



## Recent Federal Developments February 15, 2007

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### TSCA/FIFRA/EPCRA/NTP

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***ITC Issues Fifty-Ninth Report*** -- On January 22, 2007, the Toxic Substances Control Act (TSCA) Interagency Testing Committee (ITC) transmitted its 59th ITC Report to the Administrator of the U.S. Environmental Protection Agency (EPA). 72 Fed. Reg. 2756. In the 59th ITC Report, the ITC is revising the TSCA Section 4(e) *Priority Testing List* by removing 22 chemicals. Phenol, 4-(1-1-dimethylethyl)- is being removed because a recently submitted reproductive effects study meets ITC's data needs. Five tungsten compounds and 16 chemicals with insufficient dermal absorption rate data are being removed because their production volumes or worker numbers indicate low potential for occupational exposures. Comments must be received on or before **February 21, 2007**.

***EPA Withdraws Direct Final Rule Regarding Pesticide Chemical Definitions*** -- On February 2, 2007, EPA announced its decision to withdraw the direct final rule excepting from the definitions of "pesticide chemical" and "pesticide chemical residue" under Section 201(q) of the Federal Food, Drug and Cosmetic Act (FFDCA) food packaging (*e.g.*, paper and paperboard, coatings, adhesives, and polymers) that is treated with a pesticide because EPA has received adverse comments. 72 Fed. Reg. 4963. The direct final rule was published on December 6, 2006. EPA stated in that direct final rule that if it received adverse comment by January 5, 2007, EPA would publish a timely withdrawal. EPA subsequently received adverse comment on that direct final rule and is therefore withdrawing the rule. According to one comment submitted, the proposal created a "loophole" and certain products would escape regulation and FFDCA Section 408 if the manufacturer of packaging does not make a pesticidal claim or state a pesticidal purpose. The withdrawal was effective January 25, 2007.

***EPA Will Hold Exposure Modeling Public Meeting*** -- On February 14, 2007, EPA announced that it will hold an Exposure Modeling Public Meeting (EMPM) on **February 27, 2007**. 72 Fed. Reg. 7029. According to the notice, entities potentially affected are those required to conduct testing of chemical substances under TSCA, FFDCA, or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EMPM will be held at EPA's Office of Pesticide Programs (OPP), One Potomac Yard (South Building), Rooms S-4370 and S-4380, 2777 S. Crystal Drive, Arlington, Virginia, 22202. The tentative agenda includes the following items:

- Development of MUSS;
- Degradation Influenced by Soil Temperature under Cropped and Base Soil Conditions;
- Factors Impacting Pesticide Runoff from Warm-Season Turf;



- Sediment Concentrations: Implications of the Current Conceptual Model;
- Status Report on Field Evaluation and Riparian Ecosystem Management Model (REMM) Modeling of a Pesticide Runoff Buffer;
- Forest Canopy Delivery of Pesticides to a Riparian Buffer Area;
- High Priority Changes for Pesticide Root Zone Model (PRZM);
- GeoSTAC: GEOSpatial Tools and Access; and
- Kinetic Analysis of Metabolism Data.

## **REACH**

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***REACH Guidance Issued In Draft*** -- On February 9, 2007, the European Chemicals Bureau released in draft and requested comment on Registration, Evaluation, and Authorization of Chemicals (REACH) Implementation Projects (RIP) 4.1/4.2, which describes the responsibilities of officials who are expected to be involved in chemical evaluations. The document, *Technical Guidance Document for Dossier and Substance Evaluation*, is available at [http://ecb.jrc.it/DOCUMENTS/REACH/RIP\\_FINAL\\_REPORTS/](http://ecb.jrc.it/DOCUMENTS/REACH/RIP_FINAL_REPORTS/). The document describes how officials will examine testing proposals, what is included in a compliance check, and how chemicals will be evaluated to determine whether they pose a risk to human health or the environment. Comments are due by **March 5, 2007**.

## **NANOTECHNOLOGY**

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***EPA Issues Nanotechnology Fact Sheet*** -- On January 18, 2007, EPA posted a web page entitled *Fact Sheet for Nanotechnology under the Toxic Substances Control Act*. The page, which is available at <http://www.epa.gov/oppt/nano/nano-facts.htm>, provides useful information on EPA's consideration of nanotechnology under TSCA, the definition of nanomaterials, and related information.

***EPA Issues Final Nanotechnology White Paper*** -- On February 15, 2007, EPA's Office of the Science Advisor announced the release of the final *Nanotechnology White Paper* (White Paper). 72 Fed. Reg. 7435. The White Paper is intended to inform EPA management of the science issues and needs associated with nanotechnology, to support related EPA program office needs, and to communicate nanotechnology science needs to interested stakeholders. The White Paper also includes as an appendix EPA's "Nanotechnology Research Framework," which outlines how EPA will 'strategically focus its own research program to provide key information on



potential environmental impacts from human or ecological exposure to nanomaterials in a manner that complements other federal, academic, and private-sector research activities.” The White Paper is available at <http://www.epa.gov/osa/nanotech.htm>.

***New Zealand Releases Nanoscience And Nanotechnologies Roadmap*** -- On February 13, 2007, the New Zealand Ministry of Research Science and Technology released a report entitled *Nanoscience and Nanotechnologies: Roadmaps for Science*, which states that New Zealand firms working with nanomaterials are required to comply with existing laboratory research regulations and the Health and Safety in Employment Act. The report also states that cosmetic firms are required to notify the government the first time they make or import a product that contains nanoparticles other than zinc oxide or titanium dioxide. The Ministry intends the report to inform readers of national and international developments and to prepare for the challenges and opportunities resulting. To that end, the report sets the following goal: “To enhance research, private sector, and government capabilities to absorb, develop and apply nanoscience and nanotechnologies for the benefit of New Zealand.” According to the report, three objectives underpin this goal:

- Nanoscience and nanotechnologies should be developed and managed responsibly;
- Nanoscience and nanotechnologies should contribute to economic transformation through higher productivity, higher value products, and diversifying the economy; and
- Nanoscience and nanotechnologies should contribute to sustainable development and social well-being.

The report lists nine directions providing the Ministry’s view of the way the objectives should be approached. There are three overarching directions:

- Until **2010** the main focus for investment in nanoscience and nanotechnologies should remain on basic research that builds capability and critical mass;
- Additional investment in the medium term (to 2015) should be targeted to research that shows strong relevance and benefit to existing industries; and
- In the longer term, a greater proportion of investment should be targeted to supporting research and development that has more transformative application potential.



Six other directions underpin these:

- Greater emphasis should be placed on building capability in bio-nanotechnologies;
- The needs of New Zealand's existing industries should inform research in nanoscience and nanotechnologies;
- The Government will work to ensure the appropriate tools and skills are available to underpin the research directions;
- Social research should inform New Zealand's nano-related research and policy;
- The Government will support inclusive forms of public engagement that enable communities to contribute to decisions on nanoscience and nanotechnology applications; and
- The Government will ensure that regulatory arrangements are appropriate for managing nanoscience and nanotechnologies.

The Ministry of Research, Science and Technology intends to keep the directions and actions under review, track indicators of progress, and advise the Government on the need to refresh directions by 2011. The report is available on the Internet at <http://www.morst.govt.nz/Documents/work/roadmaps/MoRST-Nanotechnology-Roadmap.pdf>. Information about New Zealand's policy for notifying the government concerning cosmetics that contain nanoparticles is available on the Internet at <http://www.ermanz.govt.nz/consultations/gc/cosmeticssimsubs.pdf>.

## **FDA**

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***FDA Reinforces Commitment to Drug Safety*** -- On January 30, 2007, the U.S. Food and Drug Administration (FDA) outlined a comprehensive commitment to the safety of drugs and other medical products. The FDA report, which also responds to a set of recommendations made by the Institute of Medicine in 2006, details a series of initial steps that aim to ensure that FDA's safety programs are the best possible. FDA outlined three key goals:

- Strengthening the science that supports the FDA's medical product safety system at every stage of the product life cycle from pre-market testing and development through post-market surveillance and risk management;



- Improving communication and information flow among all stakeholders engaged in promoting the safe use of medical products; and
- Improving operations and management to ensure implementation of the review, analysis, consultation, and communication processes needed to strengthen the U.S. drug safety system.

FDA's report contain other useful information. A copy of the report "The Future of Drug Safety" is available at <http://www.fda.gov/oc/reports/iom013007.html>.

***Senators Ask FDA to Keep Regional Laboratories Open*** -- A bipartisan group of senators, including Senators Edward M. Kennedy (D-MA) and Arlen Specter (R-PA), said in a letter to the FDA that FDA should suspend plans to close as many as nine of 13 laboratories that test the safety and effectiveness of food, drugs, cosmetics, and medical devices. As part of a consolidation plan, FDA is considering closures of some of the laboratories, which are located in or near Atlanta, Boston, Cincinnati, Denver, Detroit, Kansas City, Little Rock, Los Angeles, New York City, Philadelphia, San Francisco, San Juan, and Seattle. The lawmakers wrote that the network of laboratories, run by FDA's Office of Regulatory Affairs, "could prove particularly vital in rapidly responding to public health crises" during national emergencies. FDA has not made public which labs it intends to close, but told the National Treasury Employees Union that it planned on closing an undetermined number of the laboratories by **April 2007**. As reported in the February 1, 2007, *Washington Post*, FDA spokeswoman Julie Zawisza said that FDA would respond to the lawmakers' letter soon.

***FDA Announces Availability of Global Harmonization Task Force Documents*** -- On February 6, 2007, FDA announced the availability of proposed and final documents that were prepared by Study Groups 1, 2, and 4 of the Global Harmonization Task Force (GHTF). 72 Fed. Reg. 5443. The documents represent a harmonized proposal and recommendation from the GHTF Study Groups for use by governments developing and updating their regulatory requirements for medical devices. The GHTF was developed to facilitate harmonization following a September 1992 meeting in Nice, France, at which senior regulatory officials met to evaluate international harmonization. The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. The GHTF is comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America. Each of these regions actively regulates medical devices using a unique regulatory framework.

Study Group 1 has developed a proposed document entitled "Role of Standards," Study Group 2 has developed a final document entitled "Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices," and Study Group 4 developed a proposed document entitled "Guidelines for Regulatory Auditing of Quality Management



Systems of Medical Device Manufacturers -- Part 3: Regulatory Audit Reports.” (FDA’s announcement does not provide information on Study Group 3.) Study Groups 1, 2, and 4 reports are available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0031-bkg0001-01.pdf>, <http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0031-bkg0001-02.pdf>, and <http://www.fda.gov/OHRMS/DOCKETS/98fr/07d-0031-bkg0001-03.pdf>, respectively. Information on the GHTF is available at <http://www.ghrf.org>. FDA notes that the documents are intended to provide information only, and do not describe current U.S. regulatory requirements. FDA is requesting comments on the documents by **May 7, 2007**.

## **LEGISLATIVE DEVELOPMENTS**

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***FDA Requests \$2.1 Billion As Part Of FY 2008 Budget*** -- On February 5, 2007, FDA requested nearly \$2.1 billion, as part of President Bush’s fiscal year (FY) **2008** budget. This represents more than a 1.5 percent increase over the budget submitted to Congress last year. FDA’s proposed budget includes significant increases to strengthen food safety, modernize drug safety, improve medical device safety and review, and speed approval of generic drugs. Additionally, the request includes increases to cover higher infrastructure expenses, and costs of living pay increases for FDA employees. FDA also is proposing two new user fees. The Reinspection User Fee would ensure that laboratories and facilities that fail to comply with health and safety standards bear the cost of re-inspection, and the Export Certification User Fee would cover the cost of issuing export certificates required by several foreign governments when companies export food products.

***House Passes Joint 2007 Funding Resolution*** -- The House of Representatives on January 31, 2007, voted 286-140 to pass a spending bill for FY **2007** that includes \$7.9 billion for EPA and \$18.3 billion for the Department of the Interior (DOI) and related agencies, including the Forest Service and the Bureau of Land Management. The amounts are part of a \$463.5 billion joint funding resolution (H.J. Res. 20) to govern spending unrelated to defense and homeland security for the last eight months of FY **2007**, until **September 30, 2007**. The resolution provides that most government programs, including those for EPA and DOI, will continue to be funded at their FY 2006 levels, adjusted for increased pay costs. The resolution would provide the Department of Energy (DOE) with \$120 million to process spent nuclear fuel and for other activities under the Global Nuclear Energy Partnership (GNEP) program. GNEP calls for development of a new type of a nuclear waste recycling technology that, unlike methods used in Europe and Asia, does not separate out weapons-grade plutonium.

The House-passed resolution allocates additional money for renewable energy programs and scientific research programs. The Office of Science, which funds DOE labs, would receive \$3.8 billion, an increase of \$200 million, to support research on new energy technologies, such as cellulosic ethanol. Energy efficiency and renewable energy research programs would see an increase of \$300 million to \$1.5 billion to accelerate research in these areas.



The continuing resolution also would provide \$4 billion in federal loan guarantees for clean energy technologies that are on the verge of becoming commercially viable but need additional financial assistance. The loans can be used for advanced nuclear reactors, clean-coal facilities using carbon capture and sequestration, renewable energy, and other alternative technologies.

The passage by the House of this resolution came only five days before the Bush Administration submitted a FY 2008 EPA budget. According to the Administration's budget, the overall FY 2008 budget request of \$122.3 million for OPP is largely unchanged from the \$122.1 million included in the President's FY 2007 budget proposal. The budget request calls for the establishment of \$66 million in new pesticide fees above and beyond those currently authorized. The President's FY 2008 budget anticipates that an aggregate \$306 million in new pesticide fees will be collected over the next five FYs. The newly released fee projections for the outlying FYs ending with FY 2012 are higher than the fee estimates for the outlying years included in last year's budget proposal. The President's FY 2007 budget proposal assumed the collection of \$66 million in new fees to be collected in FY 2008 (as reported above, this level is included in the current budget request). Last year's funding proposal, however, assumed the collection of \$53 million in new fees for each of FYs 2009, 2010, 2011, and 2012. In contrast, the current budget request anticipates the collection of \$57 million in FY 2009, \$60 million in FY 2010, \$66 million in FY 2011, and \$57 million in FY 2012.

The President's FY 2008 budget request for the Department of Homeland Security (DHS) calls for a total of \$25 million that includes an increase of \$15 million for the establishment of a Chemical Site Security office to regulate security of chemical plants. According to DHS budget documents, the funding will be used to establish the Chemical Security Compliance Division, which will include a national program office to manage training of inspector staff, help-desk personnel, and other administrative staff. The Division will also include experts in chemical engineering, process safety, as well as an adjudication office. DHS states that funds will also be spent on assisting chemical facilities with vulnerability assessments.

***New Subcommittee On Organic Farming*** -- The House Committee on Agriculture has approved the creation of a new Subcommittee on Horticulture and Organic Agriculture. The subcommittee has jurisdiction over fruits and vegetables, honey and bees, marketing and promotion orders, plant pesticides, quarantine, adulteration of seeds, insect pests, and organic agriculture. The Democratic Caucus met January 17, 2007, and designated Representative Dennis Cardoza (D-CA) to chair the subcommittee.

***Bills Would Address CAFE Standards*** -- Representative David Reichert (R-WA) introduced legislation (H.R. 656) on January 24, 2007, on behalf of 13 House Republicans that would raise corporate average fuel economy (CAFE) standards for cars and light trucks to 33 miles per gallon (mpg) by 2017. In a concession to the Bush Administration, the Reichert bill allows the Secretary of Transportation to establish separate standards for different-sized vehicles. The



overall average of a manufacturer's fleet, however, would have to be at least 33 mpg. The bill also would establish a CAFE credit trading system among manufacturers to add more flexibility. That system would allow companies that exceed their CAFE requirements to generate credits that they could sell to companies failing to meet the standard. The legislation joins several bills introduced in the Senate to increase vehicle fuel economy. Among these is legislation Senator Dianne Feinstein (D-CA) and 11 other senators introduced on January 22, 2007, that would increase CAFE standards from the current average of 25 mpg to 35 mpg by **2019** for all vehicles, including sport-utility vehicles and sedans. In addition to tightening CAFE standards, the bill would also establish mandatory on-board fuel economy displays that show real-time fuel consumption to encourage more fuel-efficient driving. The bill also would create a program to identify vehicles that meet or surpass mandatory fuel economy standards by giving them a green label or a gold star label. Senator Ted Stevens (R-AK) earlier in the month introduced CAFE legislation. That bill (S. 183) would increase the fuel economy standard for passenger cars to 40 mpg by **2017** and alter the way CAFE standards are set. It would authorize the Department of Transportation's (DOT) National Highway Traffic Safety Administration to set different standards for separate classes of passenger vehicles based on the size or other attributes of the vehicles.

***House Approves Legislation To Authorize Research On Alternative Fuels Infrastructure*** -- The House of Representatives approved a bill (H.R. 547) by a 400-3 vote on February 8, 2007, to authorize research to encourage greater use of alternative and low-sulfur fuels. The legislation would authorize EPA and the National Institute of Standards and Technology (NIST) to research making the current fuel distribution system compatible with biofuels, such as corn-based ethanol. This would be accomplished either by upgrading pipelines and other infrastructure or by developing additives to reduce the corrosive effect of biofuels on distribution infrastructure. The bill also would authorize research to develop less expensive, more convenient testing methods and equipment for verifying the sulfur level of fuels.

***Renewable Fuels Measure Would Include Mandates On Oil And Auto Industries*** -- Senator Tom Harkin (D-IA) introduced a bill (S. 23), the Biofuels Security Act, on January 4, 2007, that calls for passage of a biofuels bill that would establish mandates on the automobile and oil industries to make and fuel more renewable-fuel vehicles. The bill would go further than the Bush Administration's plan by calling for 60 billion gallons of renewable fuel in **2030**. It sets interim goals of 10 billion gallons in **2010** and 30 billion gallons in **2020**. With national consumption of gasoline recorded at 140 billion gallons in 2005, Harkin's bill would give ethanol about 43 percent of the U.S. gasoline market. The bill was referred to the Senate Commerce, Science, and Transportation Committee. Representative William Delahunt (D-MA) introduced a companion bill (H.R. 559) on January 18, 2007, in the House.

***Bill Would Move EPA To Issue Corporate Cleanup Regulations*** -- Senator Maria Cantwell (D-WA) introduced legislation on January 31, 2007, that would direct EPA to develop financial



assurance regulations to ensure liable parties meet their superfund cleanup obligations. Senate Environment and Public Works Chair Barbara Boxer (D-CA) and Senator Frank Lautenberg (D-NJ) co-sponsored the Cleanup Assurance and Polluter Accountability Act (S. 452). The legislation would require EPA to write financial assurance regulations within 18 months for facilities that present the highest risk associated with hazardous substances. For each year thereafter, EPA would have to publish and promulgate financial assurance rules for additional classes of facilities, giving highest priority to classes that may contain sites at which unreimbursed response costs are greater than or equal to \$12 million. Owners and operators of facilities that file for bankruptcy who are required to provide financial assurance under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) would have to notify EPA of the filing, provide an estimate of the environmental impacts resulting from their activities, and describe their corporate relationships. EPA would have to give priority to the development of requirements for facilities or industries whose prior actions indicate a high risk of default on environmental liabilities. The legislation would require the National Bankruptcy Review Commission to reconvene and evaluate the inconsistencies between the bankruptcy code and CERCLA.

**Energy Legislation** -- The House of Representatives voted 264 to 163 on January 18, 2007, to roll back two tax breaks and force oil and gas companies to renegotiate royalty-free leases, signaling the first victory for Democrats seeking to shift tax policy and budget priorities away from the oil industry and into renewable and alternative energy. The Democratic leadership bill (H.R. 6), the Clean Energy Act, would raise \$14 billion over the next decade which would be used to establish a new fund and budget account to invest in clean, renewable energy and energy efficiency. The vote fell mostly along party lines. The fate of the bill is more uncertain in the Senate, where Democrats have only a one-vote majority.

A number of other energy-related bills have been introduced in Congress. Senate Finance Committee member John Kerry (D-MA) introduced legislation (S. 103) to strip from major oil and gas companies the domestic manufacturers deduction, as has Representative Jim McDermott (D-WA), a House Ways and Means Committee member, in H.R. 453. Representative Earl Pomeroy (D-ND), another Ways and Means Committee member, introduced a bill (H.R. 196) on January 4, 2007, to make permanent tax incentives for using ethanol and biodiesel as fuel and another (H.R. 197) to extend for five years the tax code Section 45 credit for electricity produced from renewable sources.

A group of senators introduced a bill, the Drive Act, on January 18, 2007, that would cut gasoline consumption in the transportation sector. Senators Evan Bayh (D-IN) and Norm Coleman (R-MN) are two of the bill's sponsors. House Science and Technology Chair Bart Gordon (D-TN) introduced a bill (H.R. 547) on January 18, 2007, that directs the Department of Energy (DOE) to research new technologies such as fuel additives, blend stocks, and tank reconditioning methods that would allow retailers to increase the use of alternative fuels, such as



E-85 ethanol, in the nation's existing fuel infrastructure. The bill also directs DOE to develop an affordable, quick, and accurate way to test the sulfur content of ultra-low-sulfur diesel fuel.

Representative Allyson Schwartz (D-PA), a member of the House Ways and Means Committee, introduced legislation (H.R. 539) on January 17, 2007, to encourage construction of energy-efficient buildings. The Buildings for the 21st Century Act would make a number of changes to the energy-efficient commercial buildings deduction originally included in the Energy Policy Act of 2005 (Pub. L. 109-58). The Schwartz bill would increase the tax deduction for fully compliant commercial buildings by 45 cents to \$2.25 per square foot. It also would boost the deduction for partially compliant buildings by 15 cents to 75 cents per square foot. With the incentive set to expire at the end of **2008**, the legislation also would extend it through **2013**. The legislation has attracted 66 co-sponsors from both parties.

Representative Michael McNulty (D-NY), along with Representative Dave Camp (R-MI), introduced legislation (H.R. 550) on January 17, 2007, that would extend for eight years certain solar and fuel cell tax credits that were included in the same energy law. The McNulty bill would extend through **2016** a residential credit of 30 percent for the purchase of qualified photovoltaic property and solar water heating property. It also would apply to the purchase of qualified fuel cell power plants. Additionally, it would extend through **2016** a 30 percent energy credit for the business installation of qualified fuel cells, stationary microturbine power plants, and solar equipment. H.R. 550, the Securing America's Energy Independence Act of 2007, also would establish a three-year depreciation period for all solar energy equipment eligible for the business solar tax credit.

Representative Ron Lewis (R-KY) introduced a bill (H.R. 683) on January 24, 2007, that would promote investment in energy independence through coal-to-liquid fuels technology, biomass, and oil shale. Among other things, the bill would provide a credit for investment in coal-to-liquid fuels projects and temporary expensing for equipment used in those projects; an expansion and extension of the alternative fuel credit; and an expansion of expensing of oil and alternative fuel refineries.

***Solid Waste Imports Would Be Restricted*** -- Representatives John D. Dingell (D-MI) and Mike Rogers (R-MI), joined by the entire House Michigan delegation, reintroduced legislation (H.R. 518) on January 17, 2007, intended to curtail the importation of solid waste from Canada. The bill is identical to the International Solid Waste Importation and Management Act (H.R. 2431), which the House passed by voice vote in September 2006. That bill, which the Energy and Commerce Committee approved in June 2005, would have allowed states to restrict Canadian trash until EPA issues regulations to implement and enforce the Agreement Concerning the Transboundary Movement of Hazardous Waste Between the United States and Canada. Under the agreement, shipments of waste across the U.S.-Canadian border require government-to-government notification. Under the legislation, when Canada notifies the United States of a



waste shipment, EPA would be required to give substantial weight to the views of affected states and local governments before agreeing to the importation of foreign municipal waste. EPA would have to consider the impact of the imports on continued public support for state and local recycling programs; landfill capacities; air emissions and road deterioration from increased vehicular traffic; and homeland security, public health, and the environment. States would be able to enact laws or issue regulations that are consistent with international trade obligations imposing limits on receipt and disposal of foreign municipal solid waste.

***Resolution Introduced To Push The U.S. To Engage In Climate Change Negotiations*** -- Senators Joseph Biden (D-DE) and Richard Lugar (R-IN) reintroduced a Senate resolution on January 16, 2007, that calls on the Bush Administration to re-engage on international negotiations aimed at addressing global climate change. The “Sense-of-the-Senate” resolution (S.R. 30) would not be binding on the Administration, but its supporters say passage would send a strong signal to the Administration that the Senate supports resuming U.S. participation in any future global treaties to reduce greenhouse gas emissions. The Senate resolution calls for U.S. participation in negotiations under the United Nations Framework Convention on Climate Change, an international agreement that led to the Kyoto Protocol, and for a bipartisan Senate body to monitor the international talks. Senate approval of the resolution essentially would reverse a 1997 “Sense-of-the-Senate” resolution that warned the Clinton Administration against signing the Kyoto Protocol, which would have required the U.S. to undertake mandatory greenhouse gas emissions reductions. The 1997 resolution (S. Res. 98) was approved by a 95-0 vote and forced the Clinton Administration to abandon plans to present the treaty to the Senate to obtain its consent for ratification.

***Climate Change/Greenhouse Gas Bills*** -- There are multiple greenhouse gas bills circulating in Congress. Senator Bernie Sanders (I-VT) introduced a bill on January 16, 2007, that calls for cutting U.S. greenhouse gas emissions 80 percent below 1990 levels by **2050**. The bill, which Senate Environment and Public Works Committee Chair Barbara Boxer (D-CA) is co-sponsoring, calls for a gradual reduction in U.S. carbon dioxide and other greenhouse gas emissions, first by reducing emissions to 1990 levels by **2020**. Emissions then would be further reduced to 80 percent below 1990 levels over the next three decades. The measure also would provide EPA with the authority to take additional regulatory action to further reduce U.S. emissions if the legislation, along with international efforts, fail to hold global greenhouse gas emissions at 450 parts per million. That is the level that many scientists view as the tipping point for severe global climate changes. According to this bill, EPA also could take additional action if global temperatures climbed two degrees Celsius above what temperatures averaged before the industrialization of the late 18th century.

The Sanders bill is likely to vie for attention with as many as a half-dozen proposals in the 110th Congress calling for mandatory cuts in U.S. greenhouse gas emissions. Senators John McCain (R-AZ) and Joseph Lieberman (I-D-CT) introduced legislation on January 12, 2007, (S. 280) to



cut U.S. greenhouse gas emissions back to 2004 levels by **2012**. Senate Energy and Natural Resources Committee Chair Jeff Bingaman (D-NM) also is drafting a more modest proposal than the McCain-Lieberman bill to address greenhouse gas emissions.

In addition, Senators Dianne Feinstein (D-CA) and Thomas Carper (D-DE) introduced a bill on January 17, 2007, that would cap greenhouse gas emissions from power plants at 2001 levels in **2015** and require an additional one percent reduction each year through **2020**. The Electric Utility Cap-and-Trade Act (S. 317), which would allow for emissions trading, also would require further emissions cuts of 1.5 percent each year after **2020**. The bill would use emissions trading to achieve reductions. Initially, the bill would allocate 85 percent of emissions credits directly to utilities. By **2016**, 30 percent of the credits would be auctioned, and by **2036**, 100 percent of the credits would be auctioned, with 80 percent of the auction proceeds going to developing low-emissions technology. The bill also would allow power companies to comply with emissions reduction targets through offsetting emissions reductions outside of the power industry.

In the House, Representatives John Olver (D-MA) and Wayne Gilchrest (R-MD) on January 22, 2007, introduced the first House legislation in the 110th Congress that calls for capping and reducing U.S. greenhouse gas emissions through an emissions trading scheme. The legislation (H.R. 620) calls for establishing a U.S. cap-and-trade program for emissions beginning in **2012**. The House bill is the companion measure to the latest Senate climate proposal (S. 280) that Senators John McCain (R-AZ) and Joseph Lieberman (I/D-CT) introduced on January 12, 2007. The Olver-Gilchrest Climate Stewardship Act would cover the electric power, transportation, industrial, and commercial sectors and would set up a “feasible and effective” emissions trading scheme to reduce carbon dioxide and other greenhouse gas emissions over multiple decades. The latest Olver-Gilchrest bill has 16 co-sponsors and was referred on January 22, 2007, to three House panels: the House Energy and Commerce Committee, the House Science and Technology Committee, and the House Natural Resources Committee.

***CRS Report Analyzes Several Greenhouse Gas Bills*** -- The Congressional Research Service (CRS) has compiled an analysis of legislation introduced in the 110th Congress that would require reductions in emissions of greenhouse gases, focusing on three Senate bills and a fourth bill introduced in the House. The January 31, 2007, report, *Climate Change: Greenhouse Gas Reduction Bills in the 110th Congress*, provides a side-by-side comparison of S. 280, which Senator Joseph Lieberman (I/D-CT) introduced; S. 309, which Senator Bernie Sanders (I-VT) introduced; S. 317, which Senator Dianne Feinstein (D-CA) introduced; and H.R. 620, which Representative John Olver (D-MA) introduced. The report does not consider other legislation that has focused on emissions monitoring and research, which could provide the groundwork for future emissions reduction schemes, or legislation that could have an indirect effect on emissions, such as bills that promote use of renewable energy.



***New Global Warming Committee*** -- House Speaker Nancy Pelosi (D-CA) on January 18, 2007, called on several House committees to consider and approve by June a climate change bill and related legislation that increases the nation's energy independence in hopes of getting the package before the full House this summer. The House speaker's call on the committees for quick action on the legislation came as she announced a new select committee to focus on climate change and related energy issues, the Select Committee on Energy Independence and Global Warming. The non-legislative committee will focus on increasing public awareness of climate concerns by training its attention on science issues and improving public awareness of global climate change.

***Bill Would Address Cleanup Of Former Meth Labs*** -- The House overwhelmingly approved by a 426-2 vote legislation that would require EPA to establish voluntary guidelines for the cleanup of former methamphetamine laboratories. The Methamphetamine Remediation Research Act (H.R. 365) would require EPA to develop model, voluntary, health-based cleanup guidelines "based on the best currently available scientific knowledge" for states and localities to use in cleaning up former methamphetamine laboratories. The guidelines would include preliminary site assessment and the remediation of residual contaminants. NIST would be authorized to initiate a research program to develop methamphetamine equipment for field use. In addition, the bill would require the National Academy of Sciences to study the long-term health impact of exposure to methamphetamine labs on children and first-responders.

***Bill Would Address Invasive Species*** -- Representative Mark Kirk (D-IL) introduced a bill (H.R. 801) on February 7, 2007, that would mandate that the Coast Guard promulgate regulations requiring ships to exchange or treat ballast water before entering the Great Lakes. The Great Lakes Invasive Species Act includes 20 co-sponsors.

***House Panel Approves Bill Addressing Ship Emissions*** -- On February 7, 2007, the House Transportation and Infrastructure Committee unanimously approved the Maritime Pollution Prevention Act of 2007 (H.R. 802), which would amend the Act to Prevent Pollution from Ships (33 U.S.C. 1901) by requiring EPA to issue standards for sulfur dioxide and nitrogen oxide emissions from ships and to ban the use of ozone-depleting substances on ships. As approved, H.R. 802 would require EPA and the Coast Guard to administer and enforce emissions standards on ships, oil tankers, floating and fixed oil rigs, and cruise liners that the United States agreed to adopt under Annex VI to the 1973 International Convention for the Prevention of Pollution from Ships (MARPOL Convention). The new bill would give EPA primary responsibility for developing regulations for ships under Annex VI, in consultation with Coast Guard. The regulations would apply to any oceangoing vessel that is in the navigable waters of the United States; is bound for or departing from a port, shipyard, or terminal in the United States; is bearing the flag of any of the 35 countries that ratified the treaty; or is traveling through the 200-mile radius of the United States' exclusive economic zone.



***Bill Would Address Watershed Protection Agreements*** -- The Senate Committee on Energy and Natural Resources approved a bill on January 31, 2007, that would authorize on a permanent basis funding for the U.S. Forest Service to enter into agreements with public and private groups to restore and enhance watersheds. Senator Ron Wyden (D-OR) introduced the Watershed Restoration and Enhancement Agreements Act of 2007 (S. 232) on January 7, 2007. The bill would allow the Secretary of Agriculture to use Forest Service appropriations for FYs 2006 through **2011** to enter into cooperative agreements with government, private, and non-private organizations and landowners to protect, restore, and enhance fish stocks, wildlife habitat, and other resources on public and private lands. S. 232 would authorize such funding for FY 2006 and “each fiscal year thereafter,” essentially providing authorization on a permanent basis.

***House Panel Authorizes Funds For Revolving Loan Fund*** -- A House Transportation and Infrastructure subcommittee approved three separate bills on January 31, 2007, that would boost funding for the clean water state revolving fund (SRF), provide grants to curb sewer overflows, and fund pilot alternative water supply projects. The Subcommittee on Water Resources and Environment agreed by a voice vote to send to the full committee for approval the Water Quality Financing Act of 2007 (H.R. 720), which would authorize \$20 billion over five years for the clean water SRF for FYs **2008** through **2012**. Also agreed to by voice votes were the Water Quality Investment Act of 2007 (H.R. 569), which would authorize \$1.8 billion in grants to control sewer overflows, and the Healthy Communities Water Supply Act (H.R. 700), which would authorize \$125 million to fund pilot alternative water supply projects. Representatives Bill Pascrell (D-NJ) and Dave Camp (R-MI) introduced H.R. 569 on January 18, 2007.

## **MISCELLANEOUS**

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***White House Revises EO 12866*** -- On January 18, 2007, the White House issued changes to Executive Order (EO) 12866, Regulatory Planning and Review, which governs regulatory planning across the federal government. The revised EO imposes new requirements on agencies before they can draft regulations or guidance documents. The revisions to EO 12866 provide agencies specific directions on issues they need to consider before developing regulations and require that agencies submit guidance documents to the White House Office of Management and Budget (OMB) for review before they are released. Previously, OMB’s Office of Information and Regulatory Affairs (OIRA) reviewed only regulations prior to publication, not guidance documents, which are intended to be nonregulatory in nature. Among the changes in regulatory planning is a requirement that an agency identify a “specific market failure (such as externalities, market power, lack of information) or other specific problem” that it intends to address through a rulemaking. That expands on the EO’s previous requirement that an agency had to identify the failure of a private market or public situation, “where applicable.”

OMB also released a bulletin outlining agency best practices for developing guidance documents. The *Final Bulletin for Agency Good Guidance Practices* explains policies and



procedures for the development, issuance, and use of significant guidance documents by executive branch agencies. The amendment to EO 12866 is available at <http://www.whitehouse.gov/news/releases/2007/01/20070118.html>. The *Final Bulletin for Agency Good Guidance Practices* is available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf>.

***EPA Seeks Comment On Enforcement Priorities*** -- On February 9, 2007, EPA requested comment on its triennial national enforcement and compliance assurance priorities to be addressed for FYs **2008, 2009, and 2010**. 72 Fed. Reg. 6239. EPA intends to consider information submitted by commentors during the priority identification process. Final priority selections are generally incorporated into the EPA's Office of Enforcement and Compliance Assurance Workplanning Guidance (which provides national program direction for all EPA regional offices). These priorities also affect implementation of the enforcement and compliance goals and objectives outlined in the EPA Strategic Plan, as mandated under the Government Performance and Results Act. Comments and recommendations are due on or before **March 12, 2007**.

***President Bush Signs EO On Energy-Related Activities*** -- On January 24, 2007, President Bush signed EO 13423, entitled *Strengthening Federal Environmental, Energy, and Transportation Management*. The goals of the EO are to improve energy efficiency and reduce greenhouse gas emissions of federal agencies, ensure that at least half of the statutorily required renewable energy consumed by the FY comes from renewable sources, reduce water consumption, require in agency acquisitions of goods and services use of sustainable environmental products, including biobased and environmentally preferable products, and related goals intended to strengthen domestic energy management. The EO consolidates and replaces five EOs issued between 1998 and 2000. The EO is available at <http://www.whitehouse.gov/news/releases/2007/01/20070124-2.html>.

According to a fact sheet on EO 13423, the federal government will reduce oil use and improve environmental and energy performance. Specifically, the EO directs federal agencies to:

- **Reduce Oil Consumption in Fleet Vehicles.** Under EO 13423, federal agencies meeting certain conditions should reduce the fleet's petroleum consumption by two percent annually through **2015**. In addition, the EO directs federal agencies to purchase plug-in hybrid vehicles when commercially available.
- **Increase Use of Renewable and Alternative Fuels.** Federal agencies meeting certain conditions must increase their alternative fuel consumption by at least ten percent annually.



- **Use More New Renewable Power.** EO 13423 stipulates that at least 50 percent of agencies' current renewable energy purchase requirement must come from new renewable sources, such as solar, wind, biomass, landfill gas, ocean (including tidal, wave, current, and thermal), geothermal, municipal solid waste, or new hydroelectric generation capacity achieved from increased efficiency or additions of new capacity at an existing hydroelectric project.
- **Reduce Greenhouse Gas Emissions.** Under EO 13423, federal agencies must improve energy efficiency and reduce greenhouse gas emissions by cutting back on energy intensity -- how much energy is used per square foot of building space -- by three percent annually or 30 percent by **2015**, relative to the agency's energy use in FY 2003. According to the EO fact sheet, this new goal seeks to achieve in ten years the same level of improvement federal agencies achieved in the last 20 years, and is 50 percent stronger than the goal called for in the Energy Policy Act of 2005.
- **Acquire Environmentally Sound Products.** EO 13423 requires federal agencies to increase their purchase of environmentally sound products, including biobased, environmentally preferable, energy-efficient, water-efficient, and recycled-content products, and ensure the development of high performance buildings that are healthier and consume less energy.

EO 13423 revokes the following EOs: EO 13101 of September 14, 1998: Greening the Government Through Waste Prevention, Recycling, and Federal Acquisition; EO 13123 of June 3, 1999: Greening the Government Through Efficient Energy Management; EO 13134 of August 12, 1999, as amended: Developing and Promoting Biobased Products and Bioenergy; EO 13148 of April 21, 2000: Greening the Government Through Leadership in Environmental Management; and EO 13149 of April 21, 2000: Greening the Government Through Federal Fleet and Transportation Efficiency.

The fact sheet on EO 13423 is available on the Internet at <http://www.whitehouse.gov/news/releases/2007/01/20070124-5.html>.

***EPA Schedules National Advisory Committee For Acute Exposure Guideline Levels For Hazardous Substances; Public Meeting*** -- On February 5, 2007, EPA announced that the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) will meet on **March 20-22, 2007**. 72 Fed. Reg. 5288. The NAC/AEGL Committee will address various aspects of the acute toxicity and the development of acute exposure guideline levels (AEGLs) for the following chemicals: acetonitrile; acrylic acid; acrylonitrile; allyl chloride; boron tribromide; bromine chloride; carbonyl fluoride;



chloroacetonitrile; chlorobenzene; diketene; ethylene fluorohydrin; isobutyronitrile; malononitrile; methanol; N,N-dimethylformamide; oxygen difluoride; propionitrile; propylene oxide; silicon tetrafluoride; stibine; tetrachloroethylene; 1,1,1-trichloroethane; and toluene. Please consult the *Federal Register* for details.

***FDA and VA Sign MOU to Share Information on the Safe Use of Medical Products*** -- On January 30, 2007, the FDA in the U.S. Department of Health and Human Services and the Veterans Health Administration in the U.S. Department of Veterans Affairs (VA) announced that they signed a memorandum of understanding (MOU) to share information related to the review and use of FDA-regulated drugs, biologics, and medical devices. The goals of the collaboration are to enhance postmarket medical product safety data collection and risk communication. Personal health information exchanged under the agreement will be protected in accordance with federal law. The MOU is available at <http://www.fda.gov/oc/mous/domestic/225-07-4300.html>.

***EC Proposes Environmental Crimes Directive*** -- On February 9, 2007, the European Commission (EC) issued a proposed directive that would require Member States to treat serious offenses against the environment as criminal acts and to ensure that they are effectively sanctioned. The proposed directive would establish minimum sanctions for environmental crimes across the Member States, including offenses such as the illegal emission of hazardous substances into the air, water, or soil; the illegal shipment of waste; or the illegal trade in endangered species. According to the EC, in serious cases, “criminal sanctions such as prison sentences should be applied, as they have a much higher dissuasive effect than, for example, administrative sanctions.” More information, including the proposed directive, is available at <http://ec.europa.eu/environment/crime/index.htm>.

The EC states that the proposed directive “will ensure that criminals cannot exploit the significant differences which currently exist between the Member States” by eliminating current safe-havens for environmental crime within the European Union (EU). The EC’s proposed directive includes the following key elements:

- Member States would be required to ensure that a range of activities already prohibited by the EU or national legislation are considered criminal offenses, when committed intentionally or with serious negligence;
- Member States would have to ensure that particularly serious environmental crimes are punishable by a maximum of at least five years imprisonment and fines for companies of at least €750,000;



- These cases would include crimes that resulted in death or serious injury of a person or substantial damage to air, soil, water, animals, or plants, or when the offense has been committed by a criminal organization; and
- The proposed directive foresees supplementary or alternative sanctions, such as the obligation to clean up/reinstate the environment or the possibility of stopping businesses from operating.

According to a questions and answers document on the proposed directive, the EC does not intend to harmonize fully Member States' criminal laws in regard to environmental crimes. Instead, because the EC has chosen to act through a directive, Member States would be able to maintain or introduce more stringent measures than those in the directive. For instance, the EC states, Member States could establish additional offenses, extend the level of criminal culpability to simple negligence, and add additional types and higher levels of penalties.

After the EC adopts the directive, Member States would have at most 18 months to implement the directive and send their implementing legislation to the EC. The EC would then assess whether the implementing measures are in compliance with the directive. In case of insufficient implementation, the EC could bring infringement proceedings against the Member State concerned before the European Court of Justice, which can impose severe penalties.

EC spokespersons said a preliminary study examining how criminal laws in Member States currently comply with the proposed environmental crime directive found that Belgium, the Czech Republic, Germany, Ireland, Slovakia, and Sweden have the highest level of compliance. Countries with a "medium" level of compliance include Austria, Bulgaria, Denmark, Estonia, Finland, Greece, Hungary, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Romania, Spain, and the United Kingdom. Member States with the most work to do regarding their codes on environmental crimes are Cyprus, France, Italy, Malta, and Slovenia.

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