



Recent Federal Developments December 15, 2006

Bergeson & Campbell, P.C. extends its best wishes to all our clients and many friends and we wish you and your family a happy, healthy, and peaceful New Year.

TSCA/FIFRA/EPCRA/NTP

EPA Issues Final Amendments To TSCA Export Notification Reporting Requirements -- On November 14, 2006, the U.S. Environmental Protection Agency (EPA) promulgated amendments to the Toxic Substances Control Act (TSCA) Section 12(b) export notification regulations at Subpart D of 40 C.F.R. Part 707. 71 Fed. Reg. 66234. The first of EPA's amendments changes the current annual notification requirement for exporters of chemicals for which certain actions have been taken under TSCA. Under current regulations, exporters must notify EPA of the first export or intended export to a particular country in a calendar year when any of the following apply: data are required under TSCA Section 5(b); an order has been issued under TSCA Section 5; a rule has been proposed or promulgated under TSCA Section 5 or 6; or an action is pending or relief has been granted under TSCA Section 5 or 7. EPA now requires exporters of chemicals subject to a final TSCA Section 4 action to submit an export notification only for the first export or intended export to a particular country. The final rule changes the current annual export notification requirement to a one-time requirement for each of the following TSCA Section 12(b)-triggering actions per each destination country for each exporter of a chemical: an order issued, an action pending, or an action granting relief under TSCA Section 5(e); a proposed or promulgated rule under TSCA Section 5(a)(2); or an action requiring the submission of data under TSCA Section 5(b). Exporters of chemicals subject to TSCA Section 12(b)-triggering actions under TSCA Section 5(f), 6, or 7 continue to be required to submit annual export notifications to EPA, however.

EPA also changed the frequency with which EPA must notify foreign governments after its receipt of export notifications from exporters. Currently EPA notifies foreign governments annually regarding the export of chemicals subject to final TSCA Section 4 actions. Under the amendments, EPA will provide a one-time notice to each foreign government to which exported chemicals that are the subjects of any of the following actions are sent: an order issued, an action pending, or an action granting relief under TSCA Section 5(e); a rule proposed or promulgated under TSCA Section 5(a)(2); or an action requiring the submission of data under TSCA Section 5(b). EPA will continue to notify each foreign government on an annual basis regarding the export of chemicals subject to TSCA Section 5(f), 6, or 7 actions.

Importantly, EPA also promulgated *de minimis* concentration levels below which notification will not be required for the export of any chemical for which export notification under TSCA Section 12(b) is otherwise required. Specifically, export notification will not be required for such chemicals if the chemical is being exported at a concentration of less than 1% (by weight or volume), unless that chemical is a known or potential human carcinogen. For purposes of TSCA Section 12(b) export notification, the chemical is: listed as a "known to be human carcinogen"



or “reasonably anticipated to be human carcinogen” in the National Toxicology Program’s (NTP) *Report on Carcinogens*; classified as a Group 1, Group 2A, or Group 2B carcinogen by the International Agency for Research on Cancer (IARC) in the list of IARC Monographs on the Evaluation of Carcinogenic Risks to Humans and their Supplements; or characterized as a carcinogen or potential carcinogen in the Occupational Safety and Health Administration’s (OSHA) regulations related to toxic and hazardous substances (29 C.F.R. Part 1910, Subpart Z). For chemicals falling into one of the categories listed above, a *de minimis* concentration level of less than 0.1% (by weight or volume) applies. For exports of polychlorinated biphenyls (PCB), EPA will not require notification if such chemicals are being exported at a concentration of less than or equal to 50 parts per million (ppm) (by weight or volume).

The amendments also update the instructions for the submission of export notifications to EPA (40 C.F.R. Section 707.65(c)), clarifying exporters’ and EPA’s obligations when subsequent TSCA Section 12(b)-triggering actions are taken with respect to a chemical previously or currently subject to export notification due to a separate triggering action. The amended regulations will indicate in 40 C.F.R. Section 707.67 that a single export notification may refer to more than one section of TSCA where the exported chemical is the subject of multiple TSCA actions, and correct 40 C.F.R. Section 799.19 to make it clear that final multi-chemical TSCA Section 4 rules also trigger export notification. The amendments are effective **January 16, 2007**. In a related notice issued on November 28, 2006, EPA announced certain technical corrections to the final rule. 71 Fed. Reg. 68750.

EPA Suggests Submissions Either Be Sent To EPA Electronically Or By Delivery -- Do Not Use The U.S. Mail -- EPA has discovered that Inventory Update Rule (IUR) submissions coming into EPA via the U.S. mail are routinely damaged. Please consider using alternatives to the U.S. mail: either (1) a delivery service instead of the U.S. mail to send your IUR submission to EPA; or (2) sending the submission to EPA via the Internet, which is the preferred option. Since the anthrax issues occurred several years ago, materials delivered by the U.S. mail that go to government offices are irradiated. This process is causing damage to IUR submissions on paper and on CD-ROM. In the case of paper submissions, the ink melts slightly, causing the pages to stick together and the ink to blur. The submissions can be difficult to read and do not scan well, resulting in the need to hand-enter the data from the submissions. In the case of CD-ROM submissions, often the case is melted and difficult to open. In one case, the CD-ROM was also melted and unusable. More information about irradiating mail can be found at http://www.epa.gov/radiation/sources/mail_irrad.htm.

EPA’s preferred option for IUR submissions is through the Internet, using EPA’s Central Data Exchange (CDX). Information on reporting through the Internet can be found in Section 6.2 of the Instructions for Reporting and is embedded in the eIUR reporting software. Please be aware that you need to register with CDX for IUR submissions prior to using the system. Additional information can be found at <http://www.epa.gov/oppt/iur> or <http://www.epa.gov/cdx>.



EPA Issues Final Rule On Aquatic Pesticide Applications -- On November 27, 2006, EPA issued a final rule clarifying two specific circumstances in which a Clean Water Act (CWA) permit is not required before pesticides are applied. 71 Fed. Reg. 68483. The two circumstances are when: (1) pesticides are applied directly to water to control pests, including mosquito larvae, aquatic weeds, and other pests in the water; and (2) pesticides are applied to control pests that are present over or near water where a portion of the pesticide will unavoidably be deposited to the water in order to target the pests effectively. After considering two rounds of public comments, EPA concluded that the CWA does not require permits in these two situations. The final rule replaces EPA's interim and final Interpretive Statements on the Application of Pesticides to Waters of the United States in Compliance with FIFRA, published on February 1, 2005. The final rule is available at <http://www.epa.gov/npdes/agriculture>. On December 1, 2006, EPA issued technical corrections to the final rule. 71 Fed. Reg. 69622. The rule is effective **January 26, 2007**.

EPA Publishes Draft Final Rule Amending And Extending Exceptions From Definition Of "Pesticide Chemical" And "Pesticide Chemical Residue" -- On December 6, 2006, EPA published a direct final rule that amended and extended the exceptions from the definition of "pesticide chemical" and "pesticide chemical residue" contained in 40 C.F.R. Section 180.4. 71 Fed. Reg. 70667. The prior definition of "pesticide chemical" and "pesticide chemical residue" under Section 180.4 exempted only food packaging impregnated with insect repellent from these definitions. EPA states that the exemptions were based on EPA's view at the time of enactment that it had only received applications that called for that particular use and method of application.

The new rule expands the exception to the definition of "pesticide chemical" and "pesticide chemical residue" to include components of food packaging material treated in any manner with any pesticide active ingredient and distributed or sold with the purpose of controlling pests. Currently, packaging material (such as paperboard, polymers, or a coating) is considered to be an inert ingredient when a pesticidal formulation is mixed with it, requiring a separate tolerance (or exemption from a tolerance) from EPA. The effect of the new rule is that food packaging materials that have been treated with a pesticide will no longer be considered pesticide chemical residues, and will be exempt from regulation by EPA (*i.e.*, will not require a tolerance or exemption) under Sections 402(a)(2)(B) and 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The excepted food packaging materials will be regulated instead by the Food and Drug Administration (FDA) as food additives, without regard to the application technique or the mode of action of the active ingredients in the packaging material.

EPA makes it clear in the direct final rule that the active pesticide ingredients must still be registered as pesticides, and any inert ingredients in the pesticide formulation must be the subject of a tolerance or exemption from the requirement of a tolerance. Only the treated packaging material is excepted from registration or tolerance requirements.



EPA indicates that the rule will be effective **February 5, 2007**, without notice unless EPA receives adverse comments in writing by **January 5, 2007**. If EPA receives such comments, it will publish a timely withdrawal.

EPA Revokes Testing Requirements For Coke-Oven Light Oil -- On December 8, 2006, EPA announced its decision to revoke its TSCA Section 4 testing proposal for coke-oven light oil. 71 Fed. Reg. 71058. The substance was among 17 high-production volume (HPV) chemicals included in a test rule EPA published on March 16, 2006. EPA reported that since it issued the testing requirements in March, it has obtained information showing that the number of workers potentially exposed is insufficient to meet TSCA rulemaking criteria. The direct final rule is effective **February 6, 2007**, unless EPA receives adverse comment or a written request to provide oral comments to the agency by **January 8, 2007**.

EPA Drops Proposal To Reduce Frequency Of TRI Reporting -- On November 28, 2006, EPA Administrator Stephen L. Johnson stated, in a letter to Senators Frank Lautenberg (D-NJ) and Robert Menendez (D-NJ), that EPA has dropped its plan to reduce the frequency of the Toxics Release Inventory (TRI) reporting and will soon announce its position in a *Federal Register* notice. On November 30, 2006, the Senators responded that, while they welcome EPA's reversal, they intend to introduce legislation during the week of December 4, 2006, to prevent EPA from making additional attempts to change the TRI reporting frequency. According to the Senators, their legislation would also prohibit EPA from making any of its other proposed changes. A spokesperson for Lautenberg said that, due to the lame-duck Congress, the Senators intend to repropose the legislation in January 2007. The spokesperson stated that introducing the bill now "sends a very strong signal to the administration that the Democrats are not going to stand by when they take control of Congress and rubber stamp" Republican proposals. An EPA spokesperson stated that EPA intends to issue a final rule by the end of December 2006 on its proposal regarding use of the shortened TRI reporting form. The EPA spokesperson said that Johnson's letter was motivated by his desire and determination "to maintain an effective program" after a year-long review on how to strengthen the TRI.

EPA Makes Available Inventory Of Sources And Environmental Releases Of Dioxin-Like Compounds -- On December 1, 2006, EPA announced the availability of a final report titled *An Inventory of Sources and Environmental Releases of Dioxin-Like Compounds in the United States for the Years 1987, 1995 and 2000* (EPA/600/P-03/002F), which was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development (ORD). 71 Fed. Reg. 69564. The purpose of this report is to present a comprehensive inventory and overview of sources and environmental releases of dioxin-like compounds in the United States. The major identified sources of environmental releases of dioxin-like compounds are grouped into six broad categories: combustion sources, metals smelting, refining and process sources, chemical manufacturing sources, natural sources, and



environmental reservoirs. Estimates of annual releases to land, air, and water are presented for each source category and summarized for reference years 1987, 1995, and 2000.

FIFRA SAP Schedules Meeting On Endocrine Disruptor Screening Program -- On December 13, 2006, EPA announced that the FIFRA Scientific Advisory Panel (SAP) will meet on **February 27-28, 2007**, to discuss the status of the *in utero* through lactational assay in the Endocrine Disruptor Screening Program (EDSP). 71 Fed. Reg. 74901. EPA is implementing the EDSP pursuant to the FFDCFA, which requires EPA to establish a screening program using validated assays to identify pesticides that may have certain estrogenic effects in humans and other endocrine effects. EPA chartered the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) under the Federal Advisory Committee Act (FACA) to discharge its mission under the FFDCFA. The EDSP commissioned the *in utero* through lactational review to assess the assay. The purpose of the meeting is to allow the SAP to review and discuss the protocol and assay results of an *in utero* through lactational study with methoxychlor within the current context of the EDSP, and to provide advice that will inform EPA's judgment on whether to continue, modify, or suspend development of the bioassay. Comments must be submitted by **February 13, 2007**.

EPA Issues Direct Final Rule On Pesticide Tolerance Nomenclature -- On December 13, 2006, EPA issued a direct final rule making minor revisions to the terminology of certain commodity terms listed under 40 C.F.R. Part 180 Subpart C. 71 Fed. Reg. 74802. The direct final rule is effective **February 26, 2007**, without notice, unless EPA receives adverse comment on or before **February 12, 2007**. The direct final rule makes certain amendments to the C.F.R., which, according to EPA, have no substantive impact on the underlying regulations and do not otherwise impose or amend any requirements. Please consult the *Federal Register* for additional details.

CAA/CWA

EPA Issues Memorandum On TMDL Discharge Limits -- On November 15, 2006, EPA's Assistant Administrator in the Office of Water issued a memorandum entitled *Establishing TMDL "Daily" Limits in Light of the Decision by the U.S. Court of Appeals for the D.C. Circuit in Friends of the Earth, Inc. v. EPA, et al., No. 05-5015 (Apr. 25, 2006) and Implications, for NPDES Permits*. The memorandum outlines how EPA intends to apply a daily limit, or daily budget, for total daily maximum loads (TMDL) for impaired bodies of water. The memorandum directs all state agencies to begin incorporating daily permit limits in all future TMDLs and related waste load allocations. The memorandum provides examples of approaches EPA believes are flexible that states are encouraged to use to meet these requirements. The memorandum also clarifies that National Pollutant Discharge Elimination System (NPDES) permit regulations do not require that effluent limits in permits necessarily be expressed as maximum daily limits or as numeric limitations in all circumstances. The memorandum



confirms that discretion exists within EPA regardless of the time increment chosen to express the TMDL.

EPA Announces Availability Of Draft Paper On Lead -- On November 29, 2006, the Office of Air Quality Planning and Standards (OAQPS) announced the availability for public review and comment a first draft document, *Review of the National Ambient Air Quality Standards for Lead: Policy Assessment of Scientific and Technical Information* (draft Staff Paper). 71 Fed. Reg. 69117. The draft Staff Paper evaluates the policy implications of the key scientific and technical information contained in a related EPA document, *Air Quality Criteria for Lead*, required under Clean Air Act (CAA) Sections 108 and 109 for use in the periodic review of the national ambient air quality standards (NAAQS) for lead. On or about December 15, 2006, the OAQPS intends to make available for public review and comment the related draft technical support document, *Lead Human Exposure and Health Risk Assessments and Ecological Risk Assessment for Selected Areas (Pilot Phase)*. Comments on the draft Staff Paper and draft Risk Assessment must be received on or before **January 26, 2007**.

RCRA

EPA Seeks Public Comment On Draft Grant Guidelines For Underground Storage Tank Inspections -- EPA released for public comment draft grant guidelines that will establish requirements for inspecting underground storage tank systems. The draft grant guidelines on inspection requirements are available at http://www.epa.gov/oust/fedlaws/epact_05.htm#Drafts. States will have to meet the requirements to comply with provisions of the Energy Policy Act of 2005. EPA worked with states and other partners to develop the grant guidelines and, when final, will incorporate them into grant agreements between EPA and states, which help states implement the tank program. EPA will accept public comments on the draft guidelines until **December 22, 2006**. EPA's website provides the public with the draft guidelines, as well as details about how and where to submit comments.

REACH

Compromise Position Achieved On REACH -- Registration, Evaluation and Authorization of CHemicals (REACH) developments continue. At a November 30, 2006, meeting, the European Union (EU) Council of Ministers and a delegation of parliamentarians from the European Parliament (EP) adopted a compromise position on REACH. Importantly, the Council of Ministers and EP delegation agreed that for dangerous substances -- carcinogens, reproductive toxins, and those that are persistent, bioaccumulative, and toxic (PBT) -- to be authorized under REACH, manufacturers/importers must submit a substitution plan to replace the substances with safer alternatives. When there is an absence of alternatives, they must submit a research and development plan. In October 2006, the EP's Environment Committee approved a strong



substitution principle that would have mandated the replacement of these high-risk substances. The Council, however, supported nonmandatory substitution.

Under the compromise position, regulators will use the substitution plan to determine how long the more dangerous chemical should continue to be authorized for use. If no safer alternatives are available, companies will have to prepare research and development plans to find them. The substitution rules will apply to both authorization routes and from the very start of the process, meaning that substitution plans will be required immediately even for high-concern chemicals whose risks can be “adequately controlled” through exposure management measures.

In addition to resolving their differences over substitution, the EP delegation and Council of Ministers resolved other outstanding issues, such as the duty of care for chemical companies; increased research into non-animal testing; and EP appointees to serve as members of the new European Chemicals Agency. Chemicals produced in volumes below 10 tonnes remain exempt from most REACH provisions, but their status will be reviewed after seven years. Data confidentiality rules have also been tightened slightly.

The EP was scheduled to vote on REACH on December 13, 2006 (see below). The Council of Ministers will then vote on REACH on **December 18, 2006**. If, as expected, those votes uphold the compromise position, the debate on REACH will be over, and the legislation will come into effect sometime in the second quarter of **2007**.

EP Approves REACH -- On December 14, 2006, the EP completed its second reading of the REACH regulation by approving the compromise measure negotiated by a delegation of parliamentarians and the EU Council of Ministers on November 30, 2006. As expected, parliamentarians approved REACH by a comfortable margin -- 529 voted in favor of it, 98 against, and 24 abstained.

REACH, which will replace 40 existing legal texts and create a single EU regulatory scheme for all chemical substances (*i.e.*, both new and existing substances), now goes back to the Council of Ministers for approval. That approval is widely expected to come at an Environment Council meeting on **December 18, 2006**. Once approved by the Council of Ministers, the regulation will enter into force on **June 1, 2007**.

Based on the June 1, 2007, entry into force date, it is now clear that the 6-month pre-registration phase will run from **June 1, 2008, through November 30, 2008**. Companies that pre-register substances will have, depending on the production/importation volume and risk of the particular substance, either 3 1/2, 6, or 11 years (from REACH’s entry into force) to complete the registration process. The substance information exchange for a called for under the regulation will commence operations at the conclusion of the pre-registration phase.



As agreed on November 30, 2006, REACH now contains an introductory recital provision on the “duty of care.” The recital provides that REACH “is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.”

Also as agreed on November 30, 2006, manufacturers, importers, and downstream users seeking authorization for the most dangerous substances -- carcinogens, mutagens, reproductive toxins, substances that are persistent, bioaccumulative, and toxic, substances that are very persistent and very bioaccumulative, and substances for which there is scientific evidence of probable serious human health or environmental effects -- will have to submit, as part of their authorization application, a substitution plan to replace the substance with a safer alternative. Where no alternative exists, the applicant will have to submit a research and development plan aimed at finding one.

NANOTECHNOLOGY

Scientific Committee On Consumer Products Convenes Consultation On Nanomaterials And Cosmetic Products -- On November 16, 2006, the European Commission, in consultation with the Scientific Committee on Consumer Products (SCCP), issued an invitation to stakeholders to provide information on the safety of nanoscale materials in cosmetic products. Specifically, the SCCP, which is working on a request for a scientific opinion, is inviting interested parties to submit: (1) scientific peer reviewed research papers and reviews (later than 2000) on this issue; (2) data on safety evaluation (later than 2000); and (3) other publicly available, reliable scientific information that may not be easily available and which is directly relevant to this issue. The call for information will end on **December 15, 2006**. For more information, see http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_call_info_01_en.htm.

PEN Seminar On Nanotechnology Risk Research -- On November 17, 2006, the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars held a seminar to coincide with the publication of a groundbreaking new paper on nanotechnology risk research, “Safe Handling of Nanotechnology.” Co-authored by 14 esteemed international scientists, including Dr. Andrew D. Maynard and Dr. Sally S. Tinkle, each of whom spoke at the seminar, and published in the November 16, 2006, issue of the journal *Nature*, the paper asserts that “[t]he spectre of possible harm -- whether real or imagined -- is threatening to slow the development of nanotechnology unless sound, independent and authoritative information is developed on what the risks are, and how to avoid them.” The scientists identify in the paper five “grand challenges to stimulate research that is imaginative, innovative and above all relevant to the safety of nanotechnology.” According to the scientists, “systematic risk research is needed if emerging nano-industries are to thrive.” The global scientific community, they maintain, “needs to act now if strategic research is to support



sustainable nanotechnologies, in which risks are minimized and benefits maximized.” A full copy of the paper is available at <http://www.nature.com/nature/journal/v444/n7117/full/444267a.html>.

The grand challenges identified by the scientists include development of the following, all within the next 15 years: instruments to assess environmental exposure to engineered nanomaterials, within the next 3-10 years; validated methods to evaluate the toxicity of engineered nanomaterials, within the next 5-15 years; models for predicting the potential impact of engineered nanomaterials on the environment and human health, within the next 10 years; robust systems for evaluating the health and environmental impact of engineered nanomaterials from cradle to grave, within the next 5 years; and strategic programs that enable relevant risk-focused research, within the next 12 months. The scientists conclude that “[i]f the global research community can . . . rise to the challenges we have set, then we can surely look forward to the advent of safe nanotechnologies.”

Several legislators issued statements commending the new paper. Senator Ron Wyden (D-OR), who co-authored Public Law No. 108-153 (*i.e.*, the 21st Century Nanotechnology Research and Development Act), “urge[d] the federal government to take a hard look at this important article because now is [the] time to act; there is no time for delay.” In a joint statement, Representatives Sherwood Boehlert (R-NY) and Bart Gordon (D-TN), the House Science Committee Chair and ranking Democrat on that Committee, remarked that “[a]t our most recent Science Committee hearing on this subject in September, both of us made clear that we felt the Administration was moving too slowly with preparing and funding a research agenda in this area when a sense of urgency is needed. . . . There is absolutely no reason that [federal] agencies and the White House should not now quickly put together a plan and a budget to implement the recommendations in the *Nature* paper as part of the fiscal 2008 budget.” William K. Reilly, a former EPA Administrator, also praised the paper.

ABA SEER Convenes A Teleconference On Nanotechnology -- On November 16, 2006, the American Bar Association’s (ABA) Section on Environment, Energy, and Resources (SEER) convened the second session in its ongoing Nanotechnology Teleconference Series. The session, entitled “Nanotechnology: What You Need to Know on the Law, Regulation, and Science Policy Front,” provided an overview of the law, regulation, and policy of nanotechnology and featured three speakers: Dr. Jennifer Sass of the Natural Resources Defense Council (NRDC); Mr. Jim Alwood of EPA’s Office of Pollution Prevention and Toxics (OPPT); and Mr. William P. Gulledge of the American Chemistry Council’s Nanotechnology Panel.

During his presentation, and in the question and answer session that followed, Alwood in particular made some interesting remarks in connection with EPA’s ongoing review of engineered nanoscale materials. First, on the fundamental question under TSCA of whether the nanoscale version of an existing chemical substance constitutes a “new chemical substance” such



that a premanufacture notice is required, Alwood indicated that OPPT, in its forthcoming Inventory status document, “probably” will consider the nanoscale version of a chemical already listed on the TSCA Inventory to be an existing rather than a new chemical substance. Alwood explained that different particle size is not a new issue under TSCA, and that EPA’s approach to date has focused, and likely will continue to focus, on the statutory definition of “chemical substance,” specifically the phrase “particular molecular identity.” In other words, if the nanoscale version and its Inventory-listed bulk counterpart have the same molecular identity, the former is an existing chemical substance.

Second, when asked whether EPA is contemplating the issuance of a TSCA Section 5(a)(2) significant new use rule (SNUR) or a Section 4 test rule for engineered nanomaterials, Alwood stated that EPA will take appropriate regulatory action if, as more information becomes available, the information warrants it or justifies it.

Finally, the scope of TSCA to address issues arising in the context of engineered nanoscale materials was the subject of discussion during the teleconference. On this matter, and in contrast to the views of some who believe that TSCA does not provide EPA with sufficient legal authority to address such issues, Alwood stated that, in comparison to other new chemicals or technologies, there is nothing different about nanomaterials such that new legislation is needed. TSCA, he intimated, provides EPA with all the regulatory authority it needs.

Berkeley Approves Ordinance Regarding Nanoparticles -- On December 12, 2006, the Berkeley, California, City Council unanimously approved a proposal to require businesses to report nanoparticles being used, provide available toxicological information, and outline measures for safe handling of the materials. Under the proposal, all businesses that manufacture or use nanoparticles must submit a written report of the current toxicology of the nanomaterials reported; and methods for safe handling, monitoring, containing, disposing, and tracking the inventory. The proposal amends Title 15 of the Berkeley Municipal Code, Hazardous Materials and Waste Management, which requires the filing of disclosure information for hazardous materials when certain quantities are exceeded. The amendment is available at <http://www.ci.berkeley.ca.us/citycouncil/2006citycouncil/packet/121206/2006-12-12%20Item%2003%20-%20Ord%20-%20Nanoparticles.pdf>.

According to the Community Environmental Advisory Commission’s (CEAC) recommendation, Berkeley’s regulations define a hazardous material as “any material that, because of its quantity, concentration, or physical or chemical characteristics, poses a significant present or potential hazard to human health and safety or to the environment if released into the workplace or the environment.” The recommendation states that questions about the need to implement a nanoparticle reporting requirement arose during the design phase of the molecular foundries at the University of California and Lawrence Berkeley Lab. Both institutions, when questioned by the Toxics Management Division, “noted they had no special knowledge or tools to manage



nanoparticles.” After much consideration and input from staff, the Lawrence Berkeley Lab, EPA, and the Woodrow Wilson Institute, “the recommended self-reporting was considered to be a minimum regulation for nanotechnology facilities.”

The recommendation notes that, in many cases, “the user will not find sufficient information to determine the health impacts of a material. In such cases, it is hoped that a precautionary approach be used when handling the materials.” The Rationale for Recommendation states:

Nanoparticles behave differently to macro-particle compounds and should be handled and mitigated differently. Handlers may not know much about the materials they are handling, as new information is published, the handlers should keep updating their knowledge, since government is not doing a good job regulating these materials.

According to the recommendation, no alternative action was considered, “but clearly no action has potentially unacceptable consequences for nanoparticle workers and the community.” The recommendation is available at <http://www.ci.berkeley.ca.us/citycouncil/2006citycouncil/packet/120506/2006-12-05%20Item%2013%20Manufactured%20Nanoparticle%20Health%20and%20Safety%20Disclosure.pdf>.

EPA Issues Clarification Regarding Ion-Generating Washing Machines -- EPA recently announced that it has reversed its earlier determination and now has concluded that a silver ion generating washing machine is subject to registration requirements under FIFRA and does not qualify as a “device” which would not need to be registered. Many articles have confused the issue and mischaracterized the EPA determination as heralding an EPA determination to regulate differently a “nanopesticide” under FIFRA; this is not accurate.

EPA released recently the appended update regarding silver ion generating washing machines. According to the update, EPA “has determined that the Samsung silver ion generating washing machine is subject to registration requirements under [FIFRA].” EPA previously advised Samsung that the silver ion generating washing machine was a device and thus not required to be registered under FIFRA. After reevaluating the issue, EPA determined that “the silver electrode in the Samsung washing machine is a pesticide because it is a substance (silver ion) released into the laundry for the purpose of killing microbial pests.”

EPA intends to outline and clarify its position on the classification of silver ion generating washing machines in a forthcoming *Federal Register* notice. It is not clear when this notice will be issued, but we understand EPA is working on it. EPA reportedly will provide companies time to comply fully with the clarifying notice, and will work with the companies to identify data and other information needed for an application for registration.



The update notes that recent press articles have referred to the Samsung washing machine “as a product of nanotechnology.” EPA says that, since it has not yet received an application for registration from Samsung, it “has not yet come to any conclusions about whether a washing machine that releases silver ions or any other similar product involves nanomaterial.” EPA states: “Whether the silver ions are considered to be nanomaterial or not, a pesticide product must be registered under the pesticide laws based on scientific data to show that it can be used [safely] and it will be required to meet the same safety standards as any other antimicrobial or conventional pesticide product.”

Public Meeting Announced On Research Needs And Priorities Related To The Environmental, Health, And Safety Aspects Of Engineered Nanoscale Materials -- On December 4, 2006, the National Nanotechnology Coordination Office (NNCO), on behalf of the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the Committee on Technology, National Science and Technology Council (NSTC), will hold a public meeting on **January 4, 2007**, to receive input on research needs related to the environmental, health, and safety aspects of engineered nanoscale materials (hereafter referred to as nanomaterials). The NSET Subcommittee coordinates planning, budgeting, and program implementation and review to ensure a balanced and comprehensive National Nanotechnology Initiative (NNI). The NSET Subcommittee is composed of representatives from agencies participating in the NNI. The NNCO provides technical and administrative support to the NSET Subcommittee in its work. The NSET Subcommittee is seeking comment on the research needs and prioritization criteria for the research identified in the NSET Subcommittee document entitled *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, which was released on September 15, 2006. The public meeting will be held on **Thursday, January 4, 2007**, beginning at 8:30 a.m. at the FDIC Training Center, 3501 North Fairfax Drive, Arlington, VA 22226. A schedule will be published prior to the meeting. Persons interested in attending the meeting may register at http://www.nano.gov/public_ehs.html prior to the meeting. Persons interested in presenting comments at the meeting also should register at http://www.nano.gov/public_ehs.html and should do so no later than **Wednesday, December 20, 2006**. Written or electronic comments may be submitted on the same web page until **January 31, 2007**. Information on this meeting also will be posted at <http://www.nano.gov>.

The meeting is an opportunity for public participation in the prioritization of research related to environmental, health, and safety aspects of nanomaterials. Specific comment on research needs and prioritization criteria in the *Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials* document and input regarding the criteria for evaluating research priorities is welcome. (To read the document, see http://www.nano.gov/NNI_EHS_research_needs.pdf.) The public meeting will be chaired by leadership of the NEHI Working Group, the NSET Subcommittee, and the NNCO. For more information on the NNI and its various working entities, please visit <http://www.nano.gov>.



ASTM Releases Terminology For Nanotechnology Standard -- On December 4, 2006, ASTM International announced the availability of Standard E 2456-06, Terminology for Nanotechnology. According to ASTM, because of “the great need for a terminology document that is globally recognized and because of the cooperation of several organizations in making the document a reality,” the Standard is available free of charge on the ASTM website at <http://69.7.224.88/viewnews.aspx?newsID=996>.

ASTM Committee E56, which was formed in 2005, developed the Standard, which is intended to provide a precise and widely accepted terminology. ASTM developed the Standard in partnership with the following organizations:

- American Institute of Chemical Engineers;
- American Society of Mechanical Engineers;
- Institute of Electrical and Electronics Engineers;
- Japanese National Institute of Advanced Industrial Science and Technology;
- NSF International; and
- Semiconductor Equipment and Materials International.

ASTM states that, “[w]ithout a precise and widely accepted terminology, communications about nanotechnology’s risks and benefits are riddled with overgeneralizations.” Some of the terms defined in the new Standard include nanotechnology, nano-, nanoscale, and nanostructured. Because nanotechnology is a rapidly developing field, ATSM intends to reassess continually the terms and definitions, for purposes of revision when necessary. ATSM intends the terms and definitions in the Standard to describe materials containing features between approximately 1 and 100 nanometers and to differentiate those properties different from properties found in either molecules or the bulk (interior) of larger, micron-sized systems.

LEGISLATIVE DEVELOPMENTS

Senate Approves Expanded Gulf Drilling And Extended Energy Tax Incentives -- The Senate approved on December 9, 2006, a measure to expand oil and gas drilling by 8.3 million acres in the eastern Gulf of Mexico. The action was part of approval of wide-ranging tax legislation that also included a number of incentives designed to spur greater use of renewable energy sources and make energy use more efficient. The Senate approved the measure as part of the Tax Relief



and Health Care Act of 2006 (H.R. 6111), which passed on a vote of 79-9. The House of Representatives approved the legislation on December 8, 2006.

The offshore drilling provision will reopen Lease Sale 181 in the Gulf and an area to the south, which is situated in a large natural gas field near existing pipeline infrastructure. The legislation also contains 11 provisions that expand, mostly for one year through 2008, several energy tax credits, including extending a renewable energy credit for producing electricity; clean renewable energy bonds; and performance standards for sub-bituminous coal in advanced coal generation. Other credits include extensions of a deduction for energy efficient commercial buildings; a credit for new energy-efficient homes; a credit for residential energy-efficient property; a special rule for qualified methanol or ethanol fuel; and a special depreciation allowance for cellulosic biomass ethanol plant property.

Bill Extending Program That Funds Abandoned Mine Cleanup Work Gains Approval -- The Senate, on December 9, 2006, extended a program that pays for the cleanup of abandoned or inadequately restored mine sites through fees on current coal production. After the House of Representatives approved the measure, the Senate passed the 15-year reauthorization of the abandoned mine land program as part of a larger bill, the Tax Relief and Health Care Act of 2006 (H.R. 6111). The abandoned mine land program charges coal mining companies a per-ton fee and uses the money to pay for remediation of sites that were abandoned or inadequately restored before environmental standards were established under the 1977 Surface Mining Control and Reclamation Act. The legislation would rework the program's allocation formula to ensure a larger share of future abandoned mine funding goes to the eastern states, which reportedly have the most pre-1977 mining problems. The bill also would gradually reduce industry fees by 20 percent. By 2012, mining companies would pay 28 cents per ton for surface-mined coal and 12 cents for underground coal, compared with the current rate of 35 cents for each ton of surface-mined coal and 15 cents for underground coal.

Approved Measure Would Expand LUST Fund Uses -- The Senate approved a measure on December 8, 2006, allowing expanded uses of the Leaking Underground Storage Tank (LUST) Trust Fund. The measure codifies and updates a list of permitted expenditures from the LUST fund that was included in the Energy Policy Act of 2005 (Pub. L. No. 109-58). Approved by unanimous consent, the measure is awaiting President Bush's signature. The House of Representatives passed the measure on December 8, 2006, as H.R. 6111 as part of the Tax Relief and Health Care Act. The legislation would permit the fund to be used for corrective actions for the release of methyl tertiary butyl ether and other oxygenated fuel additives; secondary containment on tanks; expanded inspections of tanks; tank operator training; expanded enforcement; improved prevention measures and compliance; and development of a strategy for addressing releases on tribal lands.



The LUST Trust Fund is financed by a 0.1 cent tax on each gallon of motor fuel sold nationwide. The federal UST program receives approximately \$70 million each year, of which an average of greater than 80 percent (approximately \$56 million) is allocated for use in the administration, oversight, and cleanup of sites within the states and tribal areas. EPA has used the remaining money for negotiating and overseeing cooperative agreements, implementing programs on tribal lands, and supporting regional and state offices.

Pipeline Safety Bill Ready For President's Signature -- The Senate passed legislation on December 7, 2006, to reauthorize federal pipeline safety programs, clearing the measure for President Bush to sign it into law. The House of Representatives had approved the Pipeline Inspection, Protection, Enforcement, and Safety Act of 2006 (H.R. 5782) on December 6, 2006. The bill would establish pipeline safety requirements to be carried out by the Department of Transportation's (DOT) Pipeline and Hazardous Materials Safety Administration and authorize funding. The 2002 pipeline safety law expired September 30, 2006. Under the bill, the DOT Secretary would: regulate low-stress pipelines; establish new pipeline safety and damage protection provisions; be given authority for emergency waivers of pipeline safety rules without notice and comment; require that pipeline operators establish a human factors management plan for pipeline control rooms; and provide legislative recommendations on natural gas pipelines.

Incentives For Brownfields Redevelopment Passed -- On December 9, 2006, the Senate approved tax incentives to encourage private developers to clean up brownfields sites, including contaminated petroleum sites, which would be extended and expanded under a wide-ranging tax bill that is now set for President Bush's signature. The brownfields provision, included in H.R. 6111, would allow a developer to write off the costs of cleaning up a brownfields site in the year the cleanup takes place instead of capitalizing the cost over a period of several years. The tax incentive had been in place since 1997, but it expired December 31, 2005. The legislation would extend the incentive to December 31, 2007, and would be retroactive. The measure reportedly also includes a provision that allows for the first time developers that want to redevelop petroleum contaminated sites, such as former gas stations, to claim the tax incentive.

Fisheries Reform Bill Awaits President Bush's Signature -- President Bush is expected to sign the first reauthorization in ten years of the 1976 Magnuson-Stevens Act (PL 94-265). The House of Representatives approved the bill (H.R. 5946) on December 9, 2006. The bill gives the eight regional councils that regulate offshore fishing two years to develop and implement plans to end overfishing and ten years to rebuild overfished stocks. The bill aims to make the regional councils base their annual catch limits on scientific projections. It also directs the regional councils to establish accountability measures, though it does not specify how to do so. The bill had been stalled for months over disagreement about how far to go in restricting overfishing.



MISCELLANEOUS

ATSDR Announces Availability Of Toxicological Profiles -- On November 24, 2006, the Agency for Toxic Substances and Disease Registry (ASTDR) announced the availability of one new and five updated final toxicological profiles of priority hazardous substances comprising the eighteenth set prepared by ATSDR. They are: cyanide, hydrogen cyanide, sodium cyanide, potassium cyanide; dichlorobenzenes, 1,2-dichlorobenzene, 1,3-dichlorobenzene, 1,4-dichlorobenzene; 1,4-dioxane; hydrogen sulfide; 1,1,1-trichloroethane; and vinyl chloride. These documents are available at the ATSDR website at <http://www.atsdr.cdc.gov/toxpro2.html>.

Canada Announces Chemicals Management Plan And Takes First Steps -- On December 8, 2006, Canada announced its Chemicals Management Plan, which is intended to regulate chemicals that are harmful to human health or the environment. Canada completed categorization of the 23,000 existing substances on its Domestic Substances List (DSL) to identify those substances that are inherently toxic to humans or to the environment and that might be: persistent; and/or bioaccumulative; and substances to which people might have greatest potential for exposure.

Under this categorization scheme, approximately 4,000 substances need additional attention. Categorization results may be searched by name or CAS Number on the Internet at http://www.ec.gc.ca/CEPARRegistry/subs_list/dsl/dslsearch.cfm.

The December 9, 2006, issue of the Canada Gazette includes several notices from Environment Canada and Health Canada regarding the DSL categorization, including:

- Environment Canada and Health Canada identified 148 substances on the DSL for which they propose to take no further action. According to the notice, the 148 substances meet the criteria for persistence, bioaccumulation, and inherent toxicity to non-human organisms. Because the agencies identified no current manufacture or importation activity for the substances above 100 kilograms per calendar year (kg/year), they propose that the listed substances be subject to the Significant New Activity provisions, to ensure that any new manufacture, import, or use of any of these substances in quantities greater than 100 kg/year is notified and will undergo ecological and human health risk assessments. Comments are due in 60 days. The notice is available on the Internet at <http://canadagazette.gc.ca/partI/2006/20061209/html/notice-e.html#i6>.
- Environment Canada and Health Canada published a notice of intent to develop and implement measures to assess and manage the risks posed by certain substances to the health of Canadians and their environment.



These measures apply to approximately 200 substances identified by categorization of the DSL as being: (1) persistent, bioaccumulative, and inherently toxic to the environment and that are known to be in commerce in Canada; and/or (2) a high hazard to humans and as having a high likelihood of exposure to individuals in Canada. For each of the substances, the agencies will publish documentation of the information in their possession. The documentation will summarize the scientific information and any relevant uncertainties; specify the information necessary for improved decision-making; and, where appropriate, require submission of this data; and (3) outline how this information will be used in decisions. After receiving data from interested parties, the agencies will use the information to develop and benchmark best practices for risk management, product stewardship, and virtual elimination. The notice identifies the first batch of 15 substances, for which the agencies intend to publish documentation in **January 2007**, and the second batch of 17 substances. The agencies intend to complete their review within three years of the commencement of this action. The notice is available at <http://canadagazette.gc.ca/partI/2006/20061209/html/notice-e.html#i5>.

CPSC Votes To Approve Petition Regarding Lead -- On December 11, 2006, the Consumer Product Safety Commission (CPSC) voted unanimously to approve a petition submitted by the Sierra Club to initiate a rulemaking to regulate the amount of lead in children's jewelry to a no more than 0.06% by weight. The Commission instructed CPSC staff to prepare an advance notice of proposed rulemaking (ANPR) for publication in the *Federal Register* at some unspecified point in the future. According to the petition, lead may result in adverse health effects if children are exposed to it at specific levels. The petition urged CPSC to ban lead in children's jewelry under the Federal Hazardous Substances Act.

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