



## Recent Federal Developments April 15, 2009

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### TSCA/FIFRA/NTP/EPCRA

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#### ***EPA Convenes Public Meeting On Testing Of Certain High Production Volume Chemicals --***

On March 16, 2009, the U.S. Environmental Protection Agency (EPA) announced the scheduling of a public meeting on March 31, 2009, to provide an opportunity to comment on a proposed rule under Toxic Substances Control Act (TSCA) Section 4(a)(1)(B). 74 Fed. Reg. 11050. Section 4(a)(1)(B) requires manufacturers, importers, and processors of certain High Production Volume (HPV) chemical substances to conduct testing. EPA published a proposed rule under TSCA Section 4(a)(1)(B) to require manufacturers, importers, and processors of certain HPV chemical substances to conduct testing to obtain screening level data for health and environmental effects and chemical fate. EPA has determined preliminarily that each of the 19 chemical substances included in that proposed rule is produced in substantial quantities and that there is or may be substantial human exposure to each of them; there are insufficient data to reasonably determine or predict the effects on health or the environment of the manufacture, distribution in commerce, processing, use, or disposal of the chemicals, or of any combination of these activities; and the testing program proposed is necessary to develop such data.

***Implementation Of TRI Burden Reduction Provision Prohibited --*** In passing the Omnibus Appropriations Act, 2009, Congress prohibited EPA from implementing the 2006 Toxics Release Inventory (TRI) Burden Reduction Rule. Specifically, Section 425 of the Act states: “. . . none of the funds made available by this or any other Act may, hereafter, be used to implement the final rule promulgated by the Administrator of EPA entitled ‘Toxics Release Inventory Burden Reduction Rule’ (71 Fed. Reg. 76932); and . . . the final rule described in paragraph (1) shall have no force or effect. The affected regulatory text shall revert to what it was before the final rule described in paragraph (1) became effective, until any future action taken by the Administrator.” EPA intends to issue a rule reinstating the TRI procedures in effect before a 2006 rule was issued that reduced the reporting burden. The rule raised the limit below which the “short” form could be used from 500 pounds to 2,000 pounds per year.

***EPA Announces Strategic Plan For Evaluating Chemical Toxicity --*** On March 25, 2009, EPA announced the availability of a final document entitled *The U.S. Environmental Protection Agency’s Strategic Plan for Evaluating the Toxicity of Chemicals* (Strategic Plan). According to EPA, the purpose of the Strategic Plan is to serve as a blueprint for EPA in incorporating advances in molecular biology and computational sciences into toxicity testing and risk assessment practices across EPA. The Strategic Plan is centered on three interrelated components: toxicity pathways identification and use of this information in screening and prioritization of chemicals for further testing; the use of toxicity pathways information in risk assessment; and the institutional transition necessary to implement such practices across EPA. EPA states: “This Strategic Plan describes an ambitious and substantive improvement in the efficiency and effectiveness of the process by which environmental pollutants are evaluated for toxicity and risk.” A workgroup of EPA’s Science Policy Council oversaw the development of



the Strategic Plan, incorporating input obtained from an external peer review. The Strategic Plan is available on the Internet at [http://www.epa.gov/osa/spc/toxicitytesting/docs/toxtest\\_strategy\\_032309.pdf](http://www.epa.gov/osa/spc/toxicitytesting/docs/toxtest_strategy_032309.pdf).

EPA recently commissioned the National Research Council (NRC) of the National Academies to develop a long-range vision for toxicity testing and risk assessment. EPA states that NRC's 2007 report, *Toxicity Testing in the 21st Century: A Vision and a Strategy*, "envisions a landmark transformation that focuses on identifying and evaluating "toxicity pathways," *i.e.*, cellular response pathways responsible for adverse health effects when sufficiently perturbed by environmental agents under realistic exposure conditions." To build upon the changes advocated in the NRC document, while ensuring an internally coordinated and integrated approach, EPA established a Science Policy Council workgroup, which produced the Strategic Plan. According to EPA, the Strategic Plan "provides a framework for EPA to comprehensively move forward to incorporate this new scientific paradigm into future toxicity testing and risk assessment practices."

***NTP Announces Non-Cancer Evaluation Criteria*** -- At the annual meeting of the Society for Toxicology in mid-March, the National Toxicology Program (NTP) announced that it has developed new criteria to classify the outcomes from its non-cancer studies, including reproductive, developmental, and immunotoxicity studies. According to NTP, the new criteria build off the classification system established in 1983 by the NTP to evaluate its cancer studies. NTP will use five categories or levels of evidence to describe its non-cancer study findings: clear evidence; some evidence; equivocal evidence; no evidence; and inadequate study. NTP expects to begin applying the immunotoxicology criteria to studies for peer review by the end of **2009**. NTP states that the first reproductive and developmental studies featuring the new criteria could appear as early as **2010**. More information is available on the NTP website at <http://ntp-server.niehs.nih.gov/index.cfm?objectid=CCAEF1A9-F1F6-975E-7E0F2762A96CBD2B>.

***EPA Corrects Hazardous Chemical Reporting; Tier II Inventory Information*** -- On March 26, 2009, EPA promulgated a final rule correcting a technical error to the regulatory text in its November 3, 2008, final rule amending the Emergency Planning and Emergency Release Notification and Hazardous Chemical Reporting regulations. 74 Fed. Reg. 13124. EPA made an error in the November 2008 final rule, while reorganizing the instructions to the Tier II inventory form. EPA inadvertently listed one of the optional items, description of dikes and other safeguard measures, as a required item in 40 C.F.R. § 370.42(i)(9). The March 26, 2009, final rule corrects this error by deleting the phrase, "a description of dikes and other safeguard measures for each location listed" from 40 C.F.R. § 370.42(i)(9), and re-inserting this phrase into 40 C.F.R. § 370.42(i)(8), which has also been re-formatted to provide greater clarity. The final rule was effective March 26, 2009.



***NAC/AEGL Committee Will Meet April 14, 2009*** -- On March 26, 2009, EPA announced an April 14, 2009, meeting of the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee). 74 Fed. Reg. 13205. At the meeting, the NAC/AEGL Committee addressed aspects of the acute toxicity and the development of acute exposure guideline levels (AEGL) for the following chemicals: acrylonitrile; aldicarb; arsenic pentoxide; arsenic trichloride; calcium cyanide; carbofuran; diacetylmorphine; fluoroacetate salts; methomyl; methyl fluoroacetate; methyl iodide; methoxyethylmercuric acetate; monofluoroacetic acid; oxamyl; paraquat; perchloryl fluoride; perfluoroisobutylene; phencyclidine; phosgene; phosgene oxime; potassium cyanide; sodium cyanide; sodium fluoroacetate; tellurium hexafluoride; tetraethylpyrophosphate; tetramethylenedisulfotetramine; 1,1,1-trichloroethylene; and tungsten hexafluoride. Another meeting of the NAC/AEGL Committee is scheduled for **September 9-11, 2009**. Chemicals currently being considered for AEGL development at this meeting include: cadmium; dichlorvos; dicrotophos; dimethyl phosphite; fenamiphos; lead; methamidophos; mevinphos; monocrotophos; phosphamidon; red phosphorus; and trimethylphosphite.

***EPA Updates Guideline For Pesticide Registration*** -- On March 27, 2009, EPA announced that it will reject new applications for registering pesticide products containing unapproved inert ingredients, unless an applicant requests an approval and provides the necessary data. Under the Pesticide Registration Improvement Renewal Act (PRIA 2), EPA has 21 days after it receives a pesticide application to conduct an initial content screen to verify payment and confirm that all of the required forms, labeling, and data have been submitted. The initial content screen review worksheet lists all the basic elements of an application. More information on the screening process is available at <http://www.epa.gov/pesticides/fees/questions/pira21day-screen.htm>; the worksheet is available at [http://www.epa.gov/pesticides/fees/questions/pria21day\\_wrksht.pdf](http://www.epa.gov/pesticides/fees/questions/pria21day_wrksht.pdf).

***OECD Updates Chemical Testing Guidelines*** -- On March 27, 2009, the Organization for Economic Cooperation and Development (OECD) released an updated full list of OECD guidelines for testing of chemicals. The list has been updated to include tests adopted or updated in October 2008. OECD test guidelines are intended to represent a basic set of tools used in regulatory safety testing and subsequent chemical product notification and chemical registration. The updated list is available at <http://www.oecd.org/dataoecd/8/11/42451771.pdf>. More information on OECD's chemical testing guidelines is available at [http://www.oecd.org/departement/0,3355,en\\_2649\\_34377\\_1\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/departement/0,3355,en_2649_34377_1_1_1_1_1,00.html).

***EPA Amends The Toxic Substances Control Act Confidential Business Information Records Access System*** -- On April 7, 2009, EPA's Office of Pollution Prevention and Toxics (OPPT) issued a rule pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), giving notice that it proposes to amend the "Toxic Substance Control Act Confidential Business Information Records Access System" to "Confidential Business Information Tracking System (CBITS)" to correct the official name of the system of record notice (SORN), system location, and system



manager. 74 Fed. Reg. 15720. Persons wishing to comment on this SORN must do so by **May 18, 2009**.

***EPA Schedules PPDC Meeting*** -- On April 8, 2009, EPA announced the scheduling of a Pesticide Program Dialogue Committee (PPDC) PRIA Process Improvement Workgroup meeting on **April 20, 2009**. 74 Fed. Reg. 15968. The agenda will include a discussion of improvements in the consistency of labeling and in the content of and the ability to search the pesticide programs website. The workgroup is developing advice and recommendations on topics related to EPA's registration and registration review process. The meeting will be held on **Monday, April 20, 2009**.

***EPA Launches Redesigned ChAMP Website*** -- On April 8, 2009, EPA launched the redesign of its website for the Chemical Assessment and Management Program (ChAMP). According to EPA, it redesigned the website to provide easier navigation and to include new information and functions. The website now provides access to high and medium production volume (HPV and MPV) chemical prioritizations prepared by EPA that include hazard characterizations (HC), risk-based prioritizations (RBP), and hazard-based prioritizations (HBP). Under ChAMP, EPA is developing screening-level hazard, exposure, and risk characterizations for an estimated 6,750 chemicals produced or imported in quantities of 25,000 pounds or greater a year. Based on these assessments, EPA is prioritizing the chemicals to indicate whether additional exposure or hazard data and/or control measures may be needed to address potential hazards and risks. The redesigned ChAMP website is available at <http://www.epa.gov/champ/>.

The ChAMP website includes the following new information and functions:

- Schedule of chemicals for which EPA is developing RBPs and HBPs in 2009;
- The ability to search for completed RBPs or HBPs by Chemical Abstract Service number;
- The ability to submit comments on the prioritization process or on a chemical-specific prioritization;
- The methodology EPA uses to develop RBPs and HBPs under ChAMP;
- A summary of stakeholder input in developing the ChAMP chemical prioritization process; and
- Summaries of RBP and HBP decisions made by EPA to date.



EPA has also posted new RBPs for 69 chemicals and HBPs for 28 chemicals. The new RBPs and HBPs are identified in the summaries of RBP and HBP decisions made by EPA to date, and the RBP and HBP documents can be found on the chemical prioritizations web page.

***EPA Publishes Final List Of Initial Chemicals Selected For EDSP Screening*** -- On April 15, 2009, EPA published the final list of the first group of chemicals that will be screened under the Endocrine Disruptor Screening Program (EDSP). 74 Fed. Reg. 17579. The 67 chemicals identified for testing include pesticide active ingredients and HPV chemicals used as pesticide inert ingredients. According to the notice, the list includes chemicals that EPA, "in its discretion, has decided should be tested first, based upon exposure potential." EPA proposed a draft list of 73 chemicals in June 2007. For the final list, EPA deleted six chemicals based on recent information showing that the chemicals are no longer expected to be found in three exposure pathways. In separate notices, also published on April 15, 2009, EPA describes other aspects of the EDSP, such as the policies and procedures for initial screening (74 Fed. Reg. 17559), and the final test guidelines (74 Fed. Reg. 17479). EPA also announced the submission of an Information Collection Request concerning the EDSP to the Office of Management and Budget for review. 74 Fed. Reg. 17477. The final list of initial chemicals for screening includes the following chemicals:

Chemical Name	CAS Number
2,4-D	94757
4,7-Methano-1H-isoindole-1,3(2H)-dione,2-(2-ethylhexyl)-3a,4,7,7a-tetrahydro-	113484
Abamectin	71751412
Acephate	30560191
Acetone	67641
Atrazine	1912249
Benfluralin	1861401
Bifenthrin	82657043
Butyl benzyl phthalate	85687
Captan	133062
Carbamothioic acid, dipropyl-, S-ethyl ester	759944
Carbaryl	63252
Carbofuran	1563662
Chlorothalonil	1897456
Chlorpyrifos	2921882
Cyfluthrin	68359375
Cypermethrin	52315078
DCPA (or chlorthal-dimethyl)	1861321



Chemical Name	CAS Number
Diazinon	333415
Dibutyl phthalate	84742
Dichlobenil	1194656
Dicofol	115322
Diethyl phthalate	84662
Dimethoate	60515
Dimethyl phthalate	131113
Di-sec-octyl phthalate	117817
Disulfoton	298044
Endosulfan	115297
Esfenvalerate	66230044
Ethoprop	13194484
Fenbutatin oxide	13356086
Flutolanil	66332965
Folpet	133073
Gardona (cis-isomer)	22248799
Glyphosate	1071836
Imidacloprid	138261413
Iprodione	36734197
Isophorone	78591
Linuron	330552
Malathion	121755
Metalaxyl	57837191
Methamidophos	10265926
Methidathion	950378
Methomyl	16752775
Methyl ethyl ketone	78933
Methyl parathion	298000
Metolachlor	51218452
Metribuzin	21087649
Myclobutanil	88671890
Norflurazon	27314132
o-Phenylphenol	90437
Oxamyl	23135220
Permethrin	52645531
Phosmet	732116
Piperonyl butoxide	51036
Propachlor	1918167



Chemical Name	CAS Number
Propargite	2312358
Propiconazole	60207901
Propyzamide	23950585
Pyridine, 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)-	95737681
Quintozene	82688
Resmethrin	10453868
Simazine	122349
Tebuconazole	107534963
Toluene	108883
Triadimefon	43121433
Trifluralin	1582098

According to the notice, EPA removed two of the chemicals from the draft list, azinphos-methyl and fenvalerate, because all uses of these pesticides have ended or will end before Tier 2 data could be generated in 2012. EPA removed four other chemicals based on a reassessment of their uses that confirmed that they would only be expected to be present in two, instead of three, exposure pathways (*i.e.*, the criterion for selecting chemicals for the initial list was the presence of the chemical in at least three of the four exposure pathways where the food and occupational exposure pathways were represented). Specifically, EPA removed aldicarb, allethrin, dichlorvos, and methiocarb because changes in their use and application methods have eliminated the potential for exposure in one or more pathways.

The EDSP consists of a two-tiered approach. The purpose of Tier 1 screening, according to EPA, is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The purpose of Tier 2 testing is to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays. According to the notice regarding policies and procedures, EPA generally intends to commence Tier 1 screening of the first group of pesticide chemicals by issuing test orders under Section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA) to chemical companies identified as the manufacturer or processor of the identified chemicals and/or the pesticide registrants. EPA states that, “to address some of the more complex issues surrounding joint data development and the availability of data compensation and data protection, EPA intends to issue some orders jointly under” FFDCA Section 408(p)(5) and Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Each recipient of a test order would be directed to provide an initial response to EPA within 90 days of the issuance of the order. EPA states that this initial response is intended to be used to report the recipient’s commitment to act in response to the test order in one of several ways for each assay specified in the order, and may indicate a different response



commitment for each assay. In the notice, EPA states that it intends for the test orders to include a final submission due date of 24 months after the issuance of the order.

EPA states that it “generally intends to adopt a policy that encourages data developers to join forces and agree on how to share costs, and that also encourages companies entering the marketplace after the data are developed to pay reasonable compensation to those that developed the data.” According to EPA, to the extent permitted by FFDCA, the EDSP policies and procedures resemble the policies and procedures used for data call-ins under FIFRA.

***EPA Issues Final Test Guidelines*** -- On April 15, 2009, EPA announced the availability of several revised or updated test guidelines for the unified library of harmonized test guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS). EPA announced the availability of revised test guidelines under Series 830-Product Performance Test Guidelines, Series 835-Fate, Transport and Transformation Test Guidelines, and Series 860-Residue Chemistry Test Guidelines.

## **NANOTECHNOLOGY**

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***EP Approves Updated EU Legislation On Cosmetics That Addresses Nanomaterials*** -- On March 24, 2009, the European Parliament (EP) approved an update of European Union (EU) legislation on cosmetics. The regulation, which would replace 27 different regulations, addresses nanomaterials used as cosmetics ingredients. As requested by the EP, the new regulation introduces a safety assessment procedure for all products containing nanomaterials, that could lead to a ban on a substance if a risk to human health is identified. The EP also succeeded in requiring that any nanomaterials present in cosmetics be mentioned in the list of ingredients on the packaging. The new regulation also includes a definition of nanomaterials, which must be adapted by the European Commission (EC) in line with scientific and technological advances. Under the new regulation, nanomaterial would be defined as “an insoluble or bioresistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.” More information is available at [http://www.europarl.europa.eu/news/expert/infopress\\_page/066-52333-082-03-13-911-20090323IPR52331-23-03-2009-2009-true/default\\_en.htm](http://www.europarl.europa.eu/news/expert/infopress_page/066-52333-082-03-13-911-20090323IPR52331-23-03-2009-2009-true/default_en.htm).

***NIOSH Issues Updated “Approaches To Safe Nanotechnology”*** -- On March 31, 2009, the National Institute for Occupational Safety and Health (NIOSH) issued an updated and expanded edition of its document, “Approaches to Safe Nanotechnology.” The updated document reiterates NIOSH’s standing interim recommendation that employers take prudent measures to control occupational exposures in the manufacture and industrial use of engineered nanomaterials, as research advances for determining if such materials pose work-related health and safety risks. The new document reflects new scientific findings from ongoing research that have been published in the peer-reviewed scientific literature since the last revised draft version



of “Approaches” was issued in 2006. These include findings from NIOSH’s own strategic research program, as well as research by scientific partners from the U.S. and abroad. The revised document:

- Includes an expanded section on risk management, with a detailed discussion of factors that may affect occupational exposure to engineered nanomaterials, and expanded interim recommendations for controlling work-related exposures.
- Expands the discussion of exposure assessment and characterization for engineered nanomaterials, including a new summary table of instruments and measurement methods used in the evaluation of nanomaterial exposures.
- Is issued as a NIOSH numbered document, so that it can be cited more easily as a resource in peer-reviewed scientific publications. The original draft version in 2004 and the previous revised draft edition in 2006 were web-based electronic documents that did not have a formal NIOSH publication number.

The new document is available at [www.cdc.gov/niosh/docs/2009-125/](http://www.cdc.gov/niosh/docs/2009-125/).

***NIOSH Requests Data On CNTs*** -- On April 8, 2009, NIOSH published a notice announcing that it “intends to evaluate the scientific data on carbon nanotubes (CNTs) and develop appropriate communication documents, such as an Alert and/or Current Intelligence Bulletin [CIB], which will convey the potential health risks and recommend measures for the safe handling of these materials.” 74 Fed. Reg. 15985. CIBs are issued by NIOSH “to disseminate new scientific information about occupational hazards. A CIB may draw attention to a previously unrecognized hazard, report new data on a known hazard, or disseminate information on hazard control.” NIOSH is requesting the following information: (1) published and unpublished reports and findings from *in vitro* and *in vivo* toxicity studies with CNTs; (2) information on possible health effects observed in workers exposed to CNTs; (3) information on workplaces and products in which CNTs can be found; (4) description of work tasks and scenarios with a potential for exposure; (5) workplace exposure data; and (6) information on control measures (*e.g.*, engineering controls, work practices, personal protective equipment) that are being used in workplaces where potential exposures to CNTs occur. According to the notice, NIOSH has developed guidelines for managing the potential health concerns associated with occupational exposures to engineered nanoparticles, which “will provide the framework for developing specific recommendations for CNTs.” NIOSH’s guidelines, *Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered*



*Nanomaterials*, are available at <http://www.cdc.gov/niosh/topics/nanotech/safenano/>. Comments are due **May 15, 2009**.

### **CAA/CWA**

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***EPA Announces Public Hearings On Greenhouse Gases*** -- On March 25, 2009, EPA announced two public hearings to be held for the proposed rule “Mandatory Reporting of Greenhouse Gases.” 74 Fed. Reg. 12782. One hearing was held in Arlington, Virginia, on April 6-7, 2009. The other hearing will be held in Sacramento, California, on **April 16, 2009**. In a separate notice, issued on April 10, 2009, EPA proposed a regulation to require reporting of greenhouse gas emissions from all sectors of the economy. 74 Fed. Reg. 16448. The rule would apply to fossil fuel suppliers and industrial gas suppliers, as well as to direct greenhouse gas emitters. The proposed rule does not require control of greenhouse gases, rather it requires only that sources above certain threshold levels monitor and report emissions. Comments on the proposed rule are due by **June 9, 2009**.

***Supreme Court Allows EPA To Consider Cost To Utilities In Cooling Water Rules*** -- On April 1, 2009, the U.S. Supreme Court ruled that utility companies and regulators may apply a cost-benefit analysis under the Clean Water Act (CWA) in deciding what technology is needed to protect fish from being killed by large industrial cooling water intake structures. *Entergy Corp. v. Riverkeeper Inc.*, U.S., No. 07-588 (Apr. 1, 2009). The case was reversed and remanded to the Second Circuit. The Second Circuit ruling in 2007 is generally known as “*Riverkeeper II*.” Justice Antonin Scalia, writing for the majority, stated that the fact that the CWA “does not expressly authorize cost-benefit analysis” does not show “an intent to forbid its use.” Rather, it is “eminently reasonable” to conclude that the silence of the CWA on use of cost-benefit analysis in cooling tower regulatory cases “is meant to convey nothing more than a refusal to tie the agency’s hand as to whether cost-benefit analysis should be used, and if so to what degree.” Scalia was joined by Chief Justice John G. Roberts, Jr., and Justices Anthony Kennedy, Clarence Thomas, and Samuel A. Alito, Jr. Justice Steven G. Breyer wrote a separate opinion which concurred in part and dissented in part. Justice John Paul Stevens dissented, joined by Justices David H. Souter and Ruth Bader Ginsburg. Stevens wrote in the dissent that Congress “directly floreclosed” use of cost-benefit analysis in enacting the cooling tower provision of the Clean Air Act (CAA). The majority opinion “unsettles the scheme Congress established” with enactment of the CWA. Allowing a cost-benefit analysis “fundamentally weakens” the mandate of the statute, according to Stevens. Text of the U.S. Supreme Court’s *Entergy Corp. v. EPA* decision is available at <http://www.supremecourtus.gov/opinions/08pdf/07-588.pdf>.

***EPA Proposes Volatile Organic Compound Emission Standards For Aerosol Coatings*** -- On April 2, 2009, EPA proposed to amend the National Volatile Organic Compound (VOC) Emission Standards for Aerosol Coatings (aerosol coatings reactivity rule). 74 Fed. Reg. 14941. The VOC rule establishes national reactivity-based emission standards for the aerosol coatings



category (aerosol spray paints) under Section 183(e) of the CAA. The proposed action amends Table 2A of the aerosol coatings reactivity rule by adding compounds and associated reactivity factors based on petitions submitted to EPA; and by clarifying which VOCs are to be quantified in compliance determinations. Additionally, EPA proposed certain changes related to the notice required for a company to certify that it will assume the responsibility for compliance with record keeping and reporting requirements for a regulated entity, and taking comment on whether to change who is liable following such certification. Finally, EPA proposed minor revisions and corrections to the aerosol coatings reactivity rule. Comments must be received on or before **May 4, 2009**, unless a public hearing was timely requested. If a hearing was requested, written comments must be received by **May 18, 2009**.

***Sierra Club Petitions EPA To List Hydrogen Sulfide As A HAP*** -- The Sierra Club, and other public interest groups, filed a petition on March 30, 2009, to list hydrogen sulfide as a hazardous air pollutant (HAP). The petition states:

We assert that EPA must act to address adverse H<sub>2</sub>S impacts based on evidence of harmful exposures in numerous communities and its toxicological effects at low concentrations such as non-cancer effects and emerging evidence that H<sub>2</sub>S is a genotoxic agent, meaning it damages DNA. EPA has assessed the need to list H<sub>2</sub>S as a HAP, but no formal listing action has been taken. H<sub>2</sub>S is clearly an unlisted hazardous air pollutant.

According to the Sierra Club, in addition to listing hydrogen sulfide as a HAP, EPA should require annual reporting of hydrogen sulfide as a toxic substance under the TRI Program.

On January 25, 1999, Galveston Houston Association for Smog Prevention (GHASP) filed a petition asking EPA to list hydrogen sulfide as a HAP. On September 15, 2005, the Coalition sent a letter to David Guinnup, Office of Air Quality Planning and Standards (OAQPS), regarding Dr. Eric Winegar's findings that the hydrogen sulfide sensors overestimate and over report hydrogen sulfide to prompt EPA to review its contractor's findings.

## **REACH**

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***European Court Of Justice Determines REACH Requires Registration To Use Monomer Ingredients In Polymers*** -- On March 10, 2009, the European Court of Justice (ECJ) issued a preliminary ruling finding against four companies that had claimed that reacted monomers imported to the EU should not be subject to registration under the EU's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) law (Case No. C-558/07, *The Queen, on the Application of S.P.C.M. SA, et al. v. The Sec'y of State for Environment, Food and Rural Affairs*, 2009 E.C.J.). In an opinion by eight ECJ Advocates General, the advocates determined



that the term “monomer substances” used in the REACH regulation applies only to reacted monomers, and not to unreacted monomers in polymers, as the claimants had stated. The Advocate General’s opinion is nonbinding and may be overturned by the court when it gives its judgment. In this case, a final judgment is expected toward the end of the year. If the Advocate General’s opinion is upheld by the ECJ, manufacturers and importers of polymers will be required to register under REACH the pre-polymerization monomer ingredients of their products. The companies that filed the case stated that a requirement to register reacted monomers would be problematic for non-EU polymer manufacturers, because it could be difficult for non-EU manufacturers to obtain accurate information on monomers from their suppliers. This would be much easier for EU manufacturers, as their suppliers would also be subject to REACH, the complainants stated. Full text of the Advocate General Kokott’s opinion is available at <http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en>. Enter Case Number C-558/07 and click “submit.”

## **RCRA/SPCC**

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***EPA Delays Effective Date For SPCC Requirements*** -- On April 1, 2009, EPA announced its decision in delaying the effective date of the final rule to amending the Spill Prevention, Control, and Countermeasure (SPCC) regulations issued on December 5, 2008. 74 Fed. Reg. 14736. The amendments will now become effective on **January 14, 2010**. EPA requested public comment on whether a further delay of the effective date may be warranted. The amendments clarified regulatory requirements, tailored requirements to particular industry sectors, and streamlined certain requirements for facility owners or operators subject to the rule. With these changes, EPA expects to encourage greater compliance with the SPCC regulations, thus resulting in increased protection of human health and the environment. The amendments did not remove any regulatory requirement for owners or operators of facilities in operation before August 16, 2002, to develop, implement, and maintain an SPCC plan in accordance with the SPCC regulations then in effect. Such facilities are still required to maintain their plans during the interim until the applicable date for revising and implementing their plans under the new amendments. Information on the SPCC Rule is available at <http://www.epa.gov/emergencies/content/spcc/index.htm>. Comments on whether a further extension of the effective date may be warranted are due on or before **May 1, 2009**.

## **FDA**

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***FDA Announces Action On Reclassification Of Certain Medical Devices*** -- On April 9, 2009, the Food and Drug Administration (FDA) announced plans regarding the future reclassification of 25 Class III Medical Devices marketed since before the enactment of the Medical Device Amendments in 1976. 74 Fed. Reg. 16214. Those amendments permitted the devices in question, many of which are implants, life supporting or sustaining devices, or devices that present a potential unreasonable risk to health, to remain in commerce until FDA decided whether to reclassify them into lesser regulatory categories or require the submission of a



Premarket Approval Application (PMA) to obtain approval to continue to market. Subsequent devices of the same type were permitted to be marketed on the strength of a Premarket Notification or 510(k) notice until a decision was reached on final classification. Such a notice requires a lesser burden of proof than does a PMA. Various members of Congress, public health advocates, and other interested parties have been critical of FDA's failure to complete the reclassification, so that more evidence could be made available to support the marketing of the more hazardous of the pre-enactment products. Congress first called for FDA to act in 1990. In 2007, Congress mandated that the General Accountability Office (GAO) study the 510(k) process and make recommendations for regulations to address the reclassification that had been ongoing without resolution for a total of 31 years. GAO issued its report in January of this year, recommending that FDA move expeditiously to issue regulations either to reclassify some or all of the 25 types of devices in question or call for the submission of a PMA to obtain approval to market. The notice is in response to GAO's recommendations. According to it, manufacturers must submit by **August 7, 2009**, "a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices which has not been submitted under the Federal Food, Drug, and Cosmetic Act." The notice states that FDA "does not anticipate extending the time for submitting the required information." The notice lists the information that is required to be submitted for each device.

## **LEGISLATIVE DEVELOPMENTS**

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***Energy And Climate Bill Begins To Move In The House*** -- Representatives Henry Waxman (D-CA), Chair of the House Energy and Commerce Committee, and Representative Edward Markey (D-MA), Chair of the Energy and Commerce Subcommittee, announced plans to move an energy and climate bill through the full Committee by Memorial Day. The key provisions of the measure deal with implementation of plans to fulfill President Obama's pledge to make significant cuts in greenhouse gas emissions. The House proposal would mandate cuts in emissions of more than 80% by 2050, from 2005 levels. That is commensurate with what the President has discussed. Short term, the House bill would require even deeper cuts than those proposed by the Administration. According to Representatives Waxman and Markey, the bill would reduce emissions by 2020. The cuts would be achieved by a cap-and-trade mechanism that would require industry to have carbon allowances for each ton of greenhouse emissions emitted. Jurisdiction over the cap-and-trade program is an issue in the House. Representatives Waxman and Markey propose to have the plan administered by the Federal Energy Regulatory Commission (FERC), but others have suggested that the task fall to the Commodities Futures Trading Commission. On another jurisdictional issue, EPA would be barred by the legislation from regulating greenhouse gases as HAPs or under new source review provisions.

***President Obama Signs Omnibus Lands Legislation*** -- On March 31, 2009, President Obama signed the Omnibus Public Land Management Act of 2009 into law, adding two million acres to



wilderness areas and 1,000 miles to the Wild and Scenic Rivers System, expanding national parks and creating a 26-million-acre National Landscape Conservation System. Conservationists support the legislation, while the mining and oil and natural gas industries generally oppose the withdrawal of so much land from the “multiple use” purposes allowed on much federal land. One portion of the bill especially blocks mineral resource development in the Wyoming Range region of the Bridger-Teton National Forest. The new law expands 19 wilderness areas within ten national forests, managed by the U.S. Forest Service within the Agriculture Department. The new law also pulls together a variety of measures to help develop water supplies, to research climate change, and to study oceans.

The lands bill was assembled last year from more than 160 bills that had been unable to find traction in Congress individually. By including in it so many proposals from both sides of the aisle and most regions of the country, Senator Jeff Bingaman (D-NM) was able to come up with legislation that passed the Senate on a 73-21 vote in January and, when it needed a second approval, a 77-20 vote on March 19, 2009. The House passed the lands bill by a 285-140 vote on March 25, 2009, without going through Committee reviews of its components, a point of frustration to opponents such as Representative Doc Hastings (R-WA), the most vocal critic in the House.

***Senators Propose Increased Role For FERC*** -- Senators Jeff Bingaman (D-NM) and Harry Reid (D-NV) have proposed in separate pieces of legislation to increase the authority of FERC to accelerate the process of locating and constructing high voltage power lines. Both Senators have argued that FERC should have some form of eminent domain authority in order to cut down the red tape in constructing “green” transmission lines. They also want to see increased planning regarding the entire eastern and western grids, respectively. More efficient transmission is a feature of most climate control legislation under consideration for introduction.

***Organizations Urge No Change In Security Provisions*** -- More than 30 organizations have requested that Congress proceed with caution in proposing additional security requirements for companies. Markup of the measure for security at plants handling chemicals is scheduled for late in May. The measure will be needed because of the sunset of the present Department of Homeland Security (DHS) Appropriation that contains requirements for assessments of vulnerability, security plans, and protective measures to meet risk-based performance standards. To meet the Congressional mandate, DHS promulgated the Chemical Facilities Anti-Terrorism Standards Regulation (CFATS). Among the entities that may have to comply with CFATS are companies that manufacture, store, and distribute chemicals, energy and utilities, agriculture and food, paints and coatings, explosives mining, electronics, plastics, and healthcare. The companies speaking with Congressional members and staff are concerned that the measures under consideration will go beyond security and establish a mandate to substitute products and processes with a technology selected by the federal government.



***Appropriations Bill Axes Inventory Rule*** -- The final fiscal year 2009 Appropriations Bill contains language directing that no funds be used to implement a final rule promulgated by EPA in 2006 that reduced the reporting requirements for many businesses regarding the release of chemicals not persistent, bioaccumulative, and toxic. The rule allowed a short form with minimal information required for releases up to 2,000 pounds, whereas the rule had previously limited use of a short form to releases of 500 pounds or less. EPA reacted to the Congressional action by indicating that it would issue a regulation reinstating the procedures in effect prior to 2006. According to EPA sources, the Congressional action will affect inventory reports due July 1 for calendar year 2008 to satisfy the 1986 Emergency Planning and Community Right-To Know Act.

***Reid Measure Would Provide New Regulation Of Waste*** -- The Senate Majority Leader Harry Reid (D-NV) has proposed new legislation to appoint a commission of five Democrats and four Republicans to explore the possibility of transferring management for high level nuclear waste to some new government entity in place of the Department of Energy. One reason for the commission is to explore management of such waste if the controversial Yucca Mountain facility long under review is never finished or utilized. The budget proposal for 2010 limits any funds for the Yucca Mountain project. Industry supports the idea of a commission, but differs with Chair Reid's method of selection of members. The Nuclear Energy Institute wants a non-partisan membership, not politicians picked by the leaders of the two parties.

***House Measure Would Reward Scrapping Of Gas Guzzlers*** -- Representative Betty Sutton (D-OH) has introduced legislation to give vouchers to consumers who turn in vehicles eight years or older in order to buy new cars or use public transportation. The amount of the proposed voucher would vary between \$3,000 and \$5,000, and newer cars purchased would have to have highway gasoline consumption ratings of at least 27 mpg. Trucks would have to be rated at 24 mpg. Representative Sutton said the measure would reduce emissions, jump start auto sales, and reduce dependence on foreign oil. Senator Diane Feinstein (D-CA) and Representative Steve Israel (D-NY) introduced bills to accomplish the same purpose in January 2009.

***Bill Would Reduce Tariff On Imported Ethanol*** -- A bipartisan group of Senators, led by Senator Diane Feinstein (D-CA), has introduced legislation that would reduce the tariff on imported ethanol so that producers of ethanol-blended gasoline can afford to use the ethanol in product blended for the U.S. market. The tariffs have the effect of discouraging the use of the imported ethanol and result in the use of imported gasoline instead.



**MISCELLANEOUS**

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***McCarthy Proposed To Head EPA Air Office*** -- Gina McCarthy, the Commissioner of the Connecticut Department of Environmental Protection, has been nominated to be the Assistant Administrator for Air and Radiation at EPA. Prior to her position in Connecticut, Commissioner McCarthy held a variety of positions in state government in Massachusetts.

***EPA Terminates National Environmental Performance Track Program*** -- On March 16, 2009, EPA Administrator Jackson announced her decision to end the National Environmental Performance Track Program. Jackson stated that the program “was developed in a different era and may not speak to today’s challenges.” The program includes 200 companies and more than 500 facilities, but has been criticized by environmental advocates because they say the program ensures less federal enforcement oversight. In a memorandum to Performance Track members and others, Jackson noted she has decided to halt the current Performance Track Program “with the intent to refining those concepts that can lead us to a stronger system of environmental protection as we go forward.” Information on EPA’s Performance Track Program and Administrator Jackson’s memorandum are available at <http://www.epa.gov/performance-track>.

***Giles Nominated As Assistant Administrator For Enforcement And Compliance Assurance*** -- On March 18, 2009, President Obama announced his intent to nominate Cynthia J. Giles as the EPA Assistant Administrator for Enforcement and Compliance Assurance. Giles is currently Vice President and Director of the Conservation Law Foundation’s Rhode Island Advocacy Center, where she has focused on state and regional advocacy to combat climate change. From 2001 to 2005, Giles served as head of the Bureau of Resource Protection at the Massachusetts Department of Environmental Protection. Giles worked for EPA in a variety of capacities from 1991 to 1997, including serving as Enforcement Director from 1995-97 for Region 3, where she developed a “results-targeted” approach to enforcement. Prior to joining EPA, Giles was an Assistant U.S. Attorney, where she prosecuted violations of federal environmental laws. She holds a Bachelor of Arts from Cornell University, as well as a Juris Doctor from the University of California at Berkeley and a Masters in Public Administration from the Harvard University Kennedy School of Government. She is admitted to the bar in the State of Rhode Island, U.S. District Court for the District of Rhode Island, and State of Pennsylvania.

***Senate Confirms Lubchenco For NOAA, Holdren For White House Science Adviser*** -- On March 19, 2009, the Senate confirmed Jane Lubchenco to head the National Oceanic and Atmospheric Administration (NOAA) and science policy specialist John P. Holdren to head the White House Office of Science and Technology Policy (OSTP). Lubchenco has been a member of the science faculty of Oregon State University since 1978. Lubchenco has been a President of the American Association for the Advancement of Service. Holdren comes to OSTP from Harvard University, where he has been a professor of environmental science and public policy.



Holdren arrived shortly after Obama signed an executive memorandum requiring OSTP to devise guidelines to protect the integrity of science in federal agency activities.

***EPA Issues Statement On Jon Cannon*** -- On March 25, 2009, EPA released a statement on Jon Cannon removing his name from consideration to be Deputy Administrator of EPA. "It has come to my attention that America's Clean Water Foundation, where I once served on the board of directors, has become the subject of scrutiny. While my service on the board of that now-dissolved organization is not the subject of the scrutiny, I believe the energy and environmental challenges facing our nation are too great to delay confirmation for this position, and I do not wish to present any distraction to the agency." EPA Administrator Lisa P. Jackson said: "I'm disappointed that Jon Cannon will be unable to serve as Deputy Administrator, and I thank him for his many years of dedication to the EPA. The administration will move quickly to identify a new candidate who can help us carry out our mission to preserve environmental sustainability and create green jobs as we transition the nation to a clean energy economy."

***Stanislaus Nominated To Head EPA's Solid Waste Office*** -- On March 31, 2009, President Obama announced his intention to nominate Mathy V. Stanislaus, head of a New York-based nonprofit community revitalization group, as EPA's Assistant Administrator for Solid Waste and Emergency Response. An environmental lawyer and chemical engineer, Stanislaus co-founded and co-directs New Partners for Community Revitalization Inc., an organization whose mission is to advance the renewal of New York's low- and moderate-income neighborhoods through the redevelopment of brownfields sites, the White House stated. Stanislaus, a former EPA assistant regional counsel in Region 2 in New York City, has over two decades of experience in the environmental field, primarily in the areas of brownfields, Superfund, and solid waste, according to the White House.

***President Obama Announces Nomination Of Owens, Mulkey, And Grevatt*** -- On April 2, 2009, President Obama announced his intent to nominate Stephen A. Owens, Assistant Administrator for EPA's OPPTS. Owens served as Director of the Arizona Department of Environmental Quality (ADEQ) from January 2003 until January 2009. As ADEQ Director, Owens chaired Arizona's Climate Change Advisory Group, served as co-chair of the Western Climate Initiative, and was Secretary of The Climate Registry. Among other key concerns, Owens made children's environmental health a top priority for ADEQ and established an Office of Children's Environmental Health. From 1982-84, Owens served as Counsel to the Subcommittee on Investigations and Oversight of the U.S. House of Representatives Committee on Science and Technology. During 1985-88, he was Chief Counsel and later State Director for then U.S. Senator Al Gore. From 1999-2002, Owens served as a member of the Joint Public Advisory Committee of the North American Commission on Environmental Cooperation. In September 2008, Owens was elected President of the Environmental Council of the States, the national state environmental agency directors association, serving until he left ADEQ. Owens is widely respected and thought to be level headed, very nice, and very smart.



In a March 27, 2009, memorandum, EPA Administrator Lisa Jackson announced the interim appointments of Marcia E. Mulkey as Acting Associate Administrator for the Office of Policy, Economics and Innovations (OPEI), and Peter C. Grevatt as Senior Advisor for Children's Environmental Health. Mulkey is currently Director of the EPA Office of Enforcement and Compliance Assurance Office of Site Remediation Enforcement. From 1998-2003, Jackson states, Mulkey "directed the Office of Pesticide Programs during key phases of the effort to successfully implement the landmark Food Quality Protection Act." Jackson describes Mulkey as "one of EPA's keenest legal and policy minds." Mulkey's detail will begin on April 6, 2009. Grevatt is currently Director of the Resource Conservation and Sustainability Division within the Office of Resource Conservation and Recovery (formerly the Office of Solid Waste). According to the memorandum, while serving as Senior Science Advisor in the Office of Solid Waste and Emergency Response, he was responsible for ensuring that science, public health, and risk assessment issues were fully considered for a range of critical issues such as asbestos, polychlorinated biphenyls, lead, and arsenic. Grevatt also served as Director of the Economics, Methods and Risk Analysis Division in the then Office of Solid Waste. Jackson states that Grevatt has received numerous awards for his work and has extensive experience working with Congress, state and local governments, stakeholders, and the public. Grevatt's detail began on March 30, 2009.

***President Obama Nominates Waste Office Head*** -- On April 3, 2009, President Obama announced his intention to nominate Peter S. Silva, senior policy adviser for the Metropolitan Water District of Southern California, as EPA Assistant Administrator for water. Silva is a civil engineer with nearly 32 years of experience in the water and wastewater fields. Among the issues likely to confront the Office of Water is the question of which waters are protected by the CWA. Prior to his position with the Southern California water district, Silva was the vice chairman of the California Water Resources Control Board for six years, according to the White House. He has served in various public sector positions specializing in water resources policy with extensive experience in U.S.-Mexico border issues, the White House stated.

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