Texas Environmental Update

BEVERIDGE & DIAMOND PC

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Texas Developments

TCEQ Commissioners Approve Dallas-Fort Worth State Implementation Plan Revision

On November 5, 2008, the TCEQ Commissioners approved the adoption of a Dallas-Fort Worth ("DFW") Contingency Plan State Implementation Plan ("SIP") revision. The revision identifies emission control measures to be used to achieve the three percent contingency reduction that EPA would require if the DFW area does not meet the 1997 eight-hour ozone National Ambient Air Quality Standard ("NAAQS") by the June 10, 2010 attainment deadline. (*full article*)

TCEQ Holds HGB Eight-Hour Ozone SIP Stakeholder Group Meeting

On November 3, 2008, TCEQ held a meeting of the Houston-Galveston-Brazoria (HGB) Eight-Hour Ozone State Implementation Plan (SIP) Stakeholder Group. The meeting included updates on the development status of the HGB 1997 Eight-Hour Ozone Nonattainment Area Attainment Demonstration SIP revision and a report from the Houston-Galveston Area Council of Governments (H-GAC) regarding the local meetings held to discuss potential mobile source control strategies. *(full article)*

Meeting of TRRP-15 Work Group

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TCEQ has made available for public comment the draft October 2008 Update to the State of Texas Water Quality Management Plan (WQMP). After completion of the public participation process, certification by TCEQ on behalf of the Governor of Texas and EPA approval, the draft October 2008 Update will become part of the WQMP. *(full article)*

Upcoming TCEQ Meetings

TCEQ will be holding certain stakeholder and advisory group meetings in December. *(full article)*

Texas Rules Update

See, TCEQ website at http://www.tceq.state.tx.us/rules/whatsnew.html for information on new rule developments. *(full article)*

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Renewable Fuel Standard Update: EPA Announces 2009 RFS Targets

The U.S. Environmental Protection Agency (EPA) announced on November 14, 2008 that the federal Renewable Fuel Standard (RFS) for sales or blending of renewable fuels for 2009 will be 10.21 percent. *(full article)*

EPA Threatens Enforcement against Manufacturers of Carbon Nanotubes and Enacts Significant New Use Rules for Two Other Nanoparticles

The Environmental Protection Agency (EPA) recently published two Federal Register notices concerning the regulation of nanomaterials under the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-2692. *(full article)*

Criminal Prosecution for Failure to Develop and Implement Clean Air Act Risk Management Program Results in $100,000 Fine

In one of the first criminal enforcement cases under the Clean Air Act's Risk Management Program ("RMP"), the Hershey Creamery Company ("Hershey") recently pleaded guilty to a felony for its storage and use of anhydrous ammonia as part of the refrigeration operations at two facilities. *(full article)*

U.S. Supreme Court Vacates Injunction Against Navy's Use of Sonar

The United States Supreme Court once again has reiterated that courts may not issue broad injunctions based on the unsubstantiated possibility of environmental harm. The Court vacated two contested aspects of a preliminary injunction against the United States Navy that restricted sonar use during training exercises because plaintiffs failed to demonstrate the "likelihood" of irreparable injury to the environment without the injunction. *(full article)*

EPA Proposes New Data Requirements for Antimicrobial Pesticide Products

On October 8, 2008, the U.S. Environmental Protection Agency (EPA) proposed revisions to its data requirements for antimicrobial pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), in conjunction with its wider effort to update and streamline its data requirements for all pesticides. *(full article)*

Firm News & Events

Mark Duvall Joins Environmental Practice Group of Beveridge & Diamond, P.C.

Washington, D.C. -- Beveridge & Diamond, P.C. is pleased to announce that Mark N. Duvall has joined the Firm as a Principal and member of its Environmental Practice Group. Mr. Duvall joins the Firm from the legal department of The Dow Chemical Company, where he served as lead environmental counsel for the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA), and their foreign counterparts.

To access this article, go to http://www.bdlaw.com/news-410.html

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The three contingency control measures referenced in the Contingency Plan SIP revision are in TCEQ's volatile organic compound ("VOC") rules. These rules apply to offset lithographic printing; degassing or cleaning of stationary, marine, and transport vessels; and petroleum dry cleaning. Compliance with these regulatory measures would be required as soon as practicable, but no later than one year, after publication in the Texas Register of TCEQ's determination that implementation of the measures is necessary based upon failure to attain the 1997 eight-hour ozone NAAQS by the June 10, 2010 attainment deadline. The Contingency Plan SIP Revision also identifies 2009-2010 on-road mobile fleet turnover as the non-regulatory measure that will provide the remaining reductions needed to meet EPA's requirement for a three percent contingency reduction.

Information about this SIP revision is available on TCEQ's website at http://www.tceq.state.tx.us/implementation/air/sip/Hottop.html.

TCEQ Holds HGB Eight-Hour Ozone SIP Stakeholder Group Meeting

On November 3, 2008, TCEQ held a meeting of the Houston-Galveston-Brazoria (HGB) Eight-Hour Ozone State Implementation Plan (SIP) Stakeholder Group. The meeting included updates on the development status of the HGB 1997 Eight-Hour Ozone Nonattainment Area Attainment Demonstration SIP revision and a report from the Houston-Galveston Area Council of Governments (H-GAC) regarding the local meetings held to discuss potential mobile source control strategies.

The current TCEQ SIP submission timeline for the HGB Eight-Hour Ozone Attainment Demonstration anticipates that SIP narrative and rule proposal development and review will take place from April through August of 2009 with TCEQ Commissioner consideration in late September or early October of 2009 and submittal to EPA in April of 2010. Ongoing TCEQ rule projects include the Volatile Organic Compound (VOC) Control Techniques Update (Groups II, III and IV), which would address the Federal Clean Air Act requirement for states to revise their ozone SIP to include reasonably available control technology (RACT) and for which a stakeholder process is anticipated in early December of this year. TCEQ staff is continuing to evaluate possible control strategy measures including potential NOx control strategies. The agency is no longer evaluating chlorine emission strategies based upon its determination that such measures would not advance attainment. Although TCEQ has determined that VOC control strategies outside the HGB nonattainment area would not advance attainment, TCEQ staff indicated that this determination could be changed if new information indicates to the contrary.

Additional information including copies of the presentations made by TCEQ and H-GAC staff are available at TCEQ's website at http://www.tceq.state.tx.us/implementation/air/sip/hgb_stakeholder.html.

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Meeting of TRRP-15 Work Group

A work group of the TCEQ Texas Risk Reduction Program (TRRP) Steering Committee met on November 12, 2008 to work on development of the TRRP-15 guidance regarding "Determining Representative Concentrations." It was the first meeting of the work group, which the agency staff conceived at the April 8, 2008 Steering Committee meeting. The purpose of the work group is to provide stakeholder input to the agency on its development of the TRRP-15 guidance. The guidance focuses on response action determinations under section 350.79 of rules ("Comparison of Chemical of Concern Concentrations to Protective Concentration Levels"). The staff is developing the guidance as two separate documents - guidance for human health purposes (TRRP-15 H) and guidance for ecological receptors (TRRP-15 E).

The Remediation Division developed the work group in response to a directive from the TCEQ Commissioners to expand the Division's public outreach in the development of its TRRP guidance. The broader TRRP Steering Committee was formed in December 1999 following the introduction of the TRRP program. The guidance resulting from the work group process will be submitted to the broader Steering Committee for its consideration. The Remediation Division has worked with the Steering Committee in the development of numerous TRRP guidance documents. The guidance documents that the TCEQ has approved are available at http://www.tceq.state.tx.us/remediation/trrp/guidance.html.

TCEQ Publishes Draft October 2008 Update to Water Quality Management Plan

TCEQ has made available for public comment the draft October 2008 Update to the State of Texas Water Quality Management Plan (WQMP). After completion of the public participation process, certification by TCEQ on behalf of the Governor of Texas and EPA approval, the draft October 2008 Update will become part of the WQMP. The draft October 2008 Update addresses projected effluent limits updates for water quality planning purposes and service area population and designation of management agencies for municipal wastewater facilities.

TCEQ will be accepting written comments on the draft October 2008 Update until December 8, 2008. For additional information, please see TCEQ's website at http://www.tceq.state.tx.us/permitting/water_quality/wq_assessment/assessment/WQmanagement_comment.html.

Upcoming TCEQ Meetings

TCEQ will be holding certain stakeholder and advisory group meetings in December. These meetings include the following:

- TERP Grant Application Workshops that will be held throughout the state beginning December 2, 2008. For further information, please see TCEQ's website at http://www.tceq.state.tx.us/implementation/air/terp/terp_mtgs.html.
- UST Management and Compliance Assistance Seminar to be held December 9, 2008 in Round Rock, Texas. Please see TCEQ's website at http://www.tceq.state.tx.us/assistance/events/ust-seminar.html for additional details.
- Control Techniques Guidelines (CTG) Stakeholder Group meeting to be held December 9, 2008 in Austin, Texas. For additional information, please see TCEQ's website at http://www.tceq.state.tx.us/implementation/air/rules/ctg/control_techniques_stakeholder.html.

Texas Rules Update

See, TCEQ website at http://www.tceq.state.tx.us/rules/whatsnew.html for information on new rule developments.

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National Developments

CPSC Requests Comments on Phthalates Ban

On November 13, 2008, the Consumer Products Safety Commission (CPSC) published a request for comments on Section 108 of the Consumer Products Safety Improvement Act (CPSIA), Prohibition on Sale of Certain Products Containing Specified Phthalates. The phthalate ban is one aspect of the CPSIA, a law passed in August 2008 that significantly expands the authority of the CPSC, imposes new consumer product safety requirements for a wide range of consumer products, including limits on lead and lead paint in children's products, and increases funding for the CPSC.

Beginning February 10, 2009, Section 108 of the CPSIA prohibits persons from manufacturing for sale, offering for sale, distributing in commerce, or importing into the United States "children's toys" and "child care articles" containing more than 0.1% of benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), or di-(2-ethylhexyl) phthalate (DEHP). Also beginning February 10, 2009, Section 108 prohibits, on an interim basis, persons from manufacturing for sale, offering for sale, distributing in commerce, or importing into the United States "children's toys that can be placed in a child's mouth" and "child care articles" containing more than 0.1% of diisodecyl phthalate (DIDP), diisononyl phthalate (DINP), or di-n-octyl phthalate (DnOP). The CPSC will appoint a Chronic Hazard Advisory Panel (CHAP) "not before" February 10, 2009, and it will, after considering the effects of exposure to multiple phthalates, recommend to the CPSC whether to continue the interim ban and whether additional bans on phthalates or phthalate alternatives are needed.

On November 17, the CPSC released a General Counsel memorandum concluding that the phthalate bans adopted under the CPSIA apply only to products manufactured after the effective date of February 10, 2009.

The CPSC has expressed interest in receiving comments on several specific topics, including:

- Polyvinyl chloride (PVC) use in children's products;
- The use of non-PVC plastics in children's products;
- The use of phthalates and phthalate alternatives in children's products;
- Measurement of phthalates in children's products;
- Toxicity of phthalates and phthalate alternatives (new or unpublished data); and
- Exposure to phthalates and phthalate alternatives (new or unpublished data).

The CPSC's request for comments is available here. Comments are due no later than January 12, 2009.

For more information about the phthalate ban or these other aspects of the CPSIA, please contact Paul Hagen, phagen@bdlaw.com; Angie Colamaria, acolamaria@bdlaw.com; or Bart Kempf, bkempf@bdlaw.com.

Renewable Fuel Standard Update: EPA Announces 2009 RFS Targets

The U.S. Environmental Protection Agency (EPA) announced on November 14, 2008 that the federal Renewable Fuel Standard (RFS) for sales or blending of renewable fuels for 2009 will be 10.21 percent. For a printable PDF of this article, click here.

2009 Targets Established

EPA is required by the Energy Independence and Security Act of 2007 (EISA) to establish mandatory levels of biofuels (such as ethanol) and biodiesel in the Nation's fuel supply as part of an overall national policy to promote renewable fuel sources, reductions in

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greenhouse gas (GHG) emissions and energy independence (see Beveridge & Diamond, P.C. "Renewable Fuel Program Standard Update," available online at: http://www.bdlaw.com/news-news-270.html). EPA's November 14 announcement comes in advance of more comprehensive implementing changes to the RFS program required by EISA (known as "RFS2") currently under development by EPA. The November 14 notice provides some new information about the anticipated RFS2 rules and briefly discusses certain self-implementing EISA requirements for 2009 - including EISA's 20% GHG lifecycle reduction requirement - that are not addressed by EPA's existing RFS regulations.

Companies with questions about their obligations under the RFS and the impact of the 2009 standard, or seeking more information about EPA's forthcoming Notice of Proposed Rulemaking (NPR) and the continuing controversy over the Agency's implementation of the EISA changes, are invited to contact David M. ("Max") Williamson at (202) 789-6084 (dwilliamson@bdlaw.com) or Alan J. Sachs at (410) 230-1345 (asachs@bdlaw.com).

The RFS Program

Under the RFS program, EPA must set annual benchmarks representing the amount of renewable fuel that must be used by each gasoline refiner, blender (other than oxygenate blenders), or importer (called "obligated parties"). The RFS program includes registration, recordkeeping and reporting requirements for all renewable fuel producers and obligated parties, and established a trading market in renewable fuel credits, known as Renewable Identification Numbers (RINs). For more information about the RFS program, please see Beveridge & Diamond, P.C. update dated February 4, 2008, "Renewable Fuel Standard Program Update," available online at http://www.bdlaw.com/news-news-270.html.

EPA calculates the annual RFS by dividing the volume of renewable fuel required by EISA to be blended into gasoline for the relevant year by the volume of gasoline projected to be consumed in that year according to the Energy Information Administration (EIA). According to EPA's notice, which will be published in the Federal Register later this month, the 2009 standard is intended to result in the use of 11.1 billion gallons of renewable fuel.

Implementation of RFS2

Because EPA has not yet promulgated implementing rules for the RFS2 program, for the 2009 compliance period, obligated parties will continue to be subject to EPA's existing RFS regulations. However, EPA's November 14 notice describes several changes to the program that will require attention during the 2009 compliance period.

2009 Biomass-based Diesel Standard

EISA specifically requires use of 0.5 billion gallons of biomass-based diesel in 2009. To address this requirement, EPA states that it will not establish a target for 2009 but will increase the 2010 biomass-based diesel requirement by 0.5 billion gallons while allowing 2009 biodiesel and renewable diesel RINs to be used to meet this combined 2009/2010 requirement.

Although obligated parties will not need to demonstrate compliance with the combined biomass-based diesel standard until the end of the 2010 compliance period, EPA emphasizes that it would "behoove [obligated parties] to acquire the necessary RINs representing biodiesel and renewable diesel in 2009 in preparation for their 2010 compliance demonstration." EPA also warns that obligated parties delaying their efforts to acquire these RINs until 2010 "could find that they would be unable to acquire a sufficient number for compliance purposes."

2009 Greenhouse Gas Lifecycle Reduction Requirement

EISA mandates for calendar year 2009 that any renewable fuel produced from facilities that commence construction after December 2007 achieve at least a 20 percent reduction in lifecycle GHG emissions compared to baseline lifecycle GHG emissions. However, for 2008 and 2009, EISA also provides that any ethanol plant that is fired with natural gas, biomass,

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or any combination thereof, will automatically be deemed to be in compliance with the 20 percent lifecycle GHG reduction requirement.

While noting EISA's ambiguity regarding application of the GHG reduction requirement in 2009 prior to issuance of the RFS2 regulations, EPA's November 14 notices states that the agency will not interpret these provisions at this time because it believes there will in fact be no fuel sold in 2009 from a facility constructed after December 2007 that is not fired with natural gas, biomass, or a combination thereof (in other words, all renewable fuel sold in 2009 will be deemed in compliance with the GHG reduction requirement pursuant to EISA). EPA states that it will interpret application of the provisions in 2009 only if it "learns of such a fuel being sold."

For more information, please contact Alan J. Sachs at (410) 230-1345 (asachs@bdlaw.com) or David M. ("Max") Williamson at (202) 789-6084 (dwilliamson@bdlaw.com).

EPA Threatens Enforcement against Manufacturers of Carbon Nanotubes and Enacts Significant New Use Rules for Two Other Nanoparticles

The Environmental Protection Agency (EPA) recently published two Federal Register notices concerning the regulation of nanomaterials under the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601-2692. In the first notice, EPA clarified the TSCA Inventory status of carbon nanotubes (CNTs), explaining to manufacturers and importers that many CNTs may be "new" chemicals under TSCA subject to the premanufacture notice (PMN) requirements. This first notice warns that the agency may soon begin to initiate enforcement actions against persons in violation of the PMN provisions. In the second notice, EPA enacted significant new use rules (SNURs) for two different siloxane-modified nanoparticles, representing the agency's first nanotechnology-specific regulations and potentially signaling more aggressive regulation of nanomaterials in the future.

Inventory Status of Carbon Nanotubes

On October 31, 2008, EPA published a Federal Register notice (73 Fed. Reg. 64946) clarifying the TSCA Inventory status of CNTs. According to EPA, CNTs that are subject to TSCA jurisdiction may be "new" chemicals, with "molecular identities" that are distinct from graphite or other allotropes of carbon already listed on the TSCA Inventory. EPA reports that it has made several public statements and responses to written inquiries to establish this position, which clarifies earlier guidance from the agency that may have created some confusion among industry members about the Inventory status of CNTs. Anecdotal evidence suggests that some manufacturers or importers were relying on the Inventory listing for graphite instead of filing PMNs for their CNTs.

CNTs that are "new" chemicals would be subject to TSCA section 5(a)(1)(A) just as new non-nanoscale chemical substances would be. Section 5(a)(1) requires a company manufacturing or importing a new chemical to file with the EPA a PMN at least 90 days prior to manufacture, including importation, of the chemical for non-exempt commercial purposes. Alternatively, manufacturers or importers of CNTs may qualify under the provisions of 40 C.F.R. parts 720 or 723 for an exemption from the PMN requirements, but many of these exemptions require applications. EPA reports that it has already received several PMNs for CNTs that are new chemical substances. This latest Federal Register notice will likely increase the number of PMNs and exemption applications that it receives in the near future for CNTs.

The agency also reminds manufacturers and importers that when evaluating the TSCA Inventory status of a particular CNT, the manufacturer or importer may submit a bona fide intent to manufacture or import under 40 C.F.R. § 720.25 to determine whether a specific CNT is already on the TSCA Inventory. In addition, the agency's guidance document, entitled "TSCA Inventory Status of Nanoscale Substances – General Approach" (notice of availability at 73 Fed. Reg. 4861 (Jan. 28, 2008)), provides general guidelines to assist with this evaluation. The guidance document explains some of the basic considerations

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when assessing whether a particular CNT, or other nanoscale chemical substance, may be a new chemical potentially subject to the PMN requirements. Many CNT manufacturers or importers are likely to find the guidance of marginal benefit and will need to engage the agency directly.

According to EPA's Federal Register notice, chemical manufacturers – including those entities that import CNTs for commercial purposes – should do the following: (1) determine whether the CNTs they manufacture are outside of TSCA's jurisdiction, which is the case for chemical substances used in pesticides, foods, drugs, and cosmetics; (2) determine whether their CNTs are presently on the TSCA Inventory; (3) determine whether any PMN exemptions apply; and (4) prepare and submit PMNs for their CNTs if they are not on the TSCA Inventory and not exempt.

EPA also issued a strong warning against continued noncompliance with the PMN requirements based on its current interpretation of the TSCA Inventory status of CNTs. The notice states that "some time after March 1, 2009" the agency will begin to focus its efforts on determining whether CNT manufacturers or importers are complying with the TSCA PMN provisions. Companies that may be currently importing or manufacturing CNTs in the United States, or intend do so in the future, should carefully evaluate their compliance status. The notice may remove any defense against liability that a company may have based on a lack of sufficient notice of the agency's interpretation. Companies that may have potential violations of these or other TSCA requirements should carefully consider whether to voluntarily disclose their compliance status to EPA under the agency's "Audit Policy" (Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations, 65 Fed. Reg. 19616 (Apr. 11, 2000)). Under the Audit Policy, a company may receive up to 100% mitigation of the gravity-based component of a penalty. However, the Audit Policy does not relieve a company from paying penalties for the "economic benefit" of its noncompliance, nor does it prevent a company from experiencing potential supply chain disruptions while it completes the PMN process.

SNURs for Siloxane-Modified Nanoparticles

On November 5, 2008, EPA published a Federal Register notice promulgating direct final Significant New Use Rules (SNURs) under TSCA section 5(a)(1)(B) for certain siloxane-modified silica and alumina nanoparticles (73 Fed. Reg. 65743). These are the first SNURs known to have been issued on nanomaterials.

These substances were the subject of PMNs filed by an undisclosed company or companies in October 2005, P-05-673 and -687, for "additive, open, non-dispersive use", as indicated at 70 Fed. Reg. 46513 (Aug. 10, 2005). Following submission of notices of commencement of manufacture or import (NOCs), P-05-673 was added to the Inventory in May 2006, and -687 was added the following month. The agency provides no explanation for why it waited over two years after receiving NOCs before promulgating the SNURs.

Industry members have filed comments with EPA in the past, analyzing the flexibility that SNURs provide the agency to regulate nanomaterials that are not subject to the PMN requirements because there are non-nanoscale versions that are currently listed on the TSCA Inventory. With the increasing number of such materials entering the market, these first SNURs may indicate that the agency is contemplating greater use of SNURs to supplement the agency's current voluntary program for such nanomaterials (i.e., the Nanoscale Materials Stewardship Program). These first SNURs therefore may represent a test case before placing greater reliance on SNURs to regulate individual nanomaterials or entire categories of nanomaterials.

These first SNURs designate certain "uses" of the siloxane-modified nanoparticles to be "significant new uses" and require persons to notify EPA at least 90 days prior to manufacturing, importing or processing the nanoparticles for any of these uses. EPA designated the following uses as significant new uses: (1) use without impervious gloves or a NIOSH-approved respirator with an APF of at least 10; (2) the manufacture, process, or use of the nanoparticles as a powder; (3) or uses of the nanoparticles that are "different" than the uses described in the PMNs that the original manufacturers or importers submitted for them.

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If an entity wishes to use either of these nanoparticles for a significant new use, it must submit a 90-day notice, which is known as a Significant New Use Notice (SNUN) (and which is the same form as the PMN form). EPA will evaluate available data to determine whether the new use should be subject to risk management measures (e.g., personal protective equipment, occupational exposure limits, testing). EPA encourages, but does not require, persons submitting SNUNs for these nanoparticles to provide the results of a 90-day inhalation toxicity test (OPPTS 870.3465 test guideline) to help the agency evaluate the potential human health effects associated with them.

The two nanoparticles are listed on the confidential TSCA Inventory, so EPA has described them generically in the notice as "siloxane modified alumina nanoparticles" and "siloxane modified silica nanoparticles." To determine whether a particular siloxane-modified alumina or silica nanoparticle is subject to this SNUR, or to determine whether a use is "different" than those included on the PMNs, the manufacturer, importer or processor must demonstrate a "bona fide intent to manufacture, import or process" by providing EPA with specific information about the nanoparticle and its intended use. EPA previously reported that a particular entity filed PMNs for "siloxanes coated alumina nanoparticles" and "siloxane coated silica nanoparticles" in 2007 (72 Fed. Reg. 47026 (Aug. 22, 2007)).

As a direct final rule, the SNURs will take effect on January 5, 2009, if EPA does not receive adverse public comments on the SNURs, or a notice of intent to file such comments, by December 5, 2008.

For a printable PDF of this article, please click here.

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For more information, please contact Cindi Lewis at (202) 789-6018 (clewis@bdlaw.com); Mark Duvall at (202) 789-6090 (mduvall@bdlaw.com); Ryan Tacorda at (415) 262-4009 (rtacorda@bdlaw.com); or Phil Moffat at (202) 789-6027 (pmoffat@bdlaw.com).

Key documents are available below.

- TSCA Inventory Status of Carbon Nanotubes: http://www.epa.gov/EPA-TOX/2008/October/Day-31/t26026.htm
- TSCA Inventory Status of Nanoscale Substances--General Approach: http://www.epa.gov/oppt/nano/nmsp-inventorypaper.pdf
- EPA's Audit Policy: http://www.epa.gov/oecaerth/incentives/auditing/auditpolicy.html
- SNURs for siloxane-modified nanoparticles: http://edocket.access.gpo.gov/2008/pdf/E8-26409.pdf

Criminal Prosecution for Failure to Develop and Implement Clean Air Act Risk Management Program Results in $100,000 Fine

In one of the first criminal enforcement cases under the Clean Air Act's Risk Management Program ("RMP"), the Hershey Creamery Company ("Hershey") recently pleaded guilty to a felony for its storage and use of anhydrous ammonia as part of the refrigeration operations at two facilities. Notably, this case did not arise out of an accident or release, but instead involved only "paperwork" violations involving a commonly-used refrigerant. This case may signal two important trends: the use of OSHA inspections as a mechanism for identifying violators of environmental laws; and an increased focus on RMP enforcement. By prosecuting Hershey, the government appears to be sending a message that RMP requirements apply broadly and have teeth.

Legal Context of Hershey Case

RMP requirements originated in the 1990 Amendments to the Clean Air Act and were designed to minimize risks associated with accidental releases of certain regulated toxic substances. 42 U.S.C. § 7412(r)(7). Facilities that exceed a threshold quantity of certain

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regulated substances must develop and implement an RMP that addresses a variety of topics, including worker notification, procedures for handling an accidental release and coordination with local emergency agencies, assessments of risks to neighboring communities, and periodic audits. RMP requirements are typically included in a facility's Title V operating permit, which requires an annual certification of compliance with all permit terms.

The RMP program was modeled in large part on the Process Safety Management ("PSM") regulations, which were promulgated by the Occupational Safety and Health Administration ("OSHA") to address workplace safety issues. The PSM standard sets forth requirements for managing the use, storage, manufacturing, handling, and on-site movement of highly hazardous chemicals; compliance is enforced through regular audits. 29 C.F.R. § 1910.119.

Factual Background

Hershey, a family-owned Pennsylvania ice cream manufacturer and distributor, had a long and interwoven history of RMP and PSM compliance issues. The chronology of facts set forth in the government's criminal information is somewhat confusing, but it appears that in 2004, OSHA conducted an inspection of Hershey's facilities in connection with workplace safety issues and concluded that the company failed to comply with PSM requirements. This inspection resulted in a $100,000 civil penalty. Less than one year later, in 2005, EPA conducted an RMP inspection at one of Hershey's facilities, presumably for similar issues. The inspection allegedly revealed that Hershey twice certified compliance with RMP requirements in its annual Title V compliance certification, despite the fact that at least two consultants had advised the company that the RMP program was entirely deficient. In addition, Hershey was allegedly unresponsive to two follow-up written information requests from EPA.

In 2006, OSHA inspected the facility again, and assessed another citation for PSM violations and a $2,045 fine. Merely five months later, EPA then issued another order under the CAA, requiring Hershey to develop and implement RMPs for both facilities. Hershey took steps to comply with the CAA compliance order, and in April 2007, EPA advised the company that the program was in compliance. Notwithstanding EPA's finding, however, the following year, the United States Attorney's Office for the Middle District of Pennsylvania filed criminal charges against Hershey for the past violations. On or about October 31, 2008, Hershey pleaded guilty to a knowing violation of Section 112(r)(7) for failure to develop and implement an RMP, and agreed to pay a $100,000 fine. The company will serve one year's probation.

The Link Between RMP Enforcement and OSHA Inspections

The prosecution of Hershey follows a multi-agency initiative to target and prosecute worker safety related violations. In 2005, the Environmental Crimes Section of the Department of Justice, OSHA, and EPA joined forces to announce the "Worker Safety Initiative" ("WSI"). The WSI forged new alliances between OSHA compliance officers, criminal investigators for the EPA and FBI, and prosecutors from DOJ and the United States Attorney's Offices. As a result of the initiative, OSHA inspectors received training on how to identify certain environmental violations. The initiative also effectively expanded the jurisdiction of OSHA inspectors and increased the likelihood that worker safety violations would be prosecuted criminally. Under the OSH Act, a willful violation—even one causing death to an employee—is only punishable by misdemeanor penalties, whereas violations of certain environmental laws are punishable by felony penalties including jail time. See e.g., 29 U.S.C. § 666(e); 42 U.S.C. § 7413(c)(1).

Although not identified as such, the Hershey case appears to be a direct product of the WSI. The information obtained by OSHA inspectors in the course of the 2004 PSM compliance inspection and the subsequent administrative subpoena likely triggered EPA's RMP investigation one year later. The decision to charge the company with a felony CAA violation was also likely the result of the WSI. It is reasonable to expect that the government will continue to use environmental statutes with their higher penalties and felony provisions, as well as the federal criminal code, to prosecute cases which would probably not be brought under the criminal provisions of the OSH Act.

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Broader Application of RMP Requirements

The decision to charge Hershey criminally for violation of the RMP requirements may also illustrate a strategy by the government to use environmental laws more aggressively and proactively to address worker safety issues. Since its inception, a number of high-profile prosecutions have developed out of the WSI. Criminal charges, often brought under the endangerment provisions of the environmental protection statutes, have previously been filed against companies such as BP Products North America, McWane, Inc., Motiva Enterprises, LLC, and W.R. Grace & Co. Each of those cases, however, involved industrial accidents in which workers died or suffered serious injuries. For example, following the 2005 catastrophic explosion at BP's Texas City, Texas refinery that killed 15 contract employees and injured more than 170 others, OSHA assessed a fine of $21 million, but brought no criminal charges. Under the Clean Air Act, however, BP agreed to pay a criminal fine of $50 million and to serve a three-year probation period for a felony conviction under Section 112(r)(7) of the CAA.

The Hershey prosecution represents a significant change in enforcement focus. It involved no accidental release and no worker injuries. Rather, the only violations alleged were "paperwork" ones: the failure to develop and implement an RMP over a period of years, while falsely certifying compliance with RMP requirements. This less dramatic case may be an indicator of the government's current preference to take a more proactive stance before a catastrophe occurs.

Workplace Safety Issues Are Also Being Addressed by Congress

In April 2007, The Protecting America's Workers Act, H.R. 2049, a bill which seeks to amend the OSH Act and expand its coverage, including increased civil and criminal penalties for certain violations, was introduced and referred to the House Committee on Education and Labor. In April 2008, the Workforce Protections Subcommittee of the House Education and Labor Committee conducted a hearing on the legislation, including OSHA's lack of adequate enforcement and oversight of workplace safety and health conditions with large, multiple-facility corporations. David H. Uhlmann, the former Chief of the Environmental Crimes Section of the Department of Justice testified before the subcommittee on April 29, 2008, and advocated for strengthening the criminal enforcement provisions of the Act. There has been no further action as of this date.

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If you would like further information or to discuss the implications of this decision in more detail, please contact Thomas M. DiBiagio (202-789-6049) or Nadira Clarke (202-789-6069) regarding the criminal issues; David Friedland (202-789-6047) or Laura McAfee (410-230-1330) regarding the Clean Air Act issues; or Maddie Kadas (512-391-8010) or Mark Duvall (202-789-6090) regarding the Occupational, Safety and Health Act issues.

U.S. Supreme Court Vacates Injunction Against Navy's Use of Sonar

The United States Supreme Court once again has reiterated that courts may not issue broad injunctions based on the unsubstantiated possibility of environmental harm. The Court vacated two contested aspects of a preliminary injunction against the United States Navy that restricted sonar use during training exercises because plaintiffs failed to demonstrate the "likelihood" of irreparable injury to the environment without the injunction. The ruling provides sound footing for parties to demonstrate the overriding public interest in continuing a challenged project or activity while agencies remedy procedural violations of the National Environmental Policy Act ("NEPA").

In Winter v. Natural Resources Defense Council, No. 07-1239, 555 U.S. ___ (Nov. 12, 2008), the Supreme Court considered the propriety of a California federal district court's injunction restricting the scope of a Navy sonar-training program. Plaintiffs filed suit challenging the Navy's environmental assessment, which concluded that using "mid-frequency active" ("MFA") sonar in training to identify enemy submarines does not significantly affect the

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environment. Plaintiffs alleged that the Navy should have prepared an environmental impact statement analyzing these effects and requested a preliminary injunction until the lawsuit was resolved. The district court granted the injunction, finding that plaintiffs were likely to succeed on the merits of their NEPA claim, they had established the "possibility" of irreparable environmental harm from injury to marine mammals, and this injury outweighed any possible harm to the Navy from enjoining the sonar use. The district court also did not find persuasive an interim determination by the Council on Environmental Quality that "emergency circumstances" warranted continuing the Navy exercises notwithstanding possible environmental impacts. On appeal, the Ninth Circuit upheld the injunction.

The Supreme Court reversed. The Court determined, irrespective of plaintiffs' likelihood of success of the merits, the mere "possibility" of environmental harm is insufficient to support a preliminary injunction. Irreparable harm must be "likely" to occur if the court does not enjoin a challenged activity. Because there was no documented evidence of injury to marine mammals during the Navy's 40-year history of using MFA sonar, the Court found that plaintiffs failed to meet this standard.

Even if continued sonar use likely would irreparably injure marine mammals, the Court determined that the public interest and Navy's interest in effective military training would outweigh this injury. In doing so, the Supreme Court reaffirmed the importance of assessing the balance of equities and the public interest when considering injunctive relief. Here, plaintiffs' "most serious possible injury would be harm to an unknown number of marine mammals that they study and observe"; meanwhile the Navy would be forced to deploy an inadequately trained antisubmarine force, which could jeopardize the safety of the entire fleet. Under these conditions, the Court concluded, the balance of equities and the public interest tipped "strongly" in favor of the Navy. The challenged restrictions in the preliminary injunction therefore were improper.

While the Court did not reach the merits of the underlying NEPA claim, the procedural issues it decided are far more important and may extend beyond the particular facts of this case. Although the Court's majority focused on the overriding public interest in national security, its guidance should not be limited to cases involving the military. In reaching its conclusion, the Court confirmed that preliminary injunctions are "an extraordinary remedy never awarded as of right" and activities may not be enjoined on the basis of speculative harm. For all cases, the lower courts must identify the likelihood of irreparable injury and appropriately balance the parties' respective harms and interests and the public interest before framing any injunctive relief. When performing this balancing in future non-military cases, courts will focus on the scope of a challenged activity, its likely environmental effects, and the likely public interest impacts of enjoining the activity while procedural violations of NEPA are remedied. As a result, parties are now in a far better position to contest preliminary relief founded on claims of hypothetical environmental impacts where the activity or project at issue serves an important public interest.

For additional information or to discuss the implications of this ruling on your project, please contact Fred Wagner, fwagner@bdlaw.com, Parker Moore, pmoore@bdlaw.com, James Auslander, jauslander@bdlaw.com, or Patrick Jacobi, pjacobi@bdlaw.com.

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EPA Proposes New Data Requirements for Antimicrobial Pesticide Products

On October 8, 2008, the U.S. Environmental Protection Agency (EPA) proposed revisions to its data requirements for antimicrobial pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), in conjunction with its wider effort to update and streamline

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its data requirements for all pesticides. A full copy of the proposed requirements for antimicrobial products is available in the Federal Register at 73 Fed. Reg. 59382 (Oct. 8, 2008).

While the proposal largely retains the Agency's current data requirements for antimicrobials, it establishes 12 new use patterns specific to antimicrobial pesticides intended to make it easier for applicants to determine which data requirements apply to particular types of antimicrobial products. The proposal also incorporates nine new data requirements for antimicrobial pesticides, including four new requirements intended for use in a screening-level assessment on the fate of antimicrobials with the potential to reach a wastewater treatment plant. These products would include "down-the-drain" products as well as microbiocides used in industrial process and water systems.

EPA is accepting comments on its proposal until January 6, 2009. Affected parties, including pesticide product manufacturers, antimicrobial pesticide and microbiocide registrants, and wastewater treatment plant operators seeking more information about the Agency's regulation of antimicrobial pesticide products or the implications of EPA's proposed changes should contact
Kathy Szmuszkovicz at (202) 789-6037 (kszmuszkovicz@bdlaw.com),
Karen Hansen at (202) 789-6056 (khansen@bdlaw.com), or
Alan Sachs at (410) 230-1345 (asachs@bdlaw.com).

A. Background

Pursuant to FIFRA, every pesticide product must be registered by EPA before it may be sold or distributed in the United States. An application for a pesticide registration must demonstrate that the product will not cause "unreasonable adverse effects" to humans or the environment. To evaluate proposed product registrations or new uses of existing pesticides pursuant to this standard, FIFRA provides EPA with broad authority to require from pesticide applicants and registrants scientific data concerning each product, including its composition, toxicity, potential human exposure, environmental properties, and ecological effects.

EPA first promulgated general data requirements for pesticides in 1984, at 40 C.F.R. Part 158. Although Part 158 specifies the types of data and information generally required by EPA for conventional, biochemical and microbial pesticides, there both have been significant changes to the underlying laws and advances in science since that time and EPA and pesticide registrants have long recognized that it would be helpful for the Agency's data requirements to address with more specificity the range of applications, use patterns and other factors particularly relevant to antimicrobial pesticides.

Antimicrobial pesticide applicants have frequently found it difficult to determine which of the Agency's pesticide data requirements apply to their products, resulting in the need for unusually extensive consultation with EPA before registration and throughout the registration lifecycle. One of the Agency's primary goals in promulgating its new antimicrobial data requirements is to provide clarity to antimicrobial pesticide registrants and reduce the extensiveness of EPA consultations.

B. Applicability

EPA's proposed requirements for antimicrobial products will apply to:

- "antimicrobial pesticides" as defined by FIFRA (generally, any pesticide intended to (1) disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms, or (2) protect inanimate objects, industrial processes or systems, surfaces, water or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae or slime);
- pesticide products intended for antimicrobial uses in or on food or feed;
- antifoulant paints and coatings;
- wood preservatives; and

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- pesticide products intended to be manufactured into any of the above.

The proposed requirements, once final, are intended to apply to all new applications for registration of antimicrobial pesticides submitted after the effective date of the rule. EPA also anticipates that the new requirements will apply to applications for antimicrobial pesticides that are undergoing Agency review when the new regulation goes into effect. EPA is also considering a limited transition "window" for certain pending antimicrobial registration applications.

While EPA does not intend to apply the new requirements automatically to all existing pesticide registrations, the Agency notes that it may be necessary to call-in data on certain existing registrations, as warranted by emerging risks of concern for particular pesticides or as a result of possible future programmatic changes and priorities on existing pesticides, or during the registration reviews required by the Food Quality Protection Act of 1996 (FQPA). EPA also points out that it may be useful for all applicants, potential applicants and registrants of existing products to evaluate their products in light of the proposed requirements. The Agency continues to expressly encourage consultation with EPA during the application process.

C. Use Patterns for Antimicrobial Pesticides

Previously, in order to determine applicable data requirements for antimicrobial pesticide products, applicants relied on 12 "use categories" developed by EPA for consideration with antimicrobials. By identifying the relevant use category for a specific product, the applicant would be referred to a corresponding Part 158 pesticide "use pattern," through which the applicant could identify associated data requirements. In its proposal, EPA now seeks to promulgate the 12 existing antimicrobial use categories as independent use patterns for antimicrobial pesticides. These use patterns are:

- Agricultural premises and equipment (including many indirect food uses with mostly indoor use sites);
- Food-handling/storage establishments, premises, and equipment (including many indirect food uses due to the treatment of food contact surfaces and the resultant human exposures);
- Commercial, institutional and industrial premises and equipment (including nonfood contact areas of commercial sites);
- Residential and public access premises (including mostly nonfood areas, as well as food-handling areas in homes);
- Medical premises and equipment (including uses with the potential for repeated exposure);
- Human drinking water systems (including any methods used to provide potable water from raw water supplies, such as public water systems, water purifier units, and private water systems);
- Material preservatives (including antimicrobial chemicals added to paints, coatings, adhesives, textiles, and paper);
- Industrial processes and water systems (including microbiocides used to control the growth of bacteria, fungi, and algae in circulating water systems);1
- Antifoulant paints and coatings (including coatings and paints applied to control the growth of freshwater or marine fouling organisms, as well as ballast water);
- Wood preservatives (including products which claim to control wood degradation problems due to fungal rot or decay, sapstain, molds, or wood-destroying insects);
- Swimming pools (including products used to prevent or control the growth of bacteria or algae in swimming pools, Jacuzzis and hot tubs); and

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- Aquatic areas (including products designed to control or kill slime-forming bacteria, fungi or algae in lakes, ponds, streams, drainage ditches, or other bodies of water).

D. Summary of EPA's Proposed Data Requirements for Antimicrobial Pesticides

Under the proposal, EPA's data requirements for antimicrobial pesticides will be incorporated into Part 158 as a new subpart W.

1. New Data Requirements

The proposal includes nine new data requirements for antimicrobial products, including four new requirements that are not generally required for conventional pesticides:

Activated sludge sorption isotherm study;

Ready biodegradability study;

Porous pot study; and

Modified activated sludge, respiration inhibition test.

These four new studies are being required because of the "many down-the-drain uses" of antimicrobial pesticides, and their discharge to public treatment systems. 73 Fed. Reg. at 59,387. In its proposal, EPA explains that because many antimicrobial pesticides are typically rinsed down the drain, it is proposing these four new requirements for use in a screening-level assessment on the fate of antimicrobials that reach a wastewater treatment plant. In addition, seven higher-tiered environmental fate studies could be triggered based on a weight-of evidence evaluation of the results of the screening-level studies.

2. Product Performance Data

Consistent with its existing data requirements, EPA requires the applicant to develop product performance data for all products; however, EPA will only require the submission of product performance data from applicants that make a public health claim regarding their product.

3. Product Chemistry Data

EPA has proposed application of its existing product chemistry data requirements for conventional pesticides to antimicrobial pesticides. These chemistry data requirements include data identifying the basic identity and chemical and physical characteristics of a pesticide chemical.

4. Toxicology Data

EPA proposes modifying the application of its toxicology data requirements to reflect the differing risks of levels of exposure to antimicrobials by establishing two new groupings for antimicrobial products: "low human exposure" and "high human exposure." 73 Fed. Reg. at 59,392. For purposes of determining data requirements, EPA considers high human exposure to include:

those uses which are likely to result in human exposure over a considerable portion of the human lifespan, and which are significant in terms of frequency, duration, or magnitude of exposure (i.e., uses for which there is an expectation of high, prolonged, or repeated exposure).

40 C.F.R. § 158.2230(b)(1) (proposed). Examples of high human exposure uses of antimicrobials include uses requiring a tolerance or tolerance exemption, indirect food uses with residues equal to or greater than 200 parts per billion, use in human or animal drinking water, outdoor aquatic uses which have the potential to contaminate potable water, and wood preservatives.

Low human exposure uses are defined as those not meeting the criteria for high exposure uses. Under this approach, an application for registration of an antimicrobial with low human exposure might be required to generate fewer studies in total than would be required for high human exposure uses.

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5. Handler and Post-Application Exposure Data

EPA's proposal would codify its current practice of requiring handler exposure studies for all antimicrobial products whenever the Agency's toxicity criteria (i.e., evidence of potentially significant adverse effects have been observed in any applicable toxicity studies, or scientifically sound epidemiological or poisoning incident data indicate that adverse health effects may have resulted from handling of the pesticide) and exposure criteria (i.e., dermal or respiratory exposure may occur during use) are triggered.

Similarly, post-application exposure data would be required if a product meets one of the Agency's toxicity criteria and one of EPA's exposure criteria for outdoor uses (i.e., occupational human post-application exposure to residues could occur as the result of work-related activity or residential human post-application exposure to residues could occur following application of the pesticide to outdoor areas and spaces at residential sites) or indoor uses (i.e., occupational human post-application exposure could occur following application of the pesticide to indoor spaces or surfaces, or residential human post-application exposure could occur following application of the pesticide to indoor spaces or surfaces at residential sites).

6. Residue Chemistry Data

In its proposal, EPA seeks to modify the applicability of its existing residue chemistry data requirements to reflect the differing risks and levels of exposure of antimicrobials. For example, to determine antimicrobial residue chemistry data requirements, most antimicrobial pesticides will be classified as either direct or indirect food uses.

7. Environmental Fate Data

EPA has proposed dividing antimicrobial pesticides into two groups for the purpose of determining environmental fate and ecotoxicity data requirements: a "low environmental exposure" grouping and a "high environmental exposure" grouping. 73 Fed. Reg. at 59,405.

According to the Agency, the potential for environmental exposure is "high" for three of the antimicrobial pesticide use patterns (antifoulant paints and coatings, wood preservatives, and aquatic areas), because these uses either occur outdoors and thus discharge directly to the environment, or result in materials treated with antimicrobials being placed in the environment. In addition, EPA includes use in once-through industrial processes and water systems (a subgroup of the industrial processes and water systems use pattern in which the water is not re-used and is released after a single cycle through the system) in its high environmental exposure grouping.

By contrast, the low environmental exposure grouping includes products with use patterns in agricultural premises, food-handling establishments, medical premises, human drinking water systems, and recirculating industrial processes and water systems.

As noted above, based on EPA's concerns about the potential effects of antimicrobials on the biological treatment processes used in wastewater treatment plants -- as well as its concerns about potential bioconcentration of antimicrobials after release and possible effects on nontarget species -- the Agency is also proposing four new environmental fate data requirements to assess all products with "down-the-drain" antimicrobial uses (represented in the proposed rule by the low environmental exposure grouping, as well as once-through industrial processes and water systems). These data will allow EPA to conduct screening-level environmental fate assessments, which can then indicate the need for higher-tiered data.

8. Nontarget Organisms Data

EPA is proposing to use a tiered system of ecological effects testing to assess the potential risks of pesticide uses to nontarget animals for antimicrobial pesticides.

9. Plant Protection Data

EPA is proposing to modify the applicability of its existing nontarget plant protection data

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requirements to reflect the differing risks and levels of exposure of antimicrobial products.

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1 As described below, for purposes of determining potential environmental exposure, EPA recognizes two distinct subgroups within this use pattern – (1) once-through industrial processes and water systems and (2) recirculating industrial processes and water systems.

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