



Recent Federal Developments November 15, 2009

TSCA/FIFRA/NTP/EPCRA

EPA Issues Notice For External Peer Review Draft Of Recommended Toxicity Equivalency Factors (TEF) For Dioxin And Dioxin-Like Compounds -- On October 16, 2009, the U.S. Environmental Protection Agency (EPA) announced plans to convene an independent panel of experts to organize and conduct an external peer review meeting to review the draft document titled "Recommended Toxicity Equivalency Factors (TEFs) for Human Health Risk Assessments of Dioxin and Dioxin-Like Compounds." 74 Fed. Reg. 53233. The peer review meeting took place by teleconference on October 22, 2009. In preparing a final report, EPA will consider the peer review report of the recommendations from the external peer review teleconference and any public comments that EPA receives.

EPA Announces Availability Of EDSP Testing Battery -- On October 21, 2009, EPA issued two notices concerning its Endocrine Disruptor Screening Program (EDSP). In the first notice, EPA announced the EDSP Tier 1 battery of assays and availability of test guidelines for conducting the assays included in the battery. 74 Fed. Reg. 54416. In the second notice, EPA announced the issuance of the initial EDSP screening orders and the schedule of issuance. 74 Fed. Reg. 54422. EPA intends to issue test orders for the first group of 67 chemicals between October 29, 2009, and February 26, 2010. Screening data are due within two years of the date of the issuance of the order. Order recipients must respond according to the schedules contained in the order they receive. According to testing press articles, EPA issued the first 21 test rules on October 29, 2009. EPA states that persons other than order recipients who wish to submit "other scientifically relevant information related to one of the chemical-specific orders" should submit that information within 90 days of the order issuance date. The notice includes the following order issuance schedule:

Chemical Name	CAS Number	Order Issuance Time Frame
Abamectin	71751-41-2	January 2010
Acephate	30560-19-1	November 2009
Acetone	67-64-1	February 2010
Atrazine	1912-24-9	October 2009
Benfluralin	1861-40-1	October 2009
Bifenthrin	82657-04-3	November 2009
Butyl benzyl phthalate	85-68-7	January 2010
Captan	133-06-2	January 2010
Carbamothioic acid, dipropyl-, S-ethyl ester	759-94-4	November 2009
Carbaryl	63-25-2	November 2009
Carbofuran	1563-66-2	November 2009
Chlorothalonil	1897-45-6	December 2009



Chemical Name	CAS Number	Order Issuance Time Frame
Chlorpyrifos	2921-88-2	November 2009
Cyfluthrin	68359-37-5	November 2009
Cypermethrin	52315-07-8	November 2009
2,4-D	94-75-7	October 2009
DCPA (or chlorthal-dimethyl)	1861-32-1	October 2009
Diazinon	333-41-5	November 2009
Dibutyl phthalate	84-74-2	January 2010
Dichlobenil	1194-65-6	December 2009
Dicofol	115-32-2	December 2009
Diethyl phthalate	84-66-2	January 2010
Dimethoate	60-51-5	November 2009
Dimethyl phthalate	131-11-3	January 2010
Di-sec-octyl phthalate	117-81-7	January 2010
Disulfoton	298-04-4	November 2009
Endosulfan	115-29-7	December 2009
Esfenvalerate	66230-04-4	November 2009
Ethoprop	13194-48-4	November 2009
Fenbutatin oxide	13356-08-6	October 2009
Flutolanil	66332-96-5	December 2009
Folpet	133-07-3	January 2010
Gardona (cis-isomer)	22248-79-9	November 2009
Glyphosate	1071-83-6	January 2010
Imidacloprid	138261-41-3	January 2010
Iprodione	36734-19-7	January 2010
Isophorone	78-59-1	January 2010
Linuron	330-55-2	December 2009
Malathion	121-75-5	November 2009
Metalaxyl	57837-19-1	December 2009
Methamidophos	10265-92-6	November 2009
4,7-Methano-1H-isoindole-1,3(2H)-dione,2-(2-ethylhexyl)-3a,4,7,7a-tetrahydro-	113-48-4	January 2010
Methidathion	950-37-8	November 2009
Methomyl	16752-77-5	November 2009
Methyl ethyl ketone	78-93-3	January 2010
Methyl parathion	298-00-0	November 2009
Metolachlor	51218-45-2	December 2009
Metribuzin	21087-64-9	December 2009



Chemical Name	CAS Number	Order Issuance Time Frame
Myclobutanil	88671-89-0	December 2009
Norflurazon	27314-13-2	October 2009
o-Phenylphenol	90-43-7	January 2010
Oxamyl	23135-22-0	November 2009
Permethrin	52645-53-1	November 2009
Phosmet	732-11-6	November 2009
Piperonyl butoxide	51-03-6	November 2009
Propachlor	1918-16-7	December 2009
Propargite	2312-35-8	October 2009
Propiconazole	60207-90-1	December 2009
Propyzamide	23950-58-5	January 2010
Pyridine, 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)-	95737-68-1	January 2010
Quintozene	82-68-8	December 2009
Resmethrin	10453-86-8	November 2009
Simazine	122-34-9	December 2009
Tebuconazole	107534-96-3	December 2009
Toluene	108-88-3	February 2010
Triadimefon	43121-43-3	December 2009
Trifluralin	1582-09-8	January 2010

The notice states that EPA will provide details of the status on the orders at <http://www.epa.gov/endo>. The information posted will include the order issuance date, the recipient(s) of the order, the order recipient's response to the order, and the order due date.

EPA Launches Information On Insect Repellents -- On October 20, 2009, EPA launched a new web page containing product information on certain skin-applied insect repellents. EPA's goal is to provide the public with information on registered insect repellents and their effectiveness claims in a clear, consistent, and user-friendly format. "EPA's release of information on the effectiveness of insect repellents will help American consumers select the right product for their needs and protect themselves and their children from potentially devastating diseases spread by mosquitoes and ticks, such as West Nile virus and Lyme disease," said Steve Owens, Assistant Administrator for EPA's Office of Prevention, Pesticides and Toxic Substances (OPPTS). "This Web-based dissemination of information supports Administrator Jackson's goals of transparency and public access and protecting children's health." The new web page contains two tables listing insect repellent products that are registered by EPA: those that control mosquitoes and ticks, and those that only control mosquitoes. The web page compiles publicly available information on protection times based on product effectiveness data reviewed by EPA, and



presents it in a format that makes it easy for consumers to make informed risk management decisions to protect their health and that of their families and children. The web page also contains information on vector-borne diseases such as West Nile virus and Lyme disease, and the importance of personal protection measures. The web page can be accessed at <http://www.epa.gov/pesticides/health/mosquitoes/insectrp.htm>.

EPA Staffs Two New Positions To Address Environmental Justice Civil Rights -- On November 12, 2009, EPA announced that it has filled two new positions that focus on environmental justice issues. Lisa H. Garcia will serve as Administrator Jackson's senior adviser for environmental justice, and Patrick Sungwook Chang will serve as senior counsel for external civil rights. Both positions are newly created within the Administrator's office. EPA Administrator Lisa Jackson's memorandum is available at <http://blog.epa.gov/administrator/2009/11/12/memo-to-employees-next-steps-environmental-justice-and-civil-rights/>.

EPA Announces IRIS Update Project -- On October 21, 2009, EPA announced the establishment of the Integrated Risk Information System (IRIS) Update Project. 74 Fed. Reg. 54040. The purpose of the IRIS Update Project is to revisit a portion of the dose-response assessment values with a posting date on the IRIS database that is more than ten years old. The notice also announced the IRIS Update Project's 2009/2010 agenda and requests submission of new and relevant scientific information on health effects for the identified assessments listed in the Project's 2009/2010 agenda. Information must be submitted by **December 21, 2009**. The following IRIS assessments have been selected for inclusion in the IRIS Update Project.

Substance Name	Assessment (IRIS Posting Date)	CASRN
Barium	Cancer (1998)	7440-39-3
Bromoform	RfD (1989), cancer (1990)	75-25-2
Carbon disulfide	RfD (1990), RfC (1995)	75-15-0
Chlorobenzene	RfD (1989), cancer (1990)	108-90-7
2-Chlorophenol	RfD (1988)	95-57-8
o-Cresol	RfD (1988), cancer (1990)	95-48-7
Cumene	RfD (1997), RfC (1997), cancer (1997)	98-82-8
1,1-Dichloroethane	Cancer (1990)	75-34-3
2,4-Dimethylphenol	RfD (1990)	105-67-9
2,4-Dinitrophenol	RfD (1991)	51-28-5
2,4-Dinitrotoluene	RfD (1992)	121-14-2
Hexachlorobenzene	RfD (1988), cancer (1991)	118-74-1
Selenium	RfD (1991), cancer (1991)	7782-49-2
1,1,2-Trichloroethane	RfD (1988), cancer (1994)	79-00-5
2,4,6-Trichlorophenol	Cancer (1990).	88-06-2



IRIS Office Announces Availability Of Literature Searches -- On November 2, 2009, EPA announced the availability of literature searches for three IRIS assessments that were or may be started in 2009 and requested scientific information on health effects that may result from exposure to these chemical substances. 74 Fed. Reg. 56611. EPA is announcing the availability of additional literature searches on the IRIS website (<http://www.epa.gov/iris>). The public is invited to review the literature search results and submit additional information to EPA. Literature searches are now available for chromium VI (hexavalent chromium) (CAS 18540-29-9), ammonia (CAS 7664-41-7), and 10 alkylates-2-methylpentane (CAS 107-83-5), 2-methylbutane (CAS 78-78-4), 3-methylpentane (CAS 96-14-0), 2,2,5-trimethylhexane (CAS 3522-94-9), 2,3,3-trimethylpentane (CAS 560-21-4), 2,3,5-trimethylpentane (CAS 565-75-3), cyclohexane (CAS 110-82-7), methylcyclohexane (CAS 108-87-2), n-heptane (CAS 142-82-5), and n-octane (CAS 111-65-9) at <http://www.epa.gov/iris> under “Annual IRIS Agenda.”

EPA Issues Notices Of Peer Review Workshop -- On November 10, 2009, EPA announced peer review workshops on draft toxicological review of cis- and trans-1,2-dichloroethylene, draft toxicological review of trichloroacetic acid, and draft toxicological review of hydrogen cyanide and cyanide salts. 74 Fed. Reg. 58014 and 58015. Please consult the *Federal Register* Notices for details.

Draft Changes To Design For The Environment (Dfe) Criteria For The Safer Cleaning Products Program -- EPA’s Office of Pollution Prevention and Toxics (OPPT) is soliciting comment on several draft changes to its criteria for participation in the DfE Safer Product Labeling Program. Over 1,500 consumer and institutional products have been recognized under this program, which has approximately 200 partners. OPPT is proposing changes to its criteria for cleaning products in three areas: revising definitions of terms that describe common business practices for manufacture of DfE-labeled products; adopting new auditing provisions to ensure compliance with the applicable criteria; and expanding eligibility for participation in the program to partners who use certain innovative dispensing systems. Comments are due by **November 30, 2009**, and should be designated by docket identification number EPA-HQ-OPPT-2009-0829. Comments may be submitted electronically through the Federal eRulemaking Portal (<http://www.regulations.gov>); by mail; or hand delivered to the OPPT Document Control Office.

EPA Announces Draft Pesticide Registration Notice Concerning Drift Labeling And Petition Regarding Children’s Exposures To Pesticide Drift -- On November 4, 2009, EPA announced the availability of a Pesticide Registration (PR) Notice entitled “Pesticide Drift Labeling” (2009-X) and a draft explanatory document entitled “Pesticide Drift Labeling Interpretation.” In a separate *Federal Register* notice, EPA announced that, on October 13, 2009, Earthjustice and Farmworker Justice, on behalf of several other organizations, filed a petition requesting that EPA “systematically evaluate children’s exposures to pesticide drift and require interim prohibitions on the use of certain pesticides near homes, schools, and other places where children



congregate.” The draft PR Notice and related documents are available at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2009-0628>. Comments on the draft PR Notice and Interpretation are due **January 4, 2010**. The docket for the petition is available on the Internet at <http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPP-2009-0825>. Comments on the petition are also due **January 4, 2010**. More information regarding the draft PR Notice and the petition is provided below.

EPA states that its purpose in issuing the draft PR Notice is to provide guidance to registrants and applicants for registration on labeling statements concerning pesticide drift, and to inform the public of EPA’s policies with regard to the prevention of pesticide drift. The draft PR Notice proposes labeling statements and formats intended to improve communication of drift management requirements to pesticide applicators, and, as a result, to improve protection of people and other non-target organisms and sites from potential adverse effects that may be caused by off-target pesticide drift. The recommended statements should appear on products whose application may result in drift.

The draft PR Notice contains two types of statements: (1) a general drift statement containing a risk-protective standard, which varies according to product type; and (2) examples of product-specific drift use restrictions, along with a format for presenting these statements on product labeling. The draft PR Notice also informs registrants about the procedures they should use to amend their registrations to adopt these statements. EPA states that it “believes the use of these statements and formats on labels will provide users consistent, understandable, and enforceable directions about how to protect human health and the environment from harm that might result from pesticide drift.”

EPA Inspector General Issues Report On FIFRA Export Provision -- On November 12, 2009, the EPA Office of Inspector General (OIG) issued a report claiming that EPA is not complying with a provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that involves the exports of pesticides not registered in the United States. “EPA is not complying with FIFRA Section 17(a) which is, in part, intended to notify the government of an importing country that a potentially hazardous pesticide was imported into that country,” according to the OIG report. FIFRA Section 17(a) requires that exporters of unregistered pesticides first obtain a statement -- called a Foreign Purchaser Acknowledgement Statement -- signed by the purchaser indicating its awareness that the product is not registered and cannot be sold in the United States, the OIG found. The pesticide exporter is to provide the foreign purchaser statement to EPA, which is to forward it to the appropriate government officials in the importing countries, the OIG’s report stated. EPA has no procedures to determine if manufacturers are submitting all of the foreign purchaser statements they should, and EPA does not take action to verify the information, according to the report. EPA disputes the findings. The report, *EPA Needs to Comply with the Federal Insecticide, Fungicide, and Rodenticide Act and Improve its Oversight*



of *Exported Never-Registered Pesticides*, is available at <http://www.epa.gov/oig/reports/2010/20091110-10-P-0026.pdf>.

CAA/CWA

EPA Announced Availability Of Review Of Ozone On NAAQS -- On October 19, 2009, EPA announced the availability and request for comment on a draft document titled *Integrated Review Plan for the Ozone National Ambient Air Quality Standards Review – External Review Draft*. 74 Fed. Reg. 53498. This document contains the plans for the new periodic review of the air quality criteria for ozone (O₃)-related effects on public health and public welfare and the current O₃ standards or any revised standards that may result from the reconsideration of the 2008 O₃ standards. This draft Integrated Review Plan (IRP) is being released for the purpose of consulting with the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board and obtaining public comment on EPA's plans. The final IRP will be informed by comments received from the CASAC and the public. Comments were due by November 6, 2009.

EPA Issues Final Toxic Emissions Standards -- On October 29, 2009, EPA issued a final rule establishing work practices and emissions limits on some equipment at nine categories of small chemical manufacturing operations to reduce emissions of hazardous pollutants. 74 Fed. Reg. 56008. The rule amends 40 C.F.R. Part 63 and took immediate effect. The final rule will establish hazardous air pollutant standards for the following nine categories: agricultural chemicals and pesticides manufacturing, cyclic crude and intermediate production, industrial inorganic chemical manufacturing, industrial organic chemical manufacturing, inorganic pigments manufacturing, miscellaneous organic chemical manufacturing, plastic materials and resins manufacturing, pharmaceutical production, and synthetic rubber manufacturing. EPA estimates the final rule will affect 450 existing chemical manufacturing facilities and reduce emissions of air toxics by 248 tons per year. Particulate matter emissions would also be reduced by 570 tons annually. The rule is expected to cost affected sources a total of \$3.2 million annually.

EPA Issues Expedited Approval Of Alternative Test Procedures For Analysis Of Contaminants Under SDWA -- On November 10, 2009, EPA announced approval of alternative testing methods for use in measuring the levels of contaminants in drinking water and determining compliance with national primary drinking water regulations. 74 Fed. Reg. 57908. The Safe Drinking Water Act (SDWA) authorizes EPA to approve the use of alternative testing methods through publication in the *Federal Register*. EPA used this authority to make 25 additional methods available for analyzing drinking water samples required by regulation. The rule was immediately effective.



EPA Issues Final Rule Amending National Emission Standards For Hazardous Air Pollutants From Petroleum Refineries -- On October 28, 2009, EPA issued a final rule amending the national emission standards for hazardous air pollutants (NESHAP) for petroleum refineries to add maximum achievable control technology standards for heat exchange systems. 74 Fed. Reg. 55670. This action also amends the general provisions cross-reference table and corrects section references. The final amendments were immediately effective.

EPA Proposes To Withdraw Residual Risk Finding From NESHAP For Petroleum Refineries -- On October 28, 2009, EPA proposed to withdraw the residual risk and technology review portions of the final rule amending NESHAP for petroleum refineries issued on January 16, 2009. 74 Fed. Reg. 55505. Upon further review, EPA “has determined that the residual risk and technology reviews may not accurately characterize the risk posed by this source category.” EPA recently responded to a Request for Correction under EPA's Information Quality Guidelines from the City of Houston. In that response, EPA recognized that it is currently taking action to gather better emissions information from the refining industry. Additionally, EPA noted that during the comment period on the proposed rule, similar issues were raised concerning the representativeness of the emissions data, and whether they provide an accurate basis for characterizing the risks posed. Comments are due **November 27, 2009**.

EPA Issues Final Mandatory Reporting Of Greenhouse Gases -- On October 30, 2008, EPA issued a final rule to require reporting of greenhouse gas (GHG) emissions from all sectors of the economy. 74 Fed. Reg. 56260. The final rule applies to fossil fuel suppliers and industrial gas suppliers, direct GHG emitters and manufacturers of heavy-duty and off-road vehicles and engines. The rule does not require control of GHGs, rather it requires only that sources above certain threshold levels monitor and report emissions. The final rule is effective on **December 29, 2009**.

EPA Seeks Comment On Plan To Limit Stationary Source Emissions -- On October 27, 2009, EPA requested comment on a proposed rule that could require large industrial plants and other sources to control emissions of carbon dioxide and other GHGs. The proposed rule would govern how EPA applies the emissions control requirements under the prevention-of-significant-deterioration program to GHGs. 74 Fed. Reg. 55292. It also would apply Clear Air Act (CAA) Title V, which requires major sources to obtain operating permits, to GHGs. The EPA proposal, called the PSD tailoring rule, would set a major source threshold of 25,000 tons per year of GHGs, measured in carbon dioxide-equivalent emissions. It would apply to carbon dioxide, methane, and four other GHGs and would affect about 400 sources each year. The Title V requirements would apply to about 14,000 sources. EPA will convene a public meeting if asked timely to do so. Comments are due by **December 28, 2009**.



EPA Proposes One Year Extension Of Expiration Stormwater General Permit For Construction -- On October 21, 2009, EPA proposed to extend by one year the expiration date for a general permit issued in 2008 that covers stormwater discharges from construction activity in five states and other areas where EPA is deemed the permitting authority. 74 Fed. Reg. 53494. EPA stated it intends to delay from 2010 to 2011 the date so it can incorporate into a new general permit the requirements in effluent guidelines for the construction industry that it expects to adopt later this year. EPA stated that the current seven-month timeframe to propose and finalize a new permit is “impracticable” based on EPA’s past experience. Comments are due **November 18, 2009**.

RCRA/CERCLA

EPA Issues Notice Of Data Availability On Conditional Exclusion From Hazardous Waste And Solid Waste For Solvent-Contaminated Industrial Wipes -- On October 27, 2009, EPA announced a notice of data availability (NODA) and invited comments on a revised risk analysis supporting EPA’s proposed revisions to the Resource Conservation Recovery Act (RCRA) hazardous waste regulations governing the management of solvent-contaminated wipes. 74 Fed. Reg. 55163. The revised analysis addresses public comments received on the risk screening analysis conducted on EPA’s 2003 *Federal Register* proposal to exclude solvent-contaminated wipes from the RCRA definitions of solid and hazardous waste. To address these comments, EPA updated the data, models, and approach used in the risk analysis and then had the product peer reviewed by outside experts. The revised risk analysis, as well as the peer review comments and our response to those comments are available in the docket for this NODA. The NODA also invites comment on specific issues in light of the results of the revised risk analysis. Comments must be received within **December 28, 2009**.

EPA Issues Final Revisions To SPCC Rule -- On November 13, 2009, EPA removed three provisions from its revisions to a spill control prevention rule issued in December 2008 “to address a number of issues raised by the regulated community.” 74 Fed. Reg. 58783. The change will revise amendments published in December 2008 to the Spill Prevention, Control, and Countermeasure (SPCC) rule. EPA reported that the final revision will remove three provisions: an exclusion for farms and oil production facilities from the loading and unloading rack requirements; an exemption for produced water containers at oil facilities; and alternative eligibility criteria for certain oil production facilities. The rule will take effect **January 14, 2010**.

REACH

ECHA Creates Help Net -- On October 27, 2009, the European Chemicals Agency (ECHA) announced the creation of a new, joint network of the Regulation, Evaluation, Authorization and Restriction of Chemicals (REACH) and CLP (Classification, Labelling and Packaging) helpdesk



called Help Net. The objectives of the network are: to provide consistent, harmonised answers and the best possible advice to industry seeking to fulfill their obligations under the REACH and CLP Regulations. At its last meeting in October 2009, the REACH Helpdesk Correspondents' Network (REHCORN) was expanded to include also the national CLP Helpdesks to form a single network called Help Net. ECHA provides the Secretariat for the network. A web-based IT application (Help Net Exchange) will be used by the network to enable discussions and ensure that consistent answers are given across Europe. A Help Net Steering Group will consist of representatives of the national REACH and CLP helpdesks of the 27 Member States, Norway, Iceland, and ECHA. It will meet on a regular basis to discuss issues of common interest, future activities, and the functioning of the Network. The European Commission is an associated member of the network and the meetings of the Help Net Steering Group are also attended by observers. The new Help Net Steering Group replaces REHCORN, which had been operational as the steering body of the network of REACH helpdesks since April 2007. The Steering Group can invite representatives from candidate countries or stakeholder organizations who host a European Union (EU) wide REACH or CLP helpdesk as observers. Currently, six industry associations, along with Croatia and Turkey, are observers of the Help Net Steering Group meetings.

EU Chemicals Agency Announces Stakeholders' Day -- On October 27, 2009, ECHA announced that its third Stakeholders' Day will be held **December 7, 2009**. Participation is free of charge, but registrations must be filed by **November 30, 2009**. ECHA also will broadcast the event on the Internet via live webstreaming that will be available after the workshop. Topics include an update of the classification, labeling, and packaging, or CLP, regulation and the classification and labeling inventory that will be established in 2011. Enforcement of REACH will be discussed, as will registration dossiers and compliance for REACH, which stands for the registration, evaluation, and authorization of chemicals regulation. Details on the Stakeholders' Day, including a link to register for it, are available at http://echa.europa.eu/news/events/3rd_stakeholders_day_en.asp.

ECHA Publishes Concise Guidance On Chemical Safety Assessment -- On November 3, 2009, ECHA announced the availability of its *Guidance in a Nutshell: Chemical Safety Assessment*, which is intended to assist industry in understanding the general provisions for conducting a Chemical Safety Assessment (CSA). ECHA states that the Guidance is aimed at non-experts who would like to understand the legal requirements under the REACH regulation regarding substance assessment. The Guidance provides an overview of what the CSA is and how it is performed and documented. It also outlines the communication needs down the supply chain and the resources required, in terms of time and expertise, to comply with the legal obligations. The Guidance is available on the Internet at http://guidance.echa.europa.eu/docs/guidance_document/nutshell_guidance_csa_en.pdf.



Under REACH, a CSA is required for all substances subject to registration in quantities of ten tonnes or more per year per registrant. A CSA is not required, however, if the substance is present in a preparation and the concentration of the substance in the preparation is below certain concentration limits. Usually the manufacturer or importer of the substance has the duty to carry out the CSA and to document it in the Chemical Safety Report (CSR), as part of the registration process. The CSR of the manufacturer, and therefore the exposure scenarios, needs to cover the manufacturing process and all the identified uses and life cycle stages of the substance. The CSR of the importer must address only the identified uses and the resulting life cycle stages, leaving the manufacturing process out. Producers or importers of articles that are required to register a substance under REACH are also required to make a CSA and to document it in a CSR if the substance is present in the articles in quantities of ten tonnes or more per year. The registrant's CSR will address exclusively the use of the substance related to the article and will consider the whole lifespan of the article, including its disposal. The CSR has to be submitted to the ECHA with the technical dossier, as part of the registration process.

The three major steps in the CSA process are hazard assessment; exposure assessment; and risk characterization. The hazard assessment requires the collection and evaluation of all available and relevant information on the substance. The objective of the hazard assessment is to identify the hazards of the substance, assess their potential effects on human health and the environment, and determine, where possible, the threshold levels for exposure considered as safe. If, as a result of the hazard assessment, it can be concluded that the substance does not meet the criteria for classification as dangerous or to be considered persistent, bioaccumulative, and toxic (PBT)/very persistent, very bioaccumulative (vPvB), the CSA is complete. If the substance meets any of these criteria, two additional steps are required to complete the process. The exposure assessment is the process of measuring or estimating the dose or concentration of the substance to which humans and the environment are or may be exposed, depending on the uses of the substance. Within the exposure assessment, the definition of the conditions under which the substance is manufactured and used is critical to determine the levels of exposure. For each exposure scenario, the exposure levels of humans and the environment need to be determined. The exposure scenarios will cover all identified uses and life stages of the substance.

The third step in the CSA process is the risk characterization. For the risk characterization, the levels of exposure are compared with the threshold levels for each effect. Where it is not possible to determine a threshold level for one effect, a qualitative or semi-quantitative approach is used. Risks are regarded as controlled under REACH when the exposure levels to the substance are below the threshold levels considered as safe, both for humans and for the environment. For effects with no threshold levels, emissions and exposures have to be minimized or avoided for risks to be considered to be controlled. If risks are under control, the CSA ends here. If risks are not under control, the CSA has to be refined, by obtaining more data on the properties of the substance, changing the conditions of manufacturing or use, or making more precise exposure estimations. The CSA is documented in the CSR and the final



exposure scenarios are communicated through the supply chain via the extended Safety Data Sheet.

ECHA Convenes Public Consultation On Harmonised Classification And Labelling Of Two Chemical Substances -- On November 4, 2009, ECHA announced on its website a public consultation on the proposal to harmonize the classification and labelling of two chemical substances. Comments are welcome on the proposal within the next 45 days. All comments will be taken into account in the subsequent decision-making process. The substances in this consultation, proposed by Sweden and Germany, are:

- **Hexabromocyclododecane (HBCDD)** (Sweden) -- which is used as a flame retardant (*e.g.*, in polystyrene, then further processed for the production of insulation panels/boards or packaging products, and in textile applications). Hexabromocyclododecane is proposed to be classified in category 3 for reproductive toxicity for possible risk of both impaired fertility and harm to the unborn child, and to be labelled with “May cause harm to breastfed babies.”
- **Cryolite** (Germany) -- which is the main constituent of the electrolytic bath in the production of aluminium. Germany proposes to change the current classification by adding classification in category 3 for reproductive toxicity as “Possible risk of harm to the unborn child”; and classification as “Irritating to eyes”. It is also proposed to withdraw the current classification as “Harmful if swallowed.”

The Swedish and German authorities have submitted to ECHA comprehensive dossiers on these substances and asked for their classification and labelling to be harmonized across the EU.

Suppliers of chemicals (substances and mixtures) across Europe have a legal obligation to evaluate the hazards of chemicals and to classify and label them in an appropriate way before placing them on the market. Individual EU Member States (via their competent authorities) or industry may ask for the classification and labelling of a substance to be harmonized across Europe, however. This may happen in three situations:

- Where the substance is either:
 - carcinogenic;
 - mutagenic;
 - toxic for reproduction; and/or
 - a respiratory sensitizer.



- When the substance is a biocide or pesticide (designed to control harmful organisms).
- When there is a need to harmonize the classification at the EU level, other hazard classes than those listed above may be proposed, for example when the suppliers classify the same substance in a different or an incorrect way.

The proposal for harmonization is submitted to ECHA along with a dossier, which outlines the scientific reasons for making the request. ECHA receives these proposals and, together with its Committee for Risk Assessment, ensures that the dossier is complete and consistent. It then organizes a public consultation. The consultation period lasts for 45 days, and, at the end of it, ECHA forwards all comments received to the Member State or industry who had submitted the proposal, so that they can provide their responses. The proposal, the comments, and the responses will then be forwarded to ECHA's Committee for Risk Assessment, which consists of scientific experts from all the EU and EEA Member States and observers from stakeholder organizations. The Committee will issue a scientific opinion on the proposal, which ECHA will forward to the European Commission. The Commission then decides, on the basis of the advice from a regulatory committee of the EU Member States, on the classification and labelling of the substance concerned. If the proposal to harmonize is accepted, the substance will be added to the list of harmonized classifications in Annex VI, part 3 of the CLP Regulation. The harmonised classifications will also be made available on ECHA's website. Thereafter, all manufacturers, importers and users of the substance in the EU will need to abide by the new harmonized classification and labelling, enabling the ultimate users to be better informed about the substance, its potential effects, and how best to make use of it safely.

EU Chemicals Agency Launches Web Page On Chemicals Restrictions Under REACH -- On November 5, 2009, ECHA announced that it has created a web page that describes chemicals already restricted under REACH and the procedures for proposing new chemicals for restriction. Chemicals deemed to pose an unacceptable risk to human health or to the environment can be restricted under REACH. Proposals to restrict chemicals can be prepared by EU member states, ECHA, or upon request of the European Commission, according to ECHA. The web page aims to assist member states understand core information about restrictions by providing relevant guidance documents, by including the format to be used when a restriction proposal is being prepared, and by describing the steps to be taken to achieve a new or modified restriction, ECHA stated. It includes information about chemicals or chemical uses already restricted under Annex XVII of REACH.

ECHA Posts Webinar Online -- ECHA announced the online availability of a webinar regarding preparing and submitting a registration dossier. ECHA held the webinar on November 4, 2009, for lead registrants. The objective of the webinar was to provide lead registrants with an understanding of the main technical concepts required to be able to prepare and submit a



registration dossier. ECHA covered the following topics: exporting information as an IUCLID 5 registration dossier and submitting it via REACH-IT; dossier processing at ECHA; and receiving a registration number. The webinar is available at http://www.echa.europa.eu/news/webinars_en.asp.

ECHA has scheduled more webinars for lead registrants between the end of **2009** and the first half of **2010**. The next one, entitled "Fulfilling Information Requirements I: Gathering and Evaluating Information on Intrinsic Properties," is scheduled for **November 30, 2009**. ECHA intends to post recordings of future webinars approximately a week after each event. ECHA will compile a question and answer document of each webinar and publish it in the lead registrant discussion forum and later on the ECHA website.

NANOTECHNOLOGY

Nanomaterials Listed In Toxic Substances Data Bank -- On November 4, 2009, the National Library of Medicines announced that seven nanomaterials were added to its Hazardous Substances Data Bank in October. The data bank includes peer-reviewed toxicology data on about 5,000 chemicals. The nanomaterials that have been added include silver nanoparticles, titanium oxide nanoparticles, fullerenes, iron nanoparticles, zinc oxide nanoparticles, cerium oxide nanoparticles, and carbon nanotubes. In addition to toxicity data, the Hazardous Substances Data Bank includes therapeutic uses, recommended protective equipment and clothing, major uses, and manufacturing methods. Information in the data bank is peer-reviewed by the Scientific Review Panel, a committee of 16 experts in major subject areas such as toxicology, chemistry, pharmacology, industrial hygiene, medicine, emergency response procedures, environmental science, hazardous waste handling, and regulatory requirements. The panel meets three or four times a year to conduct a comprehensive review of the scientific information in new and updated chemical records. The data bank is available at <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>.

EPA Proposes SNURS For Carbon Nanotubes -- On November 6, 2009, EPA proposed significant new use rules (SNUR) under Section 5(a)(2) of the Toxic Substances Control Act (TSCA) for two chemical substances that were the subject of premanufacture notices (PMN). EPA identified the substances generically as multi-walled carbon nanotubes and single-walled carbon nanotubes. 74 Fed. Reg. 57430. According to the notice, these substances are subject to TSCA Section 5(e) consent orders issued by EPA. The consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs are based on and consistent with the provisions in the underlying consent orders, and designate as a significant new use the absence of the protective measures required in the corresponding consent orders. Persons who intend to manufacture, import, or process either of these two substances for an activity that is designated as a significant new use would be required by the proposed rule to notify EPA at least 90 days before commencing that activity. 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.

EPA published direct final SNURs for these substances on June 24, 2009. EPA withdrew the direct final SNURs on August 21, 2009, in response to a notice of intent to submit adverse comments. The proposed SNURs include the following information regarding the substances:

PMN Number P08177

Chemical name: Multi-walled carbon nanotubes (generic).

CAS number: Not available.

Effective date of TSCA Section 5(e) consent order: September 1, 2009 (amended).

Basis for TSCA Section 5(e) consent order: The PMN states that the generic (nonconfidential) use of the substance will be as a property modifier in electronic applications and as a property modifier in polymer composites. The order was issued under Sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA. Based on test data on analogous respirable, poorly soluble particulates and on other carbon nanotubes (CNT), EPA believes that the PMN substance may cause lung effects. To protect against this risk, the consent order requires use of a National Institute for Occupational Safety and Health (NIOSH)-approved full-face respirator with N100 cartridges. Based on physical properties of the PMN substance, EPA believes it may cause health effects via dermal exposure. To protect against this risk, the consent order requires that workers wear gloves and protective clothing impervious to the chemical substance. The consent order also prohibits any predictable or purposeful release of the PMN substance into the waters of the United States. The proposed SNUR would designate as a significant new use the absence of these protective measures.

Toxicity concern: There is a concern for lung health effects based on data for poorly soluble particulates and for other CNTs, and for lung irritation based on particle size.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study in rats (OPPTS Harmonized Test



Guideline 870.3465 or Organization for Economic Co-operation and Development (OECD) 413 test guideline) with a post-exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (BALF) analysis; and certain material characterization data would help characterize possible effects of the PMN substance. In the consent order, the PMN submitter has agreed not to exceed a specified production volume or production time limit (whichever comes first) without performing these tests.

CFR citation: 40 C.F.R. § 721.10155.

PMN Number P08328

Chemical name: Single-walled carbon nanotubes (generic).

CAS number: Not available.

Effective date of TSCA Section 5(e) consent order: September 1, 2009 (amended).

Basis for TSCA Section 5(e) consent order: The PMN states that the generic (nonconfidential) use of the substance will be as a property modifier in electronic applications and as a property modifier in polymer composites. The order was issued under Sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA. Based on test data on analogous respirable, poorly soluble particulates and on other CNTs, EPA believes that the PMN substance may cause health effects. To protect against this risk, the consent order requires use of a NIOSH-approved full-face respirator with N100 cartridges. Based on physical properties of the PMN substance, EPA believes it may cause health effects via dermal exposure. To protect against this risk, the consent order requires that workers wear gloves and protective clothing impervious to the chemical substance. The consent order also prohibits any predictable or purposeful release of the PMN substance into the waters of the United States. The proposed SNUR would designate as a significant new use the absence of these protective measures.

Toxicity concern: There is a concern for health effects based on data for poorly soluble particulates and for other CNTs, and for lung irritation based on particle size.



Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity study in rats (OPPTS Harmonized Test Guideline 870.3465 or OECD 413 test guideline) with a post-exposure observation period of up to 3 months, including BALF analysis; and certain material characterization data would help characterize possible effects of the PMN substance. In the consent order, the PMN submitter has agreed not to exceed a specified production volume or production time limit (whichever comes first) without performing these tests.

CFR citation: 40 C.F.R. 721.10156.

Comments are due **December 7, 2009**.

European Commission Adopts 2007-2009 Nanotechnology Implementation Report -- On October 29, 2009, the European Commission adopted a Communication entitled *Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009. Second Implementation Report 2007-2009*. The Communication outlines the key developments during 2007-2009 in each policy area of the Nanotechnology Action Plan 2005-2009, identifies current challenges, and draws conclusions relevant to the future European nanotechnology policy. According to the Communication, the European Commission has made significant progress on all points in the Action Plan. The Communication notes that, “[a]s a general remark, the past two years have seen a substantial development of nanotechnology, supported by a further growth in research funding and the active development of policy. . . . In view of this, efforts to address societal and safety concerns must be continued to ensure the safe and sustainable development of nanotechnology.” The Communication states that the European Commission “is considering proposing a new Nanotechnology Action Plan that would be one of the driving forces of the European Research Area and address important societal and environmental issues.” The Communication and accompanying Staff Working Document are available on the Internet at http://ec.europa.eu/nanotechnology/policies_en.html.

OSHA

OSHA Schedules Stakeholders Meeting On Combustible Dust -- On November 10, 2009, the Occupational Safety and Health Administration (OSHA) invited interested parties to participate in informal stakeholder meetings on the workplace hazards of combustible dust. 74 Fed. Reg. 57974. OSHA plans to use the information gathered at these meetings in developing a proposed standard for combustible dust. Dates and locations for the stakeholder meetings are: December 14, 2009, at 9 a.m., in Washington, D.C., December 14, 2009, at 1 p.m., in Washington, D.C.; additional meetings are planned for early 2010, and will be announced in one or more subsequent



notices. The stakeholder meetings will be conducted as a group discussion on views, concerns, and issues surrounding the hazards of combustible dust. To facilitate as much group interaction as possible, formal presentations will not be permitted. Formal input should be submitted as indicated in the Advanced Notice of Proposed Rulemaking issued on October 21, 2009. OSHA believes the stakeholder meeting discussion should center on major issues such as: possible regulatory approaches, scope, organization of a prospective standard, the role of consensus standards, economic impacts, and additional topics as time permits.

LEGISLATIVE DEVELOPMENTS

House Acts On Chemical Security Measure -- The House of Representatives passed the Chemical and Water Security Act of 2009 (Act) on November 6, 2009, by a vote of 230 to 193. The text that passed was similar to that reported out by the Transportation and Infrastructure and Homeland Security Committees, respectively, and provides an extension of the authority of the Department of Homeland Security (DHS) to enforce Chemical Facility Anti Terrorism Standards for chemical manufacturing facilities, presently set to run out in October 2010. At the same time, the Act gives jurisdiction to EPA to establish parallel chemical security programs at wastewater and drinking water facilities. Opponents of the measure had sought adoption on the floor of an amendment that would have struck a provision dealing with direction to companies in higher risk businesses to seek Inherently Safer Technology (IST) -- alternative processes or chemicals -- that might blunt the force of any terrorist attack launched, if that technology could be employed in a feasible manner. The direction to such companies could even involve the relocation of a particular facility. That amendment failed. The Senate had moved to extend the interim provisions relating to the authority of the DHS over facility security, but the Senate has yet to act on a substantive measure such as that passed in the House.

2010 Appropriations For Water Projects Has Conditions On Spending -- The Appropriations Bill for EPA agreed to by House and Senate conferees significantly expands the funds available, but contains conditions on the use of said funds. One restraint is that the contractors for the projects will have to pay prevailing wages, a source of controversy between unions and some builders as to whether such wage provisions should apply to environmental legislation. Under another provision, a percentage of projects have to be green infrastructure projects. There are also conditions relating to relieving the burden of poor communities. The monies allocated include \$3.6 billion for repair and replacement of aging water systems, \$2.1 billion for state revolving funds for sewer system improvements, and \$1.38 billion for revolving funds for improvement of state drinking water systems.

\$10.3 Billion For EPA In 2010 -- Both houses of Congress approved a \$10.3 billion spending measure for EPA for fiscal 2010, an increase of 30% over the previous year levels. Two compromise provisions involved in the final approvals were the waiver of certain emission standards for a number of older freighters used on the Great Lakes if compliance with those



standards could be shown to cause great economic hardship, and restriction of some GHG rules for a number of farming operations.

House Clears Solar Energy Bill -- The House passed legislation that would fund the development of solar research to the amount of \$2.25 billion, and require the Department of Energy to establish a plan to implement such research. The plan, dubbed the “Solar Energy Road Map” measure, would have the Department to have such a map, with a technology committee comprised of academic, industry, and other leaders that would recommend the activities that would be funded by the appropriation. At present, the Senate does not have under consideration any solar energy roadmap legislation.

EPA Authority Would Be Expanded Under Bay Clean-Up Bill -- The states that have land in the Chesapeake Bay watershed would get expanded authority and funds to clean up the watershed under legislation introduced by Senator Ben Cardin (D-MD). Perhaps even more important, EPA would get new authority to block all Clean Water Act funding to those states that fail to move to implement cleanup plans. This power resembles the power EPA has under the CAA, and could involve a federal takeover of involved state programs.

Clorox Action May Aid Chemical Security Bill Passage -- Greenpeace hailed the recent announcement by the Clorox Co. that it will begin eliminating the use of chlorine gas in making bleach as an illustration of the effect that the requirement in the proposed chemical security legislation that companies seek safer, more cost effective chemicals whenever feasible could have on reducing the risks to the public from terrorist attacks or mishaps. Language in drafts of the chemical security measure being discussed would require high risk companies to use such “inherently safer technology” where possible. Opponents state that the requirement would be a serious cost burden on small companies, but proponents say the Clorox action demonstrates that the elimination of risks can be technologically possible and feasible as a business matter. In place of chlorine, that can be poisonous if released as a liquid that turns into a gas, Clorox stated it will utilize sodium hypochlorite.

Standards For Pole Mounted Lights -- Industry and Senate representatives are said to have concluded extended discussions resulting in an agreement on legislation that would establish a set of standards for the efficiency of outdoor lighting fixtures such as those used in parking lots and on streets. The standards would be phased-in in three stages. The requirements for the first phase would provide modest savings, since the bulk of existing fixtures would comply. More substantial returns would be gained for a minority of lights that would not initially comply. In two stages in future years, the requirements would be toughened for all pole mounted lights, with very substantial improvements in efficiency forecast.



Senate Committee Moves Ahead On Climate Change -- The Democratic members of the Senate Environment and Public Works Committee on November 6, 2009, voted 11-1 to approve a climate change bill. The Republicans on the Committee, who had boycotted mark-up in Committee, all absented themselves from the vote. One Democrat, Max Baucus (D-MT), voted “no,” stating that the 20% reduction in GHG emissions by 2020 (from the levels in 2005) in the legislation was too high and would unduly affect states such as Montana in the western United States. Senator Baucus said he favored a reduction starting with 14% and working up to the 20% figure, if other nations such as China agreed to take similar action. To avoid allowing the boycott to prevent consideration of the bill by the full Senate, the Committee Chair, Senator Barbara Boxer (D-CA), used a procedural ploy that permitted the approval by only the Democrats voting, but without amendments such as the one Senator Baucus intended to offer. Commentators were split on the effect that the bypassing of the Republican Committee members would have on the chances of passage of the controversial measure by the full Senate, but agreed that the measure is not presently ready for floor consideration. (Six different Senate Committees have jurisdiction over some aspect of the climate control proposal.) The House of Representatives passed a climate control measure in September.

Senators Move To Support Solar Energy -- Three Senators have introduced a measure that would extend tax credits for the purchase of machinery to manufacture solar energy. Until the passage of the Stimulus package, credits were available only for the installation of solar energy technology, not for the tools needed to produce it. The Stimulus Package included an amount set aside for incentives to produce clean energy that included solar energy, but that amount was quickly distributed, with far more applications remaining pending than those that were accepted. The three Democrats who are sponsoring the measure, Robert Menendez of New Jersey, Debbie Stabenow of Michigan, and Michael Bennet of Colorado, stated that the amounts provided in the legislation would help prevent future job losses to European and Asian countries, whose governments are providing significant tax breaks for solar energy manufacturing.

MISCELLANEOUS

EPA Submits Report To Congress On Mercury Compounds -- EPA recently submitted a report to Congress entitled “Potential Export of Mercury Compounds from the United States for Conversion to Elemental Mercury.” EPA’s report fulfills a requirement contained in the Mercury Export Ban Act of 2008, which bans the export of elemental mercury after January 1, 2013. The statute requires EPA to provide data on mercury compounds so that Congress has sufficient information to consider in determining whether to extend the ban beyond elemental mercury to one or more mercury compounds. The report identifies sources of mercury compounds in the U.S., and reports quantities in imports, exports, and uses of these compounds in products and processes. The report also assesses the potential for key mercury compounds to be exported for reprocessing into elemental mercury. The report is available at <http://www.epa.gov/mercury/pdfs/mercury-rpt-to-congress.pdf>.



CPSC Issues Guidance On Testing/Certifying Lead Content In Children's Products -- On October 21, 2009, the Consumer Product Safety Commission (CPSC) released guidance on the testing and certification of lead content in children's products by outlining what children's products must be tested and certified to the current lead-content limit. The document seeks to answer questions prompted by a final rule issued in August outlining the agency's determination that some materials used in children's products do not inherently contain lead so they will not exceed the 300 ppm limit. The CPSC lead policy is available at <http://www.cpsc.gov/about/cpsia/leadpolicy.pdf>.

OMB Seeks Comment On Improving Efforts To Diminish Paperwork Burdens -- On October 27, 2009, the Office of Management and Budget (OMB) announced it is seeking public comment on how to "strengthen and improve" implementation of the Paperwork Reduction Act of 1995 by the Environmental Protection Agency and other federal agencies. 74 Fed. Reg. 55269. The Paperwork Reduction Act requires federal agencies to minimize the burden on the public resulting from their information collections and to maximize the practical utility of the information collected. Over the years, the number of hours that entities have spent responding to federal government information collections has increased since 2009, the number of hours responding to information collections subject to the Paperwork Reduction Act has increased more than 30 percent. Comments are due by **December 28, 2009**.

ATSDR Announces Final Priority Data Needs For Six Priority Hazardous Substances -- On October 27, 2009, the Agency for Toxic Substances and Disease Registry (ATSDR) announced the final priority data needs for six priority hazardous substances as part of the continuing development and implementation of the ATSDR Substance-Specific Applied Research Program (SSARP). 74 Fed. Reg. 55240. The exposure and toxicity priority data needs in this notice were distilled from the data needs identified in ATSDR's toxicological profiles by the logical scientific approach described in a decision guide published in the *Federal Register* on September 11, 1989. The priority data needs represent information essential to improving the database for conducting public health assessments. Research to address these priority data needs will help to determine the types or levels of exposure that may present significant risks of adverse health effects in people exposed to the six hazardous substances. The priority data needs announced in this notice reflect the opinion of ATSDR, in consultation with other federal programs, about the research needed pursuant to ATSDR's authority under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). The six chemicals are:



Substance-Specific Priority Data Needs for Six Priority Hazardous Substances

Substance	Priority data needs
Aluminum	Exposure levels in humans living near hazardous waste sites. Exposure levels in children. Exposure levels for adults and children who do not live near hazardous waste sites (as controls). Dose-response data for acute-duration* oral exposure.
Cresol	Exposure levels in humans living near hazardous waste sites. Exposure levels in children. Dose-response data for acute-duration* oral exposure.
Diazinon	Developmental toxicity data for oral exposure.
Dichloropropenes	Dose-response data for acute-duration* inhalation exposure. Immunotoxicity battery via inhalation exposure.
Guthion	Studies of developmental toxicity via oral exposure, with emphasis on neurodevelopmental toxicity.
Phenol	Exposure levels in humans living near hazardous waste sites. Exposure levels in children.

* 14 days or less.

The needs identified here do not represent the priority data needs for any other agency or program. The priority data needs are available on ATSDR's website at <http://www.atsdr.cdc.gov/pdns/>.

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