



Recent Federal Developments July 15, 2009

TSCA/FIFRA/NTP/EPCRA

EPA Issues ANPR On Testing Of Certain Nonylphenol And Nonylphenol Ethoxylate Substances -- On June 17, 2009, the U.S. Environmental Protection Agency (EPA) issued an advance notice of proposed rulemaking (ANPR) for aquatic and sediment toxicity testing under Toxic Substances Control Act (TSCA) Section 4 for nonylphenol (NP) and nonylphenol ethoxylates (NPE), and requested comment on gathering data under TSCA and through other means to facilitate the evaluation of industrial laundry worker exposure to NPEs. 74 Fed. Reg. 28654. The rule is derivative of the June 6, 2007, petition submitted by the Environmental Law and Policy Center, the Sierra Club, the Pacific Coast Federation of Fishermen's Associations, the Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE under TSCA Section 21 to initiate rulemaking proceedings under TSCA Sections 4 and 6 for these substances. EPA granted the petitioners' request for chronic aquatic toxicity testing and a few other aspects of the petitioners' TSCA Section 4 request, but denied all of the petitioners' Section 6 requests. Subsequently, on October 24, 2007, the petitioners filed suit in the U.S. District Court for the Northern District of California challenging EPA's denial of the TSCA Section 21 petition. The lawsuit was mediated and, in an agreement signed on December 30, 2008, the parties settled the case. EPA seeks comment on which chemicals it should test; which acute and chronic aquatic tests it should require; which freshwater species should be tested; and whether a saltwater fish should be tested. Comments must be received on or before **September 15, 2009**.

EPA SNURs Include Multi-Walled And Single-Walled Carbon Nanotubes -- On June 24, 2009, EPA promulgated significant new use rules (SNUR) under TSCA Section 5(a)(2) for 23 chemical substances that were the subject of premanufacture notices (PMN). 74 Fed. Reg. 29982. According to EPA, four of these chemical substances, including multi-walled carbon nanotubes (generic) (MWCNT) and single-walled carbon nanotubes (SWCNT) are subject to TSCA Section 5(e) consent orders issued by EPA. Under the SNURs, persons who intend to manufacture, import, or process any of these substances for an activity that is designated as a significant new use must notify EPA at least 90 days before commencing that activity. Once notified, EPA will evaluate the intended use and, if necessary, prohibit or limit that activity before it occurs. The effective date of the rule is **August 24, 2009**, without further notice, unless EPA receives written adverse or critical comments, or notice of intent to submit adverse or critical comments before **July 24, 2009**. If EPA receives written adverse or critical comments, or notice of intent to submit such comments before **July 24, 2009**, EPA will withdraw the relevant sections of the direct final rule before its effective date. EPA will then issue a proposed SNUR for the chemical substance(s) on which adverse or critical comments were received, providing a 30-day period for public comment. For persons intending to import or export any of the chemical substances in this rule, they are subject to the TSCA Section 13 import certification requirements and the export notification provisions of TSCA Section 12(b) as of **July 24, 2009**.



EPA states that, for the four PMN substances subject to consent orders, including MWCNTs and SWCNTs, EPA determined that activities associated with the PMN substances “may present unreasonable risk to human health or the environment.” The consent orders require protective measures intended to limit exposures or otherwise mitigate the potential unreasonable risk. The 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

According to EPA, where it determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA Section 5(e) consent order usually requires that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCEL provisions in TSCA Section 5(e) consent orders, which are modeled after Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. EPA notes that no comparable NCEL provisions for SNURs currently exist in 40 C.F.R. Part 721, Subpart B, however, and that for these cases, the individual SNURs in 40 C.F.R. Part 721, Subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the Section 721.63 respirator requirements may request to do so under Section 721.30. EPA expects that persons whose Section 721.30 requests to use the NCELs approach for SNURs are approved by EPA will be required to comply with NCEL provisions that are comparable to those contained in the corresponding TSCA Section 5(e) consent order for the same chemical substance.

EPA Launches Protection Team To Explore Bee Deaths -- On June 23, 2009, EPA announced the formation of a pollinator protection team to expand EPA’s inquiry into the possible causes of declines in pollinators, especially U.S. honey bee populations. The multi-disciplinary team will address the potential risks that pesticides may contribute to what is known as colony collapse disorder. The team will explore possible approaches, tools, and resources for reducing the potential risks of pesticides to pollinators. The team has also developed a strategic plan that focuses on three main goals for guiding EPA’s work and direction in protecting pollinators in the years ahead: advancing EPA’s scientific knowledge and assessment of pesticide risks to pollinators; improving risk management tools for mitigating potential risks to pollinators; and increasing and broadening EPA’s collaboration and communication with governmental and non-governmental organizations and the public in addressing pollinator issues. EPA has been working on multiple fronts to protect honey bees through regulatory, voluntary, and research programs. Since colony collapse disorder first focused attention on honey bee declines beginning in 2006, however, EPA has been reassessing its approach to pollinator protection.



EPA Schedules External Peer Review For Draft Toxicological Review Of Pentachlorophenol -- On June 29, 2009, EPA announced that Versar, Inc., an EPA contractor for external scientific peer review, will convene an independent panel of experts, organize, and conduct an external peer-review workshop to review the external review draft document titled, "Toxicological Review of Pentachlorophenol: In Support of Summary Information on the Integrated Risk Information System (IRIS)." 74 Fed. Reg. 31030. The draft document was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development (ORD). EPA will consider public comments and recommendations from the expert panel workshop as EPA finalizes the draft document. The draft document and EPA's peer-review charge are available primarily via the Internet on NCEA's home page under the Recent Additions and Publications menus at <http://www.epa.gov/ncea>. The external peer review will take place on **August 4, 2009**. Please consult the *Federal Register* for more information.

EPA Issues SNUR For Dodecanedioic Acid And Thiophene -- On July 8, 2009, EPA issued a SNUR for dodecanedioic acid, 1,12-dihydrazide (CAS No. 4080-98-2), which is a raw material used for coating, sealing, and curing, and thiophene, 2,5-dibromo-3-hexyl (CAS No. 116971-11-0). 74 Fed. Reg. 32460. The final rule requires persons who intend to manufacture, import, or process either of these two substances for a use that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity. EPA believes that this action is necessary because these chemical substances may be hazardous to human health and the environment. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs. The rule is effective on **August 7, 2009**.

EPA Withdraws Guidance For Submission Of Probabilistic Human Health Exposure Assessments -- In a July 15, 2009, *Federal Register* notice, EPA announced the withdrawal of the pesticide science policy document entitled "Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs." 74 Fed. Reg. 34341. According to EPA, this science policy document was intended to establish guidance for submission and review of probabilistic human health exposure assessments to EPA's Office of Pesticide Programs (OPP). The notice states that the guidance has been superseded by EPA's "Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity," and by the "Guidance for Performing Aggregate Exposure and Risk Assessment."

EPA Announces Lead Wheel Balancing Weights Petition -- On July 15, 2009, EPA announced receipt of a TSCA Section 21 petition requesting that EPA establish regulations prohibiting the manufacture, processing, and distribution in commerce of lead wheel balancing weights. 74 Fed. Reg. 34342. EPA must either grant or deny the petition within 90 days of filing. The petition incorporates by reference a previous petition submitted by the Ecology Center on May 13, 2005, which requested a very similar action. In that petition, the Ecology Center asked EPA to prohibit



the manufacturing, processing, distribution in commerce, and use and improper disposal of lead wheel balancing weights. EPA denied that petition on August 8, 2005. In the current petition, petitioners note that on August 29, 2008, EPA announced its voluntary National Lead-Free Wheel Weight Initiative (NLFWWI). According to petitioners, no more than one-third of the lead wheel weight market would potentially be changed to lead-free due to the NLFWWI. Petitioners also point to recent state actions to address wheel balancing weights: in 2008, Vermont banned lead wheel balancing weights on state-owned vehicles by January 1, 2010, and in new motor vehicles as of January 1, 2011; on April 28, 2009, Washington instituted a ban on lead wheel balancing weights effective January 1, 2011; and California, Iowa, and Maine have similar proposals under consideration. Comments are due **July 30, 2009**. The petition and information submitted by the Ecology Center and the Sierra Club, *et al.* are available in the docket at <http://www.regulations.gov>, under EPA-HQ-OPPT-2009-0467.

CAA/CWA

EPA Issues National Recommended Water Quality Criteria For Acrolein And Phenol -- On June 10, 2009, EPA announced the availability of updated national recommended water quality criteria for acrolein and phenol. 74 Fed. Reg. 27535. These criteria are based on EPA's Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000), EPA-822-B-00-004 (2000 Human Health Methodology) and supercede criteria for these chemicals previously published by EPA. EPA's recommended Clean Water Act (CWA) Section 304(a) water quality criteria are guidance to States and authorized Tribes in adopting water quality standards for protecting human health and provide guidance to EPA for promulgating Federal regulations under CWA Section 303(c), when such action is necessary.

EPA Issues Final Rule Expanding List Of National Volatile Organic Compound Emission Standards For Aerosol Coatings -- On June 23, 2009, EPA issued a final rule amending the National Volatile Organic Compound Emission Standards for Aerosol Coatings (aerosol coatings reactivity rule), which establishes national reactivity-based emission standards for the aerosol coatings category (aerosol spray paints) under Clear Air Act (CAA) Section 183(e). 74 Fed. Reg. 29595. The amendments add compounds and associated reactivity factors to Table 2 -- Reactivity Factors based on petitions EPA received from regulated entities, and clarify which volatile organic compounds are to be quantified in compliance determinations. Additionally, the final rule makes certain changes related to the notice required for a company to certify that it will assume the responsibility for compliance with recordkeeping and reporting requirements for a regulated entity, and it also addresses which party is liable following such a certification. EPA also made minor revisions and corrections to the aerosol coatings reactivity rule. Finally, EPA extended the deadline for submitting the initial notifications required in one section of the aerosol coatings regulations for 30 days, until **July 31, 2009**. The final rule was immediately effective.



Court Issues Stay Of Decision Requiring Permits For Pesticide Applications -- On June 8, 2009, the U.S. Court of Appeals for the Sixth Circuit stayed until **April 9, 2011**, its ruling that will require anyone who applies a pesticide in, over, or near waters of the United States to obtain a CWA permit. *National Cotton Council of America v. EPA*, 6th Cir., No. 06-430. EPA had sought the two-year stay in a motion filed April 9, 2009.

Chamber Of Commerce Petitions EPA For Formal Hearing On Endangerment -- On June 23, 2009, the U.S. Chamber of Commerce petitioned EPA for a formal hearing before a neutral party on EPA's proposed finding that greenhouse gas emissions from vehicles endanger public health and welfare. The Chamber acknowledges that such a procedure has never been used under the CAA, but stated it has been used by OSHA and by the Department of Transportation (DOT). The procedure could take five or six years. According to the Chamber, this time is justified by the uncertainty of the science surrounding the endangerment finding. The petition questions the scientific evidence used in the technical support document that was the basis for the proposed endangerment finding. More information on the Chamber's petition is available at <http://www.uschamber.com/co2/default>.

EPA Issues Final Hazardous Emissions Rule For Small Copper And Aluminum Foundries -- On June 25, 2009, EPA issued final national emission standards for hazardous air pollutants (NESHAP) for copper, aluminum, and other nonferrous foundries that are area sources of toxic emissions. 74 Fed. Reg. 30366. The rule, which took effect immediately, amends 40 C.F.R. Part 63 to establish NESHAP. Area sources are stationary emissions sources that emit less than 10 tons per year of any single hazardous pollutant or less than 25 tons per year of any combination of air toxics. Area sources are required to meet the generally available control technology (GACT) standard to control hazardous pollutant emissions. A major source, which must meet the more stringent maximum achievable control technology (MACT) standard, emits more than 10 tons per year of any single hazardous pollutant or more than 25 tons per year of any combination of air toxics. EPA made revisions to the rule since it was proposed in February to clarify when the work practice requirements and emissions limits apply. Existing foundries will use their calendar year 2010 production to determine whether they meet the 600- or 6,000-tons-per-year thresholds. A foundry that does not meet either threshold in 2010 but later increases production to either level will have two years to comply with the emissions standards. Foundries that exceed either the 600- or 6,000-tons-per-year thresholds but later reduce production below either level will be subject to the rule. New foundries will not have to comply with the same requirements, using their startup melting capacity to determine compliance with the 600- or 6,000-tons-per-year thresholds. The final rule also modifies the visual emissions monitoring requirements that were first proposed. Foundries will be required to perform only weekly emissions observations following 30 consecutive days of no visual emissions. The proposed rule allowed weekly observation following 90 consecutive days with no observed visual emissions.



EPA Proposes NESHAP For Asphalt Processing And Asphalt Roofing Manufacturing -- On July 9, 2009, EPA proposed NESHAP for the control of emissions from the asphalt processing and asphalt roofing manufacturing area source category. 74 Fed. Reg. 32822. These proposed emissions standards for new and existing sources are based upon EPA's proposed determination as to what constitutes the GACT for the source category. Comments must be received on or before **August 10, 2009**, unless a public hearing is requested by **July 20, 2009**. If a hearing is requested on the proposed rule, written comments must be received by **August 24, 2009**.

EPA Releases Third National Assessment Of Toxic Air Pollutants -- On June 24, 2009, EPA released the latest version of a tool that estimates health risks from breathing air toxics in the United States. The National Air Toxics Assessment (NATA), based on 2002 air emissions data, is intended to assist federal, state, local, and tribal governments identify areas and specific pollutants for further evaluation to understand better risks they may pose. Air toxics are of concern because they are known to or are suspected of causing cancer and other serious health problems, including birth defects. The report assessed 180 air toxics plus diesel particulate matter from stationary sources of all sizes and from mobile sources such as cars, trucks, buses and construction equipment. The 2002 NATA estimates that most people in the United States have an average cancer risk of 36 in 1 million if exposed to 2002 emissions levels over the course of their lifetime. In addition, 2 million people -- less than one percent of the total U.S. population -- have an increased cancer risk of greater than 100 in 1 million. Benzene was the largest contributor to the increased cancer risks. The results are best used to prioritize pollutants and areas for further study, not as the sole basis for regulation or risk reduction activities. Since the 1990 CAA Amendments, air toxic emissions have decreased by 40 percent from all sources. More information on NATA is available at <http://www.epa.gov/nata2002>.

RCRA/SPCC

EPA Announces Reorganization And Name Change For OSW Within OSWER -- On June 25, 2009, EPA announced organization changes for the Office of Solid Waste (OSW) within the Office of Solid Waste and Emergency Response (OSWER). 74 Fed. Reg. 30228. On January 18, 2009, OSW was reorganized and changed its name to the Office of Resource Conservation and Recovery (ORCR). ORCR has three divisions, which consolidate the operations of the six divisions under the OSW structure. EPA believes the reorganization will create a more efficient structure, consistent with current program priorities and resource levels, and will enable EPA to better serve the needs of the public and its key stakeholders over the next 5-10 years. EPA has increased focus on resource conservation and materials management; it is expected that focus on this important aspect of the Resource Conservation and Recovery Act (RCRA) program will continue, while maintaining a strong waste management regulatory and implementation program. EPA is taking final action to amend the Code of Federal Regulations (C.F.R.) to reflect the reorganization and name change of the OSW. The rule was effective immediately.



EPA Extends Comment Period On Solid Waste Rule -- On July 6, 2009, EPA extended the deadline for comments on a petition filed by the Sierra Club asking EPA to reconsider its 2008 rule on the definition of solid waste. 74 Fed. Reg. 31905. The rule, which EPA stated aims to encourage recycling, removes certain secondary materials from regulation under RCRA. Comments are now due by **August 13, 2009**.

REACH

ECHA Publishes New Guidance Documents -- In a June 24, 2009, press release, the European Chemicals Agency (ECHA) announced the availability of three new Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program guidance documents. *Requirement for Substances in Articles* and *Registration Data and Dossier Handling* are ECHA's first two *Guidance in a Nutshell* publications, which is a new series of shortened versions of REACH guidance documents. The other document is entitled *Guidance Fact Sheet on the Inclusion of Substances in Annex XIV (List of Substances Subject to Authorisation)*. According to ECHA, the *Requirement for Substances in Articles* document explains in simple terms the main elements of ECHA's guidance. The summary is intended to assist companies producing, importing, and/or supplying articles in the European Union (EU) and in Liechtenstein, Iceland, and Norway. It clarifies the obligations companies have under REACH in relation to substances in articles, and, ECHA states, "also helps them make the right decisions to ensure that they comply with the REACH legislation." ECHA states that the document is also relevant to exporters outside the EU and will help them to understand the requirements for substances in articles their importers have to fulfill. The document is available at http://guidance.echa.europa.eu/docs/guidance_document/nutshell_guidance_articles2.pdf. ECHA intends the *Registration Data and Dossier Handling* document to provide a simple and concise introduction to the information content of registration dossiers. In particular, it focuses on the information requirements, *i.e.*, the data on physicochemical, toxicological, and ecotoxicological properties, and the chemical safety assessment. In addition, according to ECHA, the document provides practical guidance on how to prepare and submit a registration dossier, and describes essential follow-up activities required upon registration submission. The document is available on the Internet at http://guidance.echa.europa.eu/docs/guidance_document/nutshell_guidance.pdf. The Fact Sheet summarizes the key aspects of the respective REACH guidance document, which provides an overview of the various steps from the identification of substances of very high concern, to their inclusion in the candidate list, and further to their eventual inclusion in the authorization list. The Fact Sheet is available at http://guidance.echa.europa.eu/docs/guidance_document/fact_sheets/factsheet_inclusion_annexXIV_en.pdf.

ECHA Risk Assessment Committee Adopts First Opinion On Harmonized Classification -- On July 3, 2009, the ECHA Committee for Risk Assessment (RAC) agreed by consensus not to support a proposal to classify and label diantimony trioxide (DAT) as a skin irritant throughout the EU. RAC concluded that the data available are insufficient to justify the proposal. This is RAC's



first opinion on harmonized classification and labeling throughout the EU. ECHA will now forward RAC's scientific opinion, as well as supporting evidence and comments received during the public consultation, to the European Commission for a final decision. ECHA's July 6, 2009, press release is available on the Internet at http://echa.europa.eu/doc/press/pr_09_09_first_rac_opinion_20090706.pdf. According to ECHA's press release, RAC did not adopt the classification of "irritating to skin" due to the presence of other factors in the studies that may have contributed to skin irritation other than DAT. ECHA states that substantial heat and sweat were present in all cases where skin effects were described in workplace observations. ECHA also notes that it was unclear whether DAT was the only chemical substance to which workers were exposed. RAC did recommend that "due consideration be made by the relevant authorities and/or industry to adequately control the risks of any adverse effects to workers who are exposed in hot, sweaty conditions to fumes or dust containing DAT."

European Court Rules Monomers Covered By REACH -- On July 7, 2009, the European Court of Justice (ECJ) confirmed a preliminary ruling that the term "monomer substances" used in the EU's REACH chemicals legislation refers to "reacted monomers which are integrated in polymers," and not only to unreacted monomers that retain their chemical identities and properties after a polymerization process. As a result, monomers combined to form polymers will be subject to REACH registration requirements. This is consistent with the Luxembourg-based court's judgment (Case No. C-558/07, *The Queen, on the Application of S.P.C.M. SA v. The Sec'y of State for Environment, Food and Rural Affairs*, 2009 E.C.J.). The ruling also confirms an opinion of the ECJ's Advocate General, issued in March.

NANOTECHNOLOGY

PEN Announces Report On Contaminated Site Remediation -- On July 8, 2009, the Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies (PEN) announced the availability of an article entitled *Nanotechnology and In situ Remediation: A review of the benefits and potential risks*, which discusses the use of nanomaterials in the environmental cleanup process. According to the article, nanomaterials have the potential to reduce the costs and time of cleaning up contaminated sites, as well as eliminate the need for treatment and removal of contaminated soil in the cleanup process. The article cautions that full evaluation of the possible cleanup techniques should be undertaken to mitigate all potential adverse environmental effects. The article is available through *EHP-in-Press* at <http://ehp.niehs.nih.gov/docs/2009/0900793/abstract.html>.



FDA

FDA Transparency Task Force Holds Meeting -- On June 24, 2009, the Food and Drug Administration (FDA) Transparency Task Force held a public meeting to “develop recommendations for enhancing the transparency of the agency’s operations and decision-making process.” FDA, “FDA Forms Transparency Task Force” (June 2, 2009), is available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm163899.htm>. Over 30 presenters spoke in front of the Task Force and offered suggestions on the Task Force’s responsibility. The meeting composed of 11 panels with two to three presenters each. An archived web cast and a list of presenters is available on the Internet at <http://wpc.0172.edgecastcdn.net/000172/fda/FDA.htm>.

One of the most prominent topics was a general dissatisfaction with the Freedom of Information Act (FOIA) request process. Various points of contention with the FOIA request process were put forward. First, most speakers who acknowledged FOIA were distressed by the protracted wait for a response. A backlog of requests, combined with an inefficient response method led to thousands of responses taking years to complete. Many asserted that they had eventually been called by an FDA representative and asked if they still wanted the data, as it had been so long. Others noted that they had abandoned filing FOIA requests altogether. The other major issue brought up about FOIA requests was that the redaction performed by FDA was prohibitive. In many cases, speakers argued that the level of redaction went far beyond protecting necessary confidentiality. The line between protecting confidentiality and maintaining transparency through disclosure would remain a pertinent topic throughout the meeting.

Another concern which was highlighted was the importance of protecting valuable, confidential information that belonged to a person or business. The protection of so called “trade secrets” is seemingly in direct conflict with the problem of FOIA redactions, yet many speakers stressed that this was not, in fact, the case. For most who spoke, it was the restriction of data from studies, and not the detailed information about products that upset citizens and interest groups. People on both sides of the FOIA and confidentiality issues agreed that there was a middle ground between transparency and the protection of trade secrets. Where such a middle ground is, would be the main point of contention.

A point of agreement among most presenters was that FDA could improve transparency through initiating greater outreach programs. Beyond FOIA, many called for FDA to make much of its information and services available online so that the public can easily remain informed. FDA was applauded for its recent website upgrades as well as its new transparency blog (available at <http://fdatransparencyblog.fda.gov/>), but a few commenters maintained that FDA has much still to do.



Other comments and suggestions were offered, but those mentioned above were ideas that permeated throughout the session. The Task Force is also accepting written comments through the transparency blog or through <http://www.regulations.gov> under Docket Number FDA-2009-N-0247. Comments are due on or before **August 7, 2009**.

FDA Issues Anticounterfeiting Guidance -- On July 13, 2009, FDA posted on its website a draft document for comment entitled “Guidance for Industry, Incorporation of Physical-Chemical Identifiers into Solid Oral Dosage Form Drug Products for Anticounterfeiting.” The Guidance document is available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM171575.pdf>. FDA states in the introduction to the Guidance that it was prompted by actions being taken and/or considered by industry to add inks, pigments, flavors, and other physical-chemical identifiers (PCID) to Solid Oral Dosage Form (SODF) drugs (pills, capsules) to make it more difficult for counterfeiters to duplicate said drugs and make it easier for the public and health care professionals to identify the genuine version. The Guidance addresses the design of the PCID, the manner in which it is incorporated in the SODF, and the obligation of the manufacturer in so doing to communicate information about the addition to FDA. FDA outlines several aspects of an acceptable PCID. It can be used in pills and capsules, and also incorporated into packaging and containers. The lowest level of PCID possible should be utilized to allow identification and the substance chosen should be pharmaceutically inactive and relatively inert so that it qualifies as an excipient. It should be placed in a portion of the SODF away from the active ingredient so as to avoid degradation, and should be remote from any release controlling excipients so that the PCID will not interfere with a release rate designed for the drug. The Guidance provides input on the actions the manufacturer should take to minimize the toxicological risk of any PCID utilized. The main recommendation FDA makes is for the manufacturer to use permissible direct food additives, including those affirmed as Generally Recognized as Safe (GRAS) or those listed in the FDA Inactive Ingredient Guide. If used in packaging or in a container, the same general considerations apply that apply to the incorporation of food contact substances, such as determining that the PCID will not migrate unacceptably from the packaging to the drug product. The Guidance concludes with information on reporting changes for pre-marketing and post-approval addition of PCIDs to SODFs, and to containers and packaging. It describes the several reporting categories that might apply. FDA has requested that comments on the Guidance be submitted by **October 13, 2009**.

LEGISLATIVE DEVELOPMENTS

House Subcommittee Holds Hearing On New IRIS Process -- On June 11, 2009, the House Committee on Science and Technology’s Subcommittee on Investigations and Oversight held a hearing entitled “Fixing EPA’s Broken Integrated Risk Information System.” Witnesses included John Stephenson, Director, Natural Resources and the Environment, Government Accountability Office (GAO), and Kevin Teichman, Deputy Assistant Administrator for Science,



ORD, EPA. Opening statements and witness testimony are available on the Internet at http://science.house.gov/publications/hearings_markups_details.aspx?NewsID=2485. The hearing was intended to explore the effectiveness of the restructured IRIS process implemented by EPA Administrator Lisa Jackson on May 21, 2009. Witnesses agreed that the new IRIS process was an improvement, but Stephenson remained uncertain about the effectiveness of the 23-month schedule for IRIS, as well as the purposes of some of the scheduled interagency consults. Subcommittee Chair Brad Miller (D-NC) expressed concerns about EPA's ability to maintain control of the process against outside pressure from other agencies and organizations. Representative Paul Broun (R-GA) expressed particular concern with the transparency of the new process. Questions about the publication of materials regarding the process yielded little from Teichman. He maintained that all submitted written material, whether used in the final assessment or not, would be included in the final IRIS report. When pressed on whether points and topics from oral discussions at IRIS meetings could be included, Teichman was unclear. The Subcommittee then stressed the need for continued monitoring of the IRIS process, and stated that both the Subcommittee and the GAO will remain vigilant. Issues discussed during the hearing included: maintaining the new IRIS schedule, as well as IRIS effectiveness -- more specifically, whether the lack of an advanced waiting period will allow other organizations to begin research, and the possible consequence of insufficient data; the "New Transparency" of the program and whether it will allow for greater disclosure of the process both from dialogue within and external to EPA; providing EPA adequate control to oversee the IRIS program without interference from other agencies and organizations; and separating EPA's scientific IRIS process from the influence of regulatory entities.

House Passes Climate Control Bill -- The House of Representatives took the first step toward the enactment of comprehensive climate control when it passed the American Clean Energy and Security Act (commonly referred to as the Waxman-Markey Clean Energy Bill) on June 26, 2009. The vote was 291 to 212. The measure is the first time that the House has acted to limit the growth of so-called greenhouse gas emissions. The levels set in the bill call for a 17% reduction by 2020 from 2005 levels, and an 83% reduction by 2050, said reductions to be made possible primarily by a cap-and-trade system. According to the Committee on Energy and Commerce summary of Waxman-Markey, electrical utilities would be required to meet 20% of their electricity demand through renewable energy sources and energy efficiency by 2020. Waxman-Markey also provides for the investment of \$190 billion in new clean energy and energy efficiency technologies. These new technologies include carbon capture and sequestration, electric and other advanced technology vehicles, and basic research. There will be energy-saving standards for buildings, appliances, and industry. Investments in preventing tropical deforestation are calculated to achieve additional reduction in carbon emissions. The bill also has provisions to give consumers protection against energy price increases due to the additional costs that manufacturers and suppliers will face to be in compliance. At this point, the Congressional Budget Office predicts that the legislation will cost the average family less than 50 cents per day in 2020, but there is significant disagreement on the part of Republicans



regarding this figure. The climate control bill is a highly controversial piece of legislation, and the House vote reflects the division over the provisions in the bill. The Democrats lost 44 votes but gained 8 Republican votes, and those votes represented the margin of victory. Republicans had speculated that the needed votes were not there, and now, according to AOL News, some Republicans such as James Inhofe of Oklahoma are saying that the “razor thin vote in the House spells doom in the Senate.” While Democrats are stating that Waxman-Markey will create millions of green jobs in the renewable energy business (wind, solar, electric vehicle, etc.), Republicans are saying the measure is the largest tax increase in history. House Republican leader John Boehner of Ohio said after passage that the tax on everyone driving a car or flipping on a light switch will drive up the cost of food, gasoline, and electricity. The controversial nature of Waxman-Markey is further exemplified by the fact that the Rules Committee put in a 309 page managers amendment to the bill at 3:00 a.m. on the day of the vote. Few are yet familiar with all of the provisions in that package that passed. The amendment is said to contain provisions that Republicans hoped would hinder passage, and “pet” projects for constituents of the bill proponents. There is a provision dealing with requirements for Federal agency renewable energy purchases and provisions dealing with transmission line planning and siting, and the jurisdiction of the Federal Energy Regulatory Commission (FERC) regarding same. The states have been reluctant to concede this jurisdiction to FERC. There are also provisions dealing with green buildings, industrial energy efficiency, credit markets, industrial emissions, worker training, building codes, and agricultural and forestry related offsets. The scene will now shift to the Senate. The Majority Leader, Harry Reid (D-NV) has indicated the Senate will consider climate control in the fall. Republicans are already focusing on the claim that Waxman-Markey is a tax on Americans making less than \$250,000, in direct violation of a pledge made by the President. Republicans also want to explore alternatives to the cap-and-trade provisions of the House bill, namely increased use of nuclear power, as a way to achieve reduction of emissions.

Appropriations For EPA For The Fiscal Year Ending September 30, 2010 -- In the week preceding adjournment for the Independence Day Holiday, the House of Representatives and the Senate took action regarding the appropriations for EPA for fiscal 2010. The full House passed an appropriations bill containing \$10.5 billion for EPA by a vote of 254-173. Among the major programs funded was science and technology, which received almost \$850 million for air quality, climate protection, and homeland security. Research programs include clean air, clean water, human health and ecosystems, hydraulic fracturing, and air quality. Environmental programs and management received over \$3 billion for programs such as the Sunwise project, air quality monitoring at schools, brownfields, climate protection and enforcement and environmental protection. Monies were allocated for the Great Lakes Restoration initiative, the Chesapeake Program, the Puget Sound Action Agenda, the Long Island Sound Restoration and Gulf of Mexico, Lake Pontchartrain, and Lake Champlain Programs. In a related matter, the appropriations bill restored funding for the United States Department of Agriculture Chemical Use Survey. The survey contains information on major row crops, post-harvest chemical use and



alternating annual fruit, nuts and vegetable chemical use state by state and nationally. Both environmental and industry groups wanted the survey reinstated, since it is the only public source of information regarding crop protection and fertilizer use.

The House Appropriations bill provides for slightly more money than the bill reported out of the Senate Appropriations Committee on June 18 by a 30-0 vote. That bill provides \$10.19 billion for EPA and includes priorities identified by the Appropriations Committee in its summary. The first of those is \$3.63 billion for water and sewer infrastructure, which will fund 1,327 sewer and drinking water projects nationwide. The next priority is environmental programs and management activities, including monies for climate protection, with some focus on greenhouse gas reporting. \$748 million is slated for protection programs focused on regional water bodies with the majority going to the Great Lakes Restoration initiative. Other highlights include \$1.31 billion for the Superfund program and \$843 million for science and technology programs.

Update On Chemical Security -- The Chemical Facilities Antiterrorism Act of 2009 was reported by the House Homeland Security Committee 18-11 and now must be considered by the Energy and Commerce Committee, since the measure includes provisions dealing with drinking water -- the province of Energy and Commerce. The bill seeks to make permanent a temporary system that expires on October 4, including new provisions for chemical handling facilities. The regulations would be extended to wastewater facilities, giving the Department of Homeland Security jurisdiction, and would give oversight over drinking water plant security to EPA. The House Committee rejected an effort by Republican members to remove from the bill requirements relating to inherent safer technology or "IST." Those provisions could require manufacturers operating high risk facilities to switch to less hazardous chemicals or alter operations at the facilities. The thrust of the IST provision was muted somewhat by amendments that require chemical handling facilities to assess methods to reduce the consequences of a terrorist attack and make changes to their chemicals or operations if the changes are feasible and would not impede the continued operation of the facility.

The Senate has yet to draft a bill, according to reports in the trade press quoting the Homeland Security and Governmental Affairs Committee majority counsel. The issues of IST and the inclusion of wastewater and drinking water treatment plants are expected to continue to be debated as the bills move forward in both houses, as will the inclusion of a private right to sue proviso. In the interim, a one year extension of the present temporary chemical security rules is likely. The present House and Senate Appropriations bills provide for such an extension if no final measure passes prior to the October 4 expiration date.

MISCELLANEOUS

National Conversation On Public Health And Chemical Exposure Holds Kick-Off Meeting -- On June 26, 2009, the Center for Disease Control and Prevention's National Center for



Environmental Health (NCEH) and the Agency for Toxic Substances and Disease Registry (ATSDR) launched the National Conversation on Public Health and Chemical Exposure. NCEH/ATSDR intended the meeting to launch a “collaborative initiative to identify and prioritize actions for strengthening the public health approach to chemical exposures.” The program included planned speakers, as well as time for public comments and breakout sessions to provide an opportunity for dialogue within smaller groups. More information about the National Conversation is available at <http://www.atsdr.cdc.gov/nationalconversation/>.

The meeting opened with speakers outlining the 18-month program, as well as goals for the day. Howard Frumkin, Director of NCEH/ATSDR, broke down the six topics on which work groups would focus: monitoring; scientific understanding; policies and practices; chemical emergencies; serving communities; and education and communication. These six topics also were the focus of six breakout groups that met and discussed possible goals and ideas for the future work groups. The work groups are accepting nominations for membership until **July 20, 2009**. More information regarding the nomination process is available at <http://guest.cvent.com/EVENTS/Info/Custom.aspx?cid=21&i=34667fd0-5fb9-446b-9c8d-0e9ccd1ae7cf..>

The meeting included an open comments session, during which private citizens and representatives of environmental justice and environmental interest groups spoke. The comments were mostly critical of ATSDR’s past public health assessments and their perceived shortcomings, as well as a call for the “conversation” to lead to direct action by NCEH/ATSDR. Other concerns expressed included the lack of scientific knowledge that goes into chemical policymaking, safer chemical substitutes to protect workers, reevaluation of existing chemicals, and reform of TSCA.

White House CEQ Considers Plan To Update Water Projects Guidelines -- On July 1, 2009, the White House Council on Environmental Quality (CEQ) announced that it is considering a broad revision of environmental review standards for federal water projects and is seeking public input on those revisions. 74 Fed. Reg. 31415. CEQ reported in the *Federal Register* notice that the Administration “is considering developing uniform planning standards for the development of water resources that would apply government-wide, including agencies other than the traditional water resources development agencies.” The primary agency that would be affected would be the Corps of Engineers. Other agencies traditionally involved in water resource development, to a lesser degree, are the Interior Department’s Bureau of Reclamation, the Agriculture Department’s Natural Resources Conservation Service, and the Tennessee Valley Authority. CEQ stated the contemplated revision would apply to federal water resources implementation studies, including project reevaluations and modifications except those commenced prior to the issuance of the revised guidelines. Comments are due by **July 17, 2009**. For more information, see <http://edocket.access.gpo.gov/2009/pdf/E9-15517.pdf>.



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