[11]
- The bill would also require OSHA to promulgate an occupational safety and health standard regarding material safety data sheets for cosmetics.

Back to Top

Representative Schakowsky has introduced similar bills twice before,[12] and neither got out of committee, even when the Democrats controlled the House of Representatives. In 2012, with a Republican majority in the House, more moderate cosmetic bills were introduced, but none of them got out of committee either.[13] Thus, this bill is unlikely to be enacted. However, it does highlight the continued concerns of some legislators regarding chemicals in products and the sufficiency of information available to regulators and the public regarding such chemicals. It also illustrates the embrace by such legislators of ambitious requirements for regulatory programs as a means of dealing with large numbers of chemicals in commerce.

For more information regarding the Safe Cosmetics and Personal Care Products Act and its relation to other chemicals management legislation and policies, please contact Mark Duvall, mduvall@bdlaw.com, 202-789-6090, or Alexandra Wyatt, awyatt@bdlaw.com, 202-789-6086.

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[1] Press Release, Reps. Schakowsky, Markey Statement on Introducing the Safe Cosmetics and Personal Care Products Act (Mar. 21, 2013), http://schakowsky.house.gov/index.php?option=com_content&view=article&id=3289.

[2] H.R. 1385, available at http://www.gpo.gov/fdsys/pkg/BILLS-113hr1385ih/pdf/BILLS-113hr1385ih.pdf.

[3] *See* Beveridge & Diamond, P.C., Safe Chemicals Act, First TSCA Reform Bill of 113th Congress, Reintroduced (Apr. 16, 2013), available at http://www.environmentallawportal.com/Safe-Chemicals-Act-First-TSCA-Reform-Bill-of-113th-Congress-Reintroduced.

The bill also includes provisions similar to those in the Toxic Chemicals Safety Act of 2010, H.R. 5820, http://www.gpo.gov/fdsys/pkg/BILLS-111hr5820ih/pdf/BILLS-111hr5820ih.pdf, the House TSCA modernization bill which Representative Schakowsky co-sponsored.

[4] See Beveridge & Diamond, P.C., Will FDA Get New Authority to Regulate Cosmetics? (July 5, 2012), http://www.bdlaw.com/news-1386.html; Beveridge & Diamond, P.C., Cosmetics Safety Bill Would Incorporate TSCA Bill Provisions (Aug. 2, 2010), http://www.bdlaw.com/news-935.html.

[5] The bill would not alter the FFDCA's definition of the term "cosmetic" as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap." 21 U.S.C. § 321(i). The bill would add a new, broad definition of "ingredient."

[6] 21 C.F.R. Part 701.

[7] 21 C.F.R. § 740.10.

[8] This standard would go beyond the somewhat similar standards in FDA's color additive and food additive regulations, 21 C.F.R. §§ 70.3(i), 170.3(i).

[9] 21 C.F.R. Parts 710, 720.

[10] FDA already has such guidance. See FDA, Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist (1997, updated 2008), http://www.fda.gov/Cosmetics/ GuidanceComplianceRegulatoryInformation/GoodManufacturingPracticeGMPGuidelinesInspectionChecklist/default.htm.

[11] See Beveridge & Diamond, P.C., States Propose to Regulate Chemicals While Congress Debates TSCA (Feb. 25, 2013), http://www.bdlaw.com/news-1446.html (noting various state proposals to regulate chemicals in cosmetics).

[12] See "Safe Chemicals Act of 2010," H.R. 5786, http://www.gpo.gov/fdsys/pkg/BILLS-111hr5786ih/pdf/BILLS-111hr5786ih.pdf, and "Safe Chemicals Act of 2011," H.R. 2359, http://www.gpo.gov/fdsys/pkg/BILLS-112hr2359ih/pdf/BILLS-112hr2359ih.pdf.

[13] See Beveridge & Diamond, P.C., Will FDA Get New Authority to Regulate Cosmetics? (July 5, 2012), http://www.bdlaw.com/news-1386.html.

Firm News

Beveridge & Diamond Named to National Law Journal's "Midsize Hot List" for Third Consecutive Year

The National Law Journal has again included Beveridge & Diamond on its "Midsize Hot List." The list recognizes 20 law firms of between 50 and 200 lawyers who stand out from their peers and from larger firms with unique business strategies and practice success. 2013 marks the third consecutive year that Beveridge & Diamond has been so honored.

Back to Top

As noted in the introduction to the report, “As clients demand better value for their legal spend and potential laterals more satisfaction from their careers, these firms know they’re in a good spot...The firms we’ve selected for our Midsize Hot List are led by forward-thinking attorneys who are guiding their organizations in new practice directions, amassing more business in mainstay practices and spreading into new regions.”

“We are honored and gratified to again appear on the Midsize Hot List,” said Benjamin F. Wilson, Beveridge & Diamond’s Managing Principal. “Our clients make such recognition possible through their daily collaborations with lawyers across our national office network. We strive to innovate in the delivery of our services and to continually provide our clients with outstanding results and value.”

Among the examples cited in the National Law Journal’s coverage of the firm were:

- the recent arrival of former EPA General Counsel Scott Fulton
- the recent arrival of former Assistant U.S. Attorney Peter Anderson
- litigation victories in California, Pennsylvania, and Kansas

Other recent firm accomplishments include:

- Receiving a 2013 AT&T Legal Department Diversity Award
- Receiving an Excellent Supplier Award from SunCoke Energy

Read the article here (subscription to NLJ is required).

Chambers USA 2013 Ranks Beveridge & Diamond, P.C. Among Leading Law Firms

The Chambers USA Guide to the Legal Profession has again ranked Beveridge & Diamond, P.C. as a leading environmental law practice, both nationally and regionally. In addition to firm-level rankings, individual lawyers from the Firm’s regional offices are ranked.

Chambers ranked the Firm as a leading environmental practice nationwide and in the District of Columbia, Massachusetts, and Texas. Quotes from reviews of the Firm include:

“An extremely talented group of passionate environmental specialists.”

“They have an enormous practice and every one of them is knowledgeable.”

“Excellent lawyers doing excellent work.”

Individual Beveridge & Diamond lawyers recognized include:

- Karl S. Bourdeau in Environment, District of Columbia
- David M. Friedland in Environment, District of Columbia
- Jeanine L.G. Grachuk in Environment, Massachusetts
- Stephen L. Gordon in Environment, New York
- Paul E. Hagen in Environment, District of Columbia
- John N. Hanson in Environment, District of Columbia
- Bryan J. Moore in Environment, Texas
- Stephen M. Richmond in Environment, Massachusetts
- Nicholas W. van Aelstyn in Environment, California

View Beveridge & Diamond’s Chambers USA 2013 listing.

Since 1990, Chambers and Partners has published the leading guides to the legal profession, identifying and ranking the world’s best lawyers and law firms based on in-depth, objective research. Each guide offers in-depth analysis of the legal market within a specific region (the UK, Europe, Asia, USA, Latin America).

For more information, please contact Janine Militano at jmilitano@bdlaw.com.

Back to Top

Legal 500 US Ranks Beveridge & Diamond, P.C. Among Leaders in Environmental Litigation, Transactional, and Regulatory Matters

The Legal 500 United States has again ranked Beveridge & Diamond, P.C. as a leading national environmental law practice, noting the Firm's Environmental litigation capabilities as well as its transactional and regulatory capabilities.

In addition, Legal 500 recommended three Beveridge & Diamond lawyers:

- Harold L. Segall
- Karl S. Bourdeau
- Paul E. Hagen

The Legal 500 United States provides in-depth, comprehensive analysis of law firms across the U.S.

For more information, please contact Janine Militano at jmilitano@bdlaw.com.

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