



Recent Federal Developments March 15, 2007

TSCA/FIFRA/EPCRA/NTP

EPA And FDA Request Information On Insect Repellent-Sunscreen Combination Products --

On February 22, 2007, the U.S. Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) published separate notices requesting information to determine how they should regulate insect repellent-sunscreen combination products. 72 Fed. Reg. 7979, 7941. Both EPA and FDA regulate insect repellent-sunscreen combination products. EPA has regulatory authority because of the insect repellent component, and FDA has regulatory authority because of the sunscreen component.

The issues raised by the notices potentially could be of significance for other products that have dual jurisdiction issues. Both agencies seek comments on issues such as labeling, product performance, and applicable safety standards to determine how these products should be regulated. According to the notices, EPA and FDA will work together to develop a coordinated approach to regulating the combination products. EPA is seeking information to determine how combination products should be regulated so that it can complete the reregistration eligibility decision (RED) for N,N-diethyl-metatoluamide (DEET). FDA is considering amending its monograph for over-the-counter (OTC) sunscreen products to add conditions for marketing combination products. FDA asks interested persons to review and comment on both notices, and submit comments to both agencies. Comments are due **May 23, 2007**.

EPA Announces New Human Health Research Website -- On March 1, 2007, EPA announced the launch of a new website devoted to human health research. The site describes the Human Health Research Program (HHRP), one of eight interdisciplinary research programs established by EPA's Office of Research and Development (ORD) to address high priority research needs. The site provides information on the program's science objectives, goals, research activities, and accomplishments; a 152-page bibliography of peer-reviewed manuscripts published in journals, and reports produced by researchers at EPA's ORD and by EPA-funded researchers; and links to numerous human health-related programs, laboratories, centers, and offices. The website is available at <http://www.epa.gov/hhrp>.

HHRP's research focuses on the following four themes:

- **Biological (Mechanistic) Research** -- This research seeks to understand the underlying biological processes that are triggered when individuals are exposed to environmental contaminants. The goal is to derive a consistent, flexible set of principles and guidelines for using, and drawing inferences from, scientific information when conducting risk assessments.



- **Cumulative Risk Research** -- This research looks at how people are exposed to environmental contaminants; the magnitude and timing of these exposures; how exposures translate into tissue dose and relate to potential health effects; how biomarker of exposure results can be used by risk assessors; and how exposure biomonitoring results can be used to evaluate EPA's policies and regulatory actions.

- **Research on Susceptible Subpopulations and Lifestages** -- This research develops experimental designs and statistical models to help understand and predict the effects of complex chemical mixtures and the influence of dose, exposure history, and exposure scenario on toxicity. The goal of EPA research in this area is to gain an understanding of the biological basis for the observed differences in susceptibility; identify effects in susceptible populations that are different from effects in the larger population; understand how exposure during critical periods of development can influence long-term health outcomes; and to develop methods and animal models that can be used to predict responses in susceptible populations.

- **Tools for Risk Management Decisions** -- This research develops measurement tools and biological indicators needed to assess the impact of regulatory decisions on public health to evaluate better public health outcomes and determine the effectiveness of actions to reduce health risks.

EPA Releases Final Metals Risk Assessment Framework -- On March 8, 2007, EPA announced the availability of the final *Framework for Metals Risk Assessment* (Framework). 72 Fed. Reg. 10529. According to the *Federal Register* notice announcing the Framework's availability, the purpose of the Framework is "to present key guiding principles based on the unique attributes of metals (as differentiated from organic and organometallic compounds) and to describe how these metals-specific attributes and principles may then be applied in the context of existing EPA risk assessment guidance and practices." EPA notes that the Framework "is not a prescriptive guide on how any particular type of assessment should be conducted within an EPA program or regional office." Instead, the Framework "outlines key metal principles and describes how they should be considered in conducting human health and ecological risk assessments to advance our understanding of metals impact and foster consistency across EPA programs and regions." EPA describes the Framework as "a science-based document that describes basic principles that address the special attributes and behaviors of metals and metal compounds to be considered when assessing their human health and ecological risks." The Framework is available at <http://www.epa.gov/osa/metalsframework/pdfs/metals-risk-assessment-final-3-8-07.pdf>.



According to the Framework, the following principles are more generalized, fundamental properties of metals and “should be addressed and incorporated into all inorganic metals risk assessments”: metals are naturally occurring constituents in the environment and vary in concentrations across geographic regions; all environmental media have naturally occurring mixtures of metals, and metals are often introduced into the environment as mixtures; some metals are essential for maintaining proper health of humans, animals, plants, and microorganisms; metals, unlike organic chemicals, are neither created nor destroyed by biological or chemical processes, although, these processes can transform metals from one species to another (valence states) and can convert them between inorganic and organic forms; and the absorption, distribution, transformation, and excretion of a metal within an organism depend on the metal, the form of the metal or metal compound, and the organism’s ability to regulate and/or store the metal.

EPA Issues Genomics-Related Draft Guidance -- On March 14, 2007, EPA released for comment the “External Review Draft of the Interim Guidance for Microarray-Based Assays: Data Submission, Quality, Analysis, Management and Training Considerations.” The guidance is meant to assist companies and research institutes submit data from microarrays, which are laboratory tools that simultaneously detect changes in thousands of different genes exposed to chemicals, light, and/or other environmental agents. EPA’s draft guidance addresses questions such as what type of data should be submitted, ways researchers can assess the performance of their microarrays, and strategies to analyze microarray data. A copy of the draft guidance is available at <http://www.epa.gov/osa/spc/genomicsguidance.htm>. Comments are due **April 30, 2007**.

SAB Releases Report On EPA’s Risk Assessment Practices And Exposure Guidelines -- On February 28, 2007, EPA’s Science Advisory Board (SAB) released a report entitled “Consultation on Enhancing Risk Assessment Practices and Updating EPA’s Exposure Guidelines.” EPA’s Office of the Science Advisor (SOA) asked SAB to provide input on ways to advance EPA’s human health risk assessment practices, and EPA’s Risk Assessment Forum requested that SAB provide advice on updating the 1992 Exposure Guidelines. The final report by the SAB Environmental Health Committee (EHC) and Integrated Human Exposure Committee (IHEC) provides the Committees’ comments on the relevance and priority of EPA initiatives to advance human health risk assessment practices and EPA’s approach for updating the exposure guidelines. In their report, the Committees also suggest other areas and improvements that they believe EPA should consider, and which of those would be most important. Committee members addressed five major topics that emerged during these consultations: (1) addressing aggregate exposure and cumulative risk assessment; (2) addressing populations, groups, or life stages of potential concern; (3) evaluating uncertainty and variability, including probabilistic analyses; (4) involving communities and communicating results; and (5) use of data (mechanistic, models, genomics, CompTox, *etc.*) versus defaults. The final report is available at <http://www.epa.gov/sab/pdf/sab-07-003.pdf>.



CAA/CWA

EPA Issues Final Guidelines Establishing Test Procedures For Analysis Of Pollutants Under The CWA -- On March 12, 2007, EPA issued final modifications to the testing procedures approved for analysis and sampling under the Clean Water Act (CWA) and Safe Drinking Water Act (SDWA). 72 Fed. Reg. 11200. EPA proposed these changes for public comment on August 18, 2003, and April 6, 2004, respectively. The CWA changes adopted in the final rule fall into several categories: new vendor-developed methods, as well as EPA and voluntary consensus standard bodies (VCSB) methods; updated versions of currently approved methods; revisions to method modification and analytical requirements; withdrawal of certain outdated methods; and changes to sample collection, preservation, and holding time requirements. This rule also changes regulations under the SDWA that establish drinking water sampling and analysis procedures. The changes include approval of vendor-developed methods, new EPA and VCSB methods, updated VCSB methods, and approval of a modification to the test kit used with Syngenta Method AG-625 that restricts its use in certain circumstances. The addition of new and updated methods to the wastewater and drinking water regulations provides increased flexibility to the regulated community and laboratories in the selection of analytical methods. This regulation is effective **April 11, 2007**.

NANOTECHNOLOGY

EPA Announces Availability Of Final Nanotechnology White Paper -- On February 15, 2007, EPA published a *Federal Register* notice announcing the availability of the final "Nanotechnology White Paper," which 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 these nanotechnology science issues to stakeholders and the public." 72 Fed. Reg. 7435. EPA's Nanotechnology Workgroup, which was created in December 2004 to develop a white paper examining potential environmental applications and implications of nanotechnology, prepared the White Paper. The White Paper describes issues that the Nanotechnology Workgroup believes EPA should consider to ensure that society benefits from the advances in environmental protection that nanotechnology may offer, and to understand and address any potential risks from environmental exposure to nanomaterials. The White Paper is available on the Internet at <http://www.epa.gov/osa/nanotech.htm>. Key White Paper recommendations include:

- **Environmental Applications Research:** EPA should continue to undertake, collaborate on, and support research to understand and apply information regarding environmental applications of nanomaterials.



- **Risk Assessment Research:** EPA should continue to undertake, collaborate on, and support research to understand and apply information regarding nanomaterials. To ensure that research best supports EPA decision making, EPA should conduct case studies to identify unique risk assessment considerations for nanomaterials.
- **Pollution Prevention, Stewardship, and Sustainability:** EPA should engage resources and expertise to encourage, support, and develop approaches that promote pollution prevention, sustainable resource use, and good product stewardship in the production, use, and end-of-life management of nanomaterials. Additionally, EPA should draw on new, next generation nanotechnologies to identify ways to support environmentally beneficial approaches such as green energy, green design, green chemistry, and green manufacturing.
- **Collaboration and Leadership:** EPA should continue and expand its collaborations regarding nanomaterial applications and potential human health and environmental implications.
- **Intra-Agency Workgroup:** EPA should convene a standing intra-agency group to foster information sharing on nanotechnology science and policy issues.
- **Training:** EPA should continue and expand its nanotechnology training activities for scientists and managers.

According to the White Paper, as new generations of nanomaterials evolve, so will new and possibly unforeseen environmental issues. The White Paper states that it will be crucial that EPA's "approaches to leveraging the benefits and assessing the impacts of nanomaterials continue to evolve in parallel with the expansion of and advances in these new technologies."

ED And DuPont Release Draft Nano Risk Framework -- On February 26, 2007, Environmental Defense (ED) and DuPont announced the release of a draft version of the Nano Risk Framework, which "establishes a process for ensuring the responsible development of nanoscale materials that can be widely used by companies and other organizations." ED and DuPont request comments on the draft Framework, which they will consider as they revise the Framework to make it as effective as possible for a broad audience.

According to ED and DuPont, the Framework will help companies organize and evaluate current information; assess, prioritize, and address data needs; and communicate clearly how they are mitigating risks. The draft Framework focuses on nanomaterials in industrial, chemical,



manufacturing, and consumer applications. ED and DuPont state that they recognize that nanotechnology is being used “in a wide variety of other areas, including pharmaceuticals, medical devices, and pesticides.” Given the complexity of such applications and the additional scrutiny that they typically receive, however, the Framework is not intended to apply fully to them. Comments are due **March 30, 2007**, and may be submitted via e-mail to feedback@nanoriskframework.com. ED and DuPont intend to release a final Framework in **Summer 2007**, “along with examples of how it may be used for real products under development.” More information is available at <http://www.nanoriskframework.com/>.

PEN Seminar -- Creating An Effective Oversight System For Nanotechnology -- On March 14, 2007, the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars held a seminar to coincide with the release of its latest report, “Thinking Big About Things Small: Creating an Effective Oversight System for Nanotechnology,” available at <http://www.nanotechproject.org/110/31407-thinking-big-about-things-small>. The report was authored by Mark Greenwood, a former Director of EPA’s Office of Pollution Prevention and Toxics.

The report seeks “to focus greater public attention on three sets of issues that will necessarily define the framework of an effective oversight system for nanoscale materials, regardless of the agency or regulatory statute: risk criteria (what is and is not a problem?); information needs (what do we need to know to support decision-making?); and risk management measures (what tools should be used to manage risk?).” According to Greenwood, “[c]urrent public discussions about the emerging oversight system have not given adequate attention to these topics,” and instead have focused on the suitability and jurisdictional reach of particular statutes (*e.g.*, the Toxic Substances Control Act) as well as on scientific research needs. “Essentially,” Greenwood writes, “we have let the laws set the boundaries of our discussions, rather than exploring a wider set of questions that need to be answered if society is to adequately address any potential risks from nanotechnologies.” Greenwood examines each of the three issue areas and identifies the significant policy questions within each area that, in his view, merit attention and discussion.

Ultimately, Greenwood concludes that “it is essential that all stakeholders interested in responsible management of [nanotechnology] begin to focus their energy on defining the core building blocks that define a product oversight system.” The time for this discussion, he maintains, “is now.”

LEGISLATIVE DEVELOPMENTS

Select Climate Panel Now Funded -- On March 9, 2007, the House of Representatives approved funding for the new Select Committee on Energy Independence and Global Warming under a larger bill that funds various committees through the end of the 110th Congress. Passage of the funding measure (H. Res. 202) on a vote of 269-150 ensures the Committee will be funded



through the end of the current Congress. The select Committee will play only a non-legislative role during the 110th Congress, with the House Energy and Commerce Committee expected to retain its lead role in drafting legislation to address U.S. greenhouse gas emissions.

Representative Ed Markey (D-MA) will head the new Select Committee on Energy Independence and Global Warming, with eight other Democrats named as members of the panel. Markey will be joined by Democrat Representatives Earl Blumenauer (OR), Jay Inslee (WA), John Larson (CT), Hilda Solis (CA), Stephanie Herseth (SD), Emanuel Cleaver (MO), John Hall (NY), and Jerry McNerney (CA). Republican members of the select panel, which the Republican leadership selected, will be led by ranking minority member Representative James Sensenbrenner (WI). The other Republican members are Representatives John Shadegg (AZ), Greg Walden (OR), John Sullivan (OK), Marsha Blackburn (TN), and Candice Miller (MI).

House Passes Three Water Bills -- The House of Representatives passed legislation March 9, 2007, that would provide \$14 billion over four years for infrastructure improvements at wastewater treatment plants. The Water Quality Financing Act of 2007 (H.R. 720), approved 303-108, would reauthorize the Clean Water Act State Revolving Fund (SRF) for fiscal years (FY) **2007** through **2011**. Under the SRF program, established in 1987, EPA makes capitalization grants to states, which in turn make low-interest loans to wastewater utilities. States are required to match the funds they use by at least 20 percent. The loans are intended to be repaid into the fund, making the fund self-perpetuating. Despite a veto threat from President Bush on March 8, 2007, no House members disputed the need for federal funding to replace and repair deteriorating wastewater infrastructure, and no one criticized the \$14 billion reauthorization during debate on the House floor.

On March 8, 2007, the House approved the Healthy Communities Water Supply Act of 2007 (H.R. 700), which would authorize \$125 million for grants to find alternative sources of water for communities that are experiencing critical water supply needs. On March 7, 2007, the House approved the Water Quality Investment Act of 2007 (H.R. 569), which would authorize \$1.7 billion over five years in grants to states and municipalities for reducing sewer overflows.

Bill Would Exempt Manure From Hazardous Waste Classification -- Senators Blanche Lincoln (D-AR) and Pete Domenici (R-NM), and Representatives Collin Peterson (D-MN) and Ralph Hall (R-TX) introduced in their respective chambers on March 8, 2007, the Agricultural Protection and Prosperity Act (S. 807; H.R. 1398), a proposal under which livestock manure would not be classified as hazardous waste regulated under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Without clarification, the sponsors of the legislation believe that requirements under CERCLA could unfairly be applied to ranchers and farmers both large and small.



House Energy Panel Adopts Broad Oversight Agenda -- The House Energy and Commerce Committee on March 1, 2007, adopted a broad oversight agenda for the 110th Congress, pledging to examine issues ranging from climate change and the federal Superfund Program to national energy policy, the implications of trade on labor and the environment, and federal oversight of drug makers. The Committee approved the two-year agenda by voice vote. On the environment, the Committee said it would carry out “a broad review of the global climate change issue, with a particular focus on the role of human activity in global warming.” The panel said it expects to review strategies of the Energy Department, EPA, and the Federal Energy Regulatory Commission in that area. Separately, the Committee expects to review the management, operations, activities, and funding of the Superfund Program, which is intended to clean up the country’s most contaminated hazardous waste sites. The Committee also said it would conduct an “extensive review” of the EPA budget, as well as of EPA’s funding decisions, resource allocations, grants, research activities, enforcement actions, and relations with state and local governments, among other things. It also will examine EPA’s implementation of the Clean Air Act, including rulemaking involving new source review provisions and mercury emissions.

Bill Would Provide Tax Breaks To Private Landowners -- Senate Finance Committee leaders introduced legislation on February 28, 2007, that would provide tax incentives to private landowners to help protect endangered species on their properties. The Endangered Species Recovery Act (S. 700) would provide up to \$400 million a year for two new tax credits, plus additional deductions and exclusions, for those who voluntarily agree to put easements on their properties or agree to restore, enhance, or manage endangered species habitat on their land. Committee Chair Max Baucus (D-MT) and Senator Michael Crapo (R-ID) sponsored the legislation. Co-sponsors include Senators Charles Grassley (R-IA), the Committee’s ranking member, and Blanche Lincoln (D-AK).

Bill Passed That Would Ease Brownfield Re-Development Grants -- The House of Representatives approved by voice vote on February 27, 2007, legislation intended to clarify and streamline the Department of Housing and Urban Development’s (HUD) requirements for local communities to redevelop brownfield sites. The Brownfields Redevelopment Enhancement Act (H.R. 644) would end requirements that force communities first to obtain brownfields redevelopment loan guarantees from HUD before they can be awarded grants from the department’s Brownfields Economic Development Initiative. The loan guarantees are provided under Section 108 of the Housing and Community Development Act.

According to the bill, by unlinking grants for brownfields development from Section 108 community development loan guarantees, more communities will have access to funding to redevelop brownfield sites. H.R. 644 would make brownfields-related environmental cleanup and economic development activities eligible for community development block grant assistance. Funding would be authorized for FY **2008** through **2012**.



Environmental Justice Legislation Introduced -- Legislation introduced in the House and Senate on February 15, 2007, would require EPA to address human health and environmental problems in low-income and minority communities. The Environmental Justice Act of 2007 would fully implement Executive Order (EO) 12898, which President Clinton signed in 1994. The EO requires that EPA make achieving environmental justice part of its mission. Representative Hilda Solis (D-CA) and Senator Richard Durbin (D-IL) introduced the legislation in their respective chambers (H.R. 1103; S. 642). H.R. 1103 was referred to the House Committees on Energy and Commerce and Natural Resources, and S. 642 was referred to the Senate Committee on Environment and Public Works. Information on EPA's environmental justice program is available at <http://www.epa.gov/environmentaljustice/index.html>. The text of EO 12898 is available at <http://www.epa.gov/fedrgstr/eo/>.

MISCELLANEOUS

DPR Announces Toll-Free Telephone Number For Complaints And Releases 2005 Pesticide Illness Summary -- On February 28, 2007, the California Department of Pesticide Regulation (DPR) announced 1-87PestLine (1-877-378-5463), a toll-free telephone number for complaints. Callers will be transferred to their local County Agricultural Commissioner's Office, and recorded information will be provided in English and Spanish. According to DPR, many people are currently unaware of how or where to report pesticide complaints. DPR expects 1-87PestLine to improve reporting and response time, which "could be especially helpful for illness investigations." DPR will produce two new print guides for the public later this year. DPR is targeting one of the guides to people involved in pesticide emergencies, and DPR intends the other to "help people understand DPR's regulatory work, and how they can participate in setting pesticide policies." More information on 1-87PestLine is available on the Internet at <http://www.cdpr.ca.gov/docs/pressrls/2007/070228.htm>.

DPR announced 1-87 PestLine in conjunction with its release of the Pesticide Illness Surveillance Program (PISP) 2005 summary of pesticide illness reports. In 2005, DPR investigated 1,323 cases and confirmed pesticide exposure as a potential causal factor in 911 cases, compared to 1,238 investigations and 828 cases confirmed in 2004. Of the 911 cases confirmed in 2005, 647 were agricultural, 263 were non-agricultural, and DPR could not classify one case. In 2004, there were 390 agricultural cases and 438 non-agricultural. More information on the PISP 2005 summary is available at <http://www.cdpr.ca.gov/docs/whs/2005pisp.htm>.

According to DPR, non-occupational injury reports have declined since 2002, when federal funding ran out for a project linking DPR to reports from the California Poison Control System, which provides emergency responders with information on toxic exposures. DPR states that the System led it to "hundreds of pesticide cases annually," and that "[m]any involved home accidents." DPR resumed the project with its own funds in October 2006.



DPR is working with the California Office of Environmental Health Hazard Assessment (OEHHA) on a pilot project intended to improve physician reporting of pesticide cases. While state law requires such reporting, DPR states that compliance “has been spotty for years, despite extensive DPR efforts to inform the medical community of its responsibilities.” Using federal funds, DPR and OEHHA are working to integrate pesticide reporting into a statewide, internet-based system. The project now under development involves cooperation with local health officials and agricultural commissioners in three pilot counties.

CSB Releases Final Strategic Plan For 2007-2012 -- On February 23, 2007, the U.S. Chemical Safety Board (CSB) released its new Strategic Plan for **2007** through **2012**. CSB is an independent federal agency charged with investigating industrial chemical accidents. CSB makes safety recommendations to plants, industry organizations, labor groups, and regulatory agencies, including the Occupational Safety and Health Administration and EPA. CSB’s board members are appointed by the President and confirmed by the Senate. CSB uses the Strategic Plan as a guide in setting priorities and allocating resources in support of its mission to prevent chemical accidents. The Strategic Plan emphasizes conducting new CSB safety studies that will include significant safety recommendations. CSB also intends to focus on broadly disseminating report findings, lessons, and recommendations through innovative agency outreach efforts. In the Plan, CSB establishes five strategic goals that it hopes to accomplish over the next six years. The four mission goals focus on investigating chemical accidents, conducting safety studies, broadly disseminating agency findings, and successfully closing safety recommendations. The fifth enabling goal targets the development and retention of a high-performing workforce. The Strategic Plan is available at http://www.csb.gov/new_releases/docs/CSBStrategicPlan2007-2012.pdf.

The Strategic Plan was revised substantively during 2006, with a heightened emphasis on investigations, studies, recommendations, and outreach efforts that have a significant potential to impact chemical safety. Each of these five long-term strategic goals include key objectives, key actions for implementation, and associated specific metrics used to measure progress.

CSB must review and revise the Strategic Plan every three years according to the Government Performance Results Act of 1993. The Strategic Plan details the legislative mandate, agency goals, factors affecting goal achievement, and relationships with other agencies.



Jim Jones Becomes Deputy Assistant Administrator Of OPPTS -- On March 13, 2007, EPA announced that Jim Jones, Director of EPA's Office of Pesticide Programs will become Deputy Assistant Administrator under Jim Gulliford, Assistant Administrator, Office Prevention, Pesticides and Toxic Substances (OPPTS) effective **March 26, 2007**.

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