



Recent Federal Developments October 15, 2007

TSCA/FIFRA/EPCRA/NTP

EPA Issues Technical Amendment To Pesticide Tolerance Nomenclature -- On September 18, 2007, the U.S. Environmental Protection Agency (EPA) issued a direct final rule modifying the terminology of certain commodity terms listed under 40 C.F.R. Part 180, Subpart C. 72 Fed. Reg. 53134. EPA took action to establish a uniform listing of commodity terms. The rule is effective on **November 2, 2007**, without notice, unless EPA receives adverse comment by **October 18, 2007**. If EPA receives adverse comments, EPA will publish a *Federal Register* document to withdraw the direct final rule before the effective date.

EPA Issues Draft Scientific And Ethical Approaches For Observational Exposure Studies -- On October 4, 2007, EPA announced the availability of a draft document titled *Scientific and Ethical Approaches for Observational Exposure Studies*. 72 Fed. Reg. 56757. The draft document presents “state-of-the-science” approaches for conducting observational exposure studies based on sound science and conforming to the highest ethical standards. These studies, which collect information on how people come into contact with chemicals as they go about their everyday activities, are critical to EPA’s mission to protect human health. This document is intended to serve as a resource and reference for researchers and is not meant to represent an official EPA “guidance document.” Comments are due by **November 19, 2007**.

EPA Issues Significant New Use Rules On 38 Chemical Substances -- On September 19, 2007, EPA promulgated significant new use rules (SNUR) under Toxic Substances Control Act (TSCA) Section 5(a)(2) for 38 chemical substances which were the subject of premanufacture notices (PMN). 72 Fed. Reg. 53470. One of these chemical substances is also subject to a TSCA Section 5(e) consent order issued by EPA. This action requires persons who intend to manufacture, import, or process any of these 38 chemical substances for an activity that is designated as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs. The rule is effective **November 19, 2007**, without further notice, unless EPA receives adverse or critical comments, or notice of intent to submit adverse or critical comments before **October 19, 2007**.

EPA Issues Draft PR Notice Regarding Environmental Hazard Statements For Outdoor Residential Pesticides -- On October 3, 2007, EPA announced the availability of a draft Pesticide Registration (PR) Notice, which provides guidance regarding recommended environmental hazard language for outdoor residential use pesticides. 72 Fed. Reg. 56344. The draft PR Notice recommends new statements that EPA intends to replace language created for agricultural products “with statements that are easier for consumers to understand.” In the draft PR Notice, the new environmental hazard statements are divided by product type (*e.g.*, liquid ready-to-use (RTU), broadcast granular), and specific language recommendations are provided for each



product type. According to EPA, the language recommended would minimize risks to the human health and the environment, with emphasis on reducing risks to water. Revisions to product labels using these new statements would be made by notification. Comments are due **November 2, 2007**.

GAO Issues Report On Different Approaches On Chemical Regulation In U.S. And Europe --

On September 25, 2007, the Government Accountability Office (GAO) issued a report, *Comparison of U.S. and Recently Enacted European Union Approaches to Protect against the Risks of Toxic Chemicals*, outlining the differences between the approaches for chemical regulation in the United States and European Union (EU). According to the report, one of the key differences is that the EU's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program requires companies to develop information and chemicals' effects on human health and the environment, while the U.S. approach under TSCA generally does not, unless EPA issues a specific rule requiring data. The GAO report is available at <http://www.gao.gov/new.items/d07825.pdf>.

EPA Issues Final SNUR For Mercury Switches In Motor Vehicles --

On October 5, 2007, EPA promulgated a final SNUR under TSCA Section 5(a)(2) for elemental mercury (CAS No. 7439-97-6) used in certain convenience light switches, anti-lock braking system (ABS) switches, and active ride control system switches. 72 Fed. Reg. 56903. The rule amends 40 C.F.R. Part 721 and requires persons who intend to manufacture, import, or process elemental mercury for a use designated by the rule as a significant new use to notify EPA at least 90 days before commencing the manufacturing or processing of the chemical substance for such significant new use. The required notification will provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs. In addition, to display the Office of Management and Budget (OMB) control number for the information collection requirements contained in the final rule, EPA is amending the table of OMB approval numbers for EPA regulations that appears in 40 C.F.R. Part 9. The rule is effective on **November 5, 2007**.

EPA Reopens Comment Period On Implementation Of Emerging Pathogens And Disinfection Hierarchy For Antimicrobial Products --

On September 19, 2007, EPA announced its decision to reopen the comment period for a notice of availability concerning implementation of the emerging pathogens and disinfection hierarchy guidance for antimicrobial products published in the July 25, 2007, *Federal Register*. 72 Fed. Reg. 53579. The comment period is reopened for an additional 60 days. The comment period is reopened because additional time has been requested by several pesticide entities to prepare detailed comments on the planned implementation. Comments must be received on or before **November 19, 2007**.



EPA Proposes NAC/AEGL For Hazardous Substances -- On September 19, 2007, EPA, on behalf of the National Advisory Committee for Acute Exposure Guideline Levels (AEGL) for Hazardous Substances (NAC/AEGL Committee), provided for public comment a list of proposed AEGL values for 37 hazardous substances. 72 Fed. Reg. 53577. The substances are:

Hazardous Substances Name	CAS Number
1,2,3-trimethylbenzene	526-73-8
1,2,4-trimethylbenzene	95-63-6
1,3,5-trimethylbenzene	108-67-8
Adamsite	578-94-9
Aluminum phosphide	20859-73-8
Arsenic trioxide	1327-53-3
Biphenyl	92-52-4
bis-Chloromethyl ether	542-88-1
Calcium phosphide	1305-99-3
Cyclohexyl isocyanate	3173-53-3
Diphenylchloroarsine	712-48-1
Ethylchloroarsine	598-14-1
Hexafluoroacetone	684-16-2
Hexafluoropropylene	116-15-4
Ketene	463-51-4
Magnesium aluminum phosphide	None
Magnesium phosphide	12057-74-8
Methyl chlorosilane	993-00-0
Methyl dichlorosilane	75-54-7
Methyl t-butyl ether	1634-04-4
Methylchloroarsine	593-89-5
Nitrogen mustard HN-1 bis(2-chloroethyl)ethylamine	538-07-8
Nitrogen mustard HN-2 bis(2-chloroethyl)methylamine	51-75-2
Nitrogen mustard HN-3 tris(2-chloroethyl)amine	555-77-1
Phenylchloroarsine	696-28-6
Phenylmercaptan	108-98-5
Potassium phosphide	20770-41-6
Propargyl alcohol	107-19-7
Selenium hexafluoride	7783-79-1
Silane	7803-62-5
Sodium phosphide	12058-85-4
Strontium phosphide	12504-13-1
Sulfuryl chloride	7791-25-5



Hazardous Substances Name	CAS Number
Tetramethoxy silane	681-84-5
Trimethoxy silane	2487-90-3
Vinyl acetate monomer	108-05-4
Zinc phosphide	1314-84-7

Comments are due **October 19, 2007**.

Coalition Petitions EPA And CPSC To Regulate Air Fresheners -- On September 19, 2007, a coalition of environmental groups petitioned EPA and the Consumer Product Safety Commission (CPSC) to take a variety of actions to protect the U.S. from alleged health problems associated with air fresheners. The petition focuses on volatile organic compounds (VOC) released by air fresheners and claims that some of the fresheners contain phthalates, which are listed as reproductive toxicants under California's Proposition 65. The coalition includes the Sierra Club, the Alliance for Healthy Homes, the National Center for Healthy Housing, and the Natural Resources Defense Council (NRDC). The petition asks EPA to issue rules to collect under TSCA health and safety studies, require manufacturers to test products for respiratory exposures and sensitization, and require labeling of all air fresheners that contain phthalates. The petition asks CPSC to ban the use of chemicals listed on Proposition 65 and to promulgate a rule requiring air freshener manufacturers to list their ingredients. A spokesperson for EPA said that EPA will review the petition and respond in the 90 days allowed under TSCA. More information is available at <http://www.nrdc.org/media/2007/070919.asp>.

FMC Corporation Files Suit Against EPA For Establishing An Incorrect Burden Of Proof For Adjudicatory Hearings -- On August 16, 2007, FMC Corporation (FMC) filed a complaint against EPA in the United States District Court for the Eastern District of Virginia (FMC Complaint). *FMC Corp. v. EPA*, Civil Action No. 1-07CV819 GBL/BRP (Aug. 16, 2007). The outcome of this case could have broad implications for pesticides facing cancellation proceedings. FMC filed its Complaint after EPA denied FMC's petition to EPA seeking to revise the current EPA regulations that set forth the burden of proof to be employed in any trial-type adjudicatory hearing regarding the proposed cancellation of pesticide registrations containing the active ingredient carbofuran. Under the current regulations, the registrant bears the "ultimate burden of persuasion" in cancellation proceedings. Under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Sections 6(b) and 6(d), when EPA proposes to cancel a pesticide registration, it must, upon the request of any adversely affected party, convene an adjudicatory hearing. In November 2006, FMC submitted a petition asking EPA to amend its regulations regarding the burden of proof applicable to a hearing convened under FIFRA Section 6(b). The regulation at issue states that "[o]n all issues arising in connection with the hearing, the ultimate burden of persuasion shall rest with the proponent of the registration." In its petition, FMC challenged the requirement that the burden of proof rests with the registrant as the



“proponent of the registration,” when it is EPA that is the initiator and proponent of the action to cancel the registration. FMC cited Administrative Procedure Act (APA) Section 556(d) in support of its position, which provides that in an on-the-record agency adjudication, “the proponent of a rule or order has the burden of proof” unless a statute provides otherwise. FMC states that there is nothing in FIFRA or its legislative history that “purports to change the APA’s allocation of the burden of proof in cancellation hearings.” EPA denied FMC’s petition on April 3, 2007.

EPA Launches Pesticide Label System -- On September 19, 2007, EPA made available images of pesticide labels that have been approved by EPA’s Office of Pesticide Programs (OPP) under FIFRA. The Pesticide Product Label System contains: the initially approved label for pesticide products registered under FIFRA Section 3; subsequent versions of labels that have changed via amendment or notification; and associated correspondence about the terms of registration, specifying any required changes in the final printed label. Label images are indexed by EPA registration number and the date of initial registration of amendment. EPA said because some label amendments address only portions of the label, users may have to review several labels for a single product to determine the complete terms of registration. The images are available at <http://www.epa.gov/pesticides/pestlabels/index.htm>.

EPA Clarifies Position On Ion-Generating Equipment -- On September 21, 2007, EPA clarified its position on the distinction between devices and pesticides with regard to ion-generating equipment and explained why such equipment will be regulated as pesticides. 72 Fed. Reg. 54039. Potentially affected equipment include, but are not limited to, “washing machines containing electrodes that emit silver, copper, or zinc ions and ion generators used in swimming pools to kill algae and as an adjunct to the chlorination process.”

According to EPA, the key distinction between pesticides and devices is whether the pesticidal activity of the article is due to physical or mechanical actions or due to a substance or mixture of substances. EPA states that some of the types of products that were specifically identified as devices in a November 19, 1976, notice included, but were not limited to, “ultra violet light systems, ozone generators, water and air filters (except those containing substances or mixtures of substances), and ultrasonic devices making claims to inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites.” In the September 21, 2007, notice, EPA states that, in 1976, it was not aware of equipment such as the ion-generating washing machine that was presented to EPA in 2005 by a manufacturer.

EPA states that it “is aware that there may be some confusion in the regulated community” regarding EPA’s interpretation of the distinction between pesticides and devices. EPA will work with producers of ion generators to identify what data and other information are required to support an application for registration and to obtain registrations to bring such equipment into compliance for equipment being distributed or sold in the U.S. on September 21, 2007. Any



person distributing or selling such equipment on or prior to September 21, 2007, may continue the distribution or sale of such equipment until March 21, 2008. EPA does not speculate what becomes of entities that neglect to obtain FIFRA registration by that date, but the inference is EPA would take the position the product is an unregistered pesticide and its marketing would be susceptible to enforcement action.

Any producer or importer of such equipment who distributes or sells the equipment on or prior to September 21, 2007, and who wishes to continue that distribution or sale after March 21, 2008, may do so only if a prospective registrant has commenced the registration process for the equipment by submitting, at a minimum, an Application for Pesticide Registration Form (EPA Form No. 8570-1) for the equipment. The form should be submitted to EPA on or before **March 21, 2008**. EPA states that, on the form, only the following information must be provided: Section I, Item 4: Company and Product Name; Section I, Item 5: Name and Address of Applicant; Section II, check "other" and place in explanation "Ion Generator FR Notice"; and all of Section IV. The form is available on the Internet at <http://www.epa.gov/opprd001/forms/8570-1.pdf>.

Persons distributing or selling such equipment on or prior to September 21, 2007, other than the producer or importer, may continue to distribute or sell such equipment until their inventories are exhausted. Further, any producer or importer of such equipment who is distributing or selling the equipment on or prior to September 21, 2007, who wishes to continue that distribution or sale after March 23, 2009, may do so only if a prospective registrant has submitted to EPA a completed registration package for the equipment on or before March 23, 2009. Producers or importers of such equipment may continue to distribute or sell such equipment only until such time as EPA acts upon the application or the application is withdrawn. Again, EPA states, "persons distributing or selling such equipment on or prior [September 21, 2007,] other than the producer or importer may continue to distribute or sell such equipment until their inventories are exhausted."

EPA Amends Perfluoroalkyl Sulfonates SNUR -- On October 9, 2007, EPA amended a SNUR under TSCA Section 5(a)(2) to include certain additional perfluoroalkyl sulfonate (PFAS) chemicals. 72 Fed. Reg. 57222. EPA amended the PFAS SNUR at 40 C.F.R. Section 721.9582 by adding a new Table 3, which includes the PFAS chemicals currently on the public TSCA Inventory that are not already covered by the SNUR. The rule requires manufacturers, including importers, to notify EPA at least 90 days before commencing the manufacture or import of the PFAS chemicals listed in Table 3 of the regulatory text for the significant new uses described in the notice on or after November 8, 2007. EPA believes that this action is appropriate because these chemical substances may be hazardous to human health and the environment. This required notice will provide EPA the opportunity to evaluate intended significant new uses and associated activities before they occur and, if necessary, to prohibit or limit those uses or activities. The rule is effective **November 8, 2007**.



EPA Selects Acting Director For EFED/OPP -- Dr. Donald Brady has been selected to serve as Acting Director of OPP's Environmental Fate and Effects Division, beginning October 21, 2007. Dr. Brady was selected from a very impressive list of candidates responding to the PAVE announcement issued in August. Dr. Brady brings to this position a wealth of relevant regulatory experience, with more than 25 years of public service at EPA. Currently, as Chief of the Municipal Branch in EPA's Water Permits Division, he is responsible for management of wet-weather permitting programs under Section 402 of the Clean Water Act (CWA). Prior to that time, Dr. Brady served for ten years as Chief of the Watershed Branch, Assessment and Watershed Protection Division, in EPA's Office of Wetlands, Oceans and Watersheds. In this capacity, he was responsible for management of the Total Maximum Daily Load (TMDL) program required by CWA Section 303(d). Section 303(d) requires states and, in some cases, EPA to identify waters that do not meet Water Quality Standards and to establish TMDLs which describe reductions in pollutant loadings necessary to attain Water Quality Standards. Dr. Brady has a BA in Political Science from Fordham University, and both a Masters and Ph.D. in Government from Georgetown University.

CAA/CWA/SDWA/ESA

EPA Proposes National Emission Standards For Hazardous Pollutants For Iron And Steel Foundries Area Sources -- On September 17, 2007, EPA proposed National Emission Standards for Hazardous Air Pollutants (NESHAP) for two area source categories (iron foundries and steel foundries). 72 Fed. Reg. 52984. The proposed requirements for the two area source categories are combined in one subpart. The proposed rule establishes different requirements for foundries based on size. Small iron and steel foundries would be required to comply with pollution prevention management practices for metallic scrap, the removal of mercury switches, and binder formulations. Large iron and steel foundries would be required to comply with the same pollution prevention management practices as small foundries in addition to emissions limitations for melting furnaces and foundry operations. EPA is also co-proposing two alternatives. One alternative would set a higher size threshold for large foundries. The second alternative proposes that all iron and steel foundries comply with the pollution prevention management practices for metallic scrap, the removal of mercury switches, and binder formulations. The proposed standards reflect the generally achievable control technology and/or management practices for each subcategory. Comments are due **October 17, 2007**, unless a public hearing is requested by September 27, 2007. If a hearing is requested on this proposed rule, written comments must be received by **November 1, 2007**.

EPA Issues Control Techniques Guidelines For Paper, Film, And Foil Coatings -- On October 9, 2007, EPA amended its decision that pursuant to Section 183(e)(3)(C) of the Clean Air Act (CAA), EPA has determined that control techniques guidelines (CTG) will be substantially as effective as national regulations in reducing emissions of VOCs in ozone national ambient air quality standard (NAAQS) nonattainment areas from the following three Group III product



categories: paper, film, and foil coatings; metal furniture coatings; and large appliance coatings. 72 Fed. Reg. 57215. EPA issued CTGs in lieu of national regulations for these product categories. The CTGs will, according to EPA, provide guidance to the states concerning EPA's recommendations for reasonably available control technology-level controls for these product categories. EPA also listed the three Group III consumer and commercial product categories addressed in this notice pursuant to CAA Section 183(e). The action was immediately effective.

EPA Proposes Implementation Approval To Regulate Fine Particle Emissions -- On September 21, 2007, EPA proposed to facilitate implementation of a PM_{2.5} Prevention of Significant Deterioration (PSD) program in areas attaining the particulate matter less than 2.5 micrometers (PM_{2.5}) NAAQS by developing PM_{2.5} increments, Significant Impact Levels (SIL), and a Significant Monitoring Concentration (SMC). 72 Fed. Reg. 54112. EPA also proposed to revoke the annual PM₁₀ increments. "Increments" are maximum increases in ambient PM_{2.5} concentrations (PM_{2.5} increments) allowed in an area above the baseline concentration. The SILs and SMCs are numerical values that represent thresholds of insignificant, *i.e., de minimis*, modeled source impacts or monitored (ambient) concentrations, respectively. EPA is proposing such values for PM_{2.5} that will be used as screening tools by a major source subject to PSD to determine the subsequent level of analysis and data gathering required for a PSD permit application for emissions of PM_{2.5}. Comments are due by **November 20, 2007**.

EPA Proposes NESHAP For Paint Stripping And Miscellaneous Surface Coating Operations At Area Sources -- On September 17, 2007, EPA proposed NESHAP for area sources engaged in paint stripping and miscellaneous surface coating operations. 72 Fed. Reg. 52958. EPA has listed "Paint Stripping," "Plastic Parts and Products (Surface Coating)," and "Autobody Refinishing Paint Shops" as area sources of hazardous air pollutants (HAP) that contribute to the risk to public health in urban areas under the Integrated Urban Air Toxics Strategy. EPA combined these three source categories into one set of standards for purposes of the rulemaking. These proposed standards, when final, would require all methylene chloride containing paint stripping and miscellaneous surface coating operations at area sources to comply with equipment requirements and/or management practices that minimize specific HAP emissions. The standards would also establish training requirements for persons who spray apply coatings. These standards, when final, would apply to all area sources that perform methylene chloride-containing paint stripping and miscellaneous surface coating activities, except when other NESHAP apply. Comments must be received on or before **October 17, 2007**.

RCRA/CERCLA

EPA Proposes Amendments To Oil Spill Prevention, Control, And Countermeasure Rule -- On October 15, 2007, EPA proposed revisions to certain regulatory requirements for facilities subject to the Spill Prevention, Control, and Countermeasure (SPCC) rule. 72 Fed. Reg. 58377. The revisions will tailor and streamline requirements to particular industry sectors and facility



owners or operators subject to the rule. EPA is proposing to exempt from SPCC regulations: hot-mix asphalt and hot-mix asphalt containers; pesticide application equipment and related mix containers used at farms; heating oil containers at single-family residences; and completely buried oil storage tanks at nuclear power generation facilities that meet the Nuclear Regulatory Commission design criteria and quality assurance criteria at 10 C.F.R. Part 50, Appendices A and B. Additionally, EPA is proposing to streamline the rule and allow the use of an SPCC Plan template for a subset of qualified facilities known as “Tier 1” qualified facilities (*i.e.*, with no individual oil storage container with a capacity greater than 5,000 U.S. gallons up to an aggregate of 10,000 gallons. Several requirements for oil production facilities, including: modify the definition of “production facility”, consistent with the proposed amendments to the definition of “facility”; extend the timeframe by which a new oil production facility must prepare and implement an SPCC Plan; exempt flow-through process vessels at oil production facilities from the sized secondary containment requirements, while maintaining general secondary containment requirements and requiring additional oil spill prevention measures; exempt flowlines and intra-facility gathering lines at oil production facilities from all secondary containment requirements, *while establishing more specific oil spill prevention measures*; and clarify the definition of “permanently closed” as it applies to an oil production facility. Nothing in this proposed rule removes any regulatory requirement for owners or operators of facilities in operation before August 16, 2002, to develop, implement, and maintain an SPCC plan in accordance with the SPCC regulations then in effect. These facilities are required to maintain their plans until the applicable date for revising and implementing plans under the new amendments. Public comments on the proposed changes are due by **December 14, 2007**. Information about the SPCC rule proposed amendments is available at http://www.epa.gov/oilspill/spcc_oct07.htm.

NANOTECHNOLOGY

PEN Releases Survey On Public Awareness Of Nanotechnology -- On September 25, 2007, the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars held a seminar on its latest effort to gauge the public’s awareness of and attitudes toward nanotechnology. A report discussing the findings of the 2007 national nanotechnology survey conducted for PEN by Peter D. Hart Research Associates, Inc. (Hart) is available at <http://www.nanotechproject.org/135/9252007-place-title-here>. A webcast of the PEN seminar can be viewed at http://www.wilsoncenter.org/index.cfm?fuseaction=topics.home&topic_id=166192.

Hart surveyed the public in 2006 and found that awareness of nanotechnology has not increased since then. It estimates that “only 6% of the public has heard a lot about [nanotechnology] and about two in five (42%) say they have heard nothing at all about it.” Among those least likely to have heard about nanotechnology are women, older people, and people with less education and lower incomes. Importantly, Hart also found that “after hearing a brief description of the



potential benefits and risks of nanotechnology, unaware adults are significantly more likely to say that the risks will outweigh benefits.” Several survey questions focused on the use of nanotechnology in food and food-related products. Hart found that “one in three adults (29%) would not purchase food enhanced with nanotechnology and another 62% need more information to do so,” while “[t]hirteen percent (13%) of adults say that they would not use food storage products enhanced with nanotechnology and 73% would need more information about nanotechnology used in food storage products before they would use them.”

PEN Hosts A Seminar On Responsible NanoCode -- PEN hosted on October 9, 2007, a seminar on the *Responsible NanoCode*, a voluntary, principles-based Code of Conduct for entities involved in the research, development, manufacture, and retail sale of products using nanotechnologies. Developed by a working group organized in late 2006 by The Royal Society, the United Kingdom’s (UK) national academy of science, in conjunction with Insight Investment, the Nanotechnology Industries Association (NIA), and the UK government-sponsored Nanotechnology Knowledge Transfer Network, a copy of the draft Code is available at the *Responsible NanoCode* website, <http://www.responsiblenanocode.org/index.html>. Interested parties to submit comments and suggested amendments or additions to the draft Code by **November 12, 2007**. Comments should be submitted by e-mail to consultation@responsiblenanocode.org.

DEFRA Will Publish Revised VRS Guidance -- According to the fourth quarterly report for the UK’s Voluntary Reporting Scheme (VRS) for Manufactured Nanomaterials, the Department for Environment, Food, and Rural Affairs (DEFRA) received no new submissions during the most recent quarter. Since the VRS began in September 2006, DEFRA has received a total of nine submissions, seven from industry and two from academia. In late July 2007, the Advisory Committee on Hazardous Substances (ACHS) reported the findings of its review of the VRS. ACHS concluded that improvements to the VRS guidance documents were needed to increase participation levels and enhance the quality and relevance of data submitted. ACHS recommended changes to the scheme literature to make its purpose clearer and make the specific data requested from industry more explicit. The report states that DEFRA will publish revised guidance shortly. The VRS is scheduled to end in **September 2008**, at which time DEFRA will evaluate its success and consider alternatives, including compulsory data submissions, if necessary. The report is available at <http://www.defra.gov.uk/environment/nanotech/pdf/vrs-4.pdf>. More information about the VRS is available on the Internet at <http://www.defra.gov.uk/environment/nanotech/policy/pdf/vrs-nanoscale.pdf>.



FDA

FDA Issues Draft Guidance On Microbiological Considerations For Antimicrobial Food Additive Submissions -- The Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration (FDA) posted on its web page on October 3, 2007, a draft guidance for industry entitled “Microbiological Considerations for Antimicrobial Food Additive Submissions.” The document is available at <http://www.cfsan.fda.gov/~dms/antguid.html>. The posting states that the guidance is being distributed for comment only at this point and that electronic or written comments should be filed by **November 26, 2007**.

The guidance sets forth its current thinking regarding the data requirements for a Food Additive Petition (FAP), a Food Contact Notification (FCN), or Threshold of Regulation (TOR) request for an antimicrobial food additive intended to control microbes in or on food. The guidance applies to additives directly added to food, used in food processing, or utilized in food packaging or contact articles. CFSAN urges affected companies to discuss with it in advance any studies designed to address the Center’s concerns, and to meet with CFSAN personnel prior to the submission of a FAP, FCN, or TOR to determine if the submitter is providing adequate data for review.

The guidance lists the CFSAN concerns that led to development of the guidance. CFSAN is responsible for establishing that the use of the additive is safe, *i.e.*, that there is a reasonable certainty of no harm from use. CFSAN is also responsible for preventing consumer deception that might occur if the consumer believes the food he or she is using is fresher or of greater value than it is, and CFSAN is responsible for establishing a tolerance for any additive at the lowest level reasonably required to accomplish the intended effect. The data outlined in the guidance are necessary for CFSAN to accomplish each of these tasks. The guidance describes the types of data that should be included, elements of the study design to acquire those data, and unique circumstances that need to be taken into consideration when designing such studies.

FDA Objects To Procter And Gamble Hand Sanitizer Claims -- On September 14, 2007, the FDA Cincinnati District Office sent a Warning Letter to Procter and Gamble (P&G) regarding claims made for Vicks® Early Defense™ Foaming Hand Sanitizer (Hand Sanitizer). The letter deals with the marketing of a product pursuant to an Over the Counter (OTC) monograph that is not yet final, a practice permitted by FDA so long as the manufacturer complies with any conditions in the monograph in question. The Warning Letter serves as a reminder to manufacturers that FDA does monitor the labeling and Internet promotion of such products and may step in when companies exceed what FDA believes to be the permitted uses. This is particularly true where the product is intended to be used by children and is to be used in a manner not previously sanctioned, at least in FDA’s view.



The District Office contends that P&G made claims in its labeling and on its website that the Hand Sanitizer, which contains the active ingredient triclosan, can be applied and left on the skin without rinsing, and that these claims are improper, since the proposed monograph only permits the use of triclosan if it is rinsed off after use. The District Office also objects to statements regarding fighting germs that cause colds, claiming that such claims were not sanctioned by the monograph, and there was not sufficient evidence to demonstrate that triclosan was generally recognized as safe and effective in preventing individuals from becoming infected with the germs that cause colds.

The Cincinnati District Office indicated in the Warning Letter that FDA would not object to the marketing of a triclosan-containing product as long as it was “formulated and labeled in accordance with the conditions covered under the OTC Drug Review.” The District Office added the caveat that the marketing was subject to the risk that a final monograph or rule might require reformulation or relabeling. Finally, the District Office acknowledged that FDA was not aware of significant health risks associated with the product. It should be noted that a Warning Letter only tells one side of the story. Companies often respond to such letters, and FDA will post the responses on its website. No response has been posted to date.

REACH

The European Chemicals Bureau Issues Two Final Guidance Sections For REACH -- The European Chemicals Bureau released on September 14, 2007, two sections of final guidance designed to help companies that purchase chemicals, also known as “downstream users,” comply with the European Union’s Registration, Evaluation, and Authorization of Chemicals (REACH) law. The two completed sections are part of a broader document called REACH Implementation Project 3.5 Guidance on Downstream-User Requirements, the Bureau said. The completed sections address the roles and obligations of downstream users and steps they should take to prepare for compliance with REACH. “The sections will become part of the final guidance document expected to be available by December 2007,” the Bureau said. In addition, the Bureau released on September 12, 2007, a variety of “scoping studies” that describe information, such as ways different industries use chemicals as well as safety data sheets and other measures that downstream users employ to communicate information about the hazards of chemicals they use. Links to the scoping studies and completed sections of guidance are available at <http://ecb.jrc.it/whatsnew>.

LEGISLATIVE DEVELOPMENTS

President Signs PRIA Reauthorization Bill -- On October 9, 2007, President Bush signed the Pesticide Registration Improvement Renewal Act (S. 1983), which reauthorizes and amends the Pesticide Registration Improvement Act (PRIA). The House of Representatives approved the legislation by unanimous consent September 24, 2007, and the Senate approved the bill by



unanimous consent August 2, 2007. The legislation authorizes EPA to collect \$110 million in maintenance fees (to support tolerance reassessment and reregistration) and about \$80 million to \$90 million in registration fees from the pesticide industry over the next five years. From these funds, the legislation provides:

- At least \$1 million for each of fiscal years (FY) 2008-2012 for worker protection programs, depending on the amount of fees collected;
- \$500,000 for each of FYs 2008-2012 for pesticide safety education programs;
- Predictable time lines and incentives for the pesticide industry to develop new products; and
- Increases in registration fees to expand the number of covered pesticide products.

While the new bill is very similar to existing law, it contains a few changes. Currently, registration fees are divided into about 90 categories based on the level of risk and proposed use of the pesticide. The new bill adds another 40 categories. In addition, the new bill modifies the definition of small businesses that are eligible for a partial waiver of fees, among other differences. The new bill extends the provisions of the first PRIA, which went into effect in 2004, an additional five years to 2012.

Bills Propose National Health Tracking Network -- On September 24, 2007, Representative Nancy Pelosi (D-CA) and Senator Harry Reid (D-NV) unveiled legislation to create a national public-health tracking network to coordinate and share data in a massive effort to examine the links between public health and exposure to chemicals, pesticides, and other environmental contaminants. The Coordinated Environmental Public Health Act of 2007 (H.R. 3643 and S. 2082) is intended to improve understanding how the environment affects human health and to facilitate sharing of health data among local, state, and federal agencies. The bill would amend the Public Health Service Act to require the Centers for Disease Control and Prevention (CDC) and EPA to work with other federal agencies, as well as state and local officials, to expand the National Environmental Public Health Tracking Program network to all states and to help federal, state, and local officials develop the infrastructure to share information through this network. The information-sharing network would build upon existing databases and surveillance programs, including the Public Health Information Network, the National Health and Nutrition Examination Survey, state cancer registries, and the Hazardous Substance Release/Health Effects Database. The main source of data for the network will be the CDC's National Environmental Public Health Tracking Program, which has gathered public health data from 17 pilot initiatives to begin setting up a national health tracking network. The bill would also create a National



Environmental Health Rapid Response Service, which CDC would spearhead, to coordinate response efforts to unusual or higher than expected illness incidence or environmental exposures. In addition, the proposal allocates \$50 million for expansion of the CDC's biomonitoring program.

Bill Would Ban Import And Manufacture Of Asbestos-Containing Products -- On October 4, 2007, the Senate unanimously passed a bill that would ban products containing asbestos. The Ban Asbestos in America Act of 2007, which Senator Patty Murray (D-WA) introduced, would amend TSCA and require EPA to issue regulations prohibiting the importation, manufacturing, processing, or distribution of asbestos-containing materials. The bill also would allow limited exemptions, including government uses and "diaphragms for existing electrolysis installations." The ban covers the six regulated forms of asbestos and three durable fibers. The bill directs EPA to issue rules to ensure that asbestos products are off the shelves within two years of the bill's enactment. The bill also would amend the Public Health Service Act to require CDC, the National Institute for Occupational Safety and Health (NIOSH), and the Agency for Toxic Substances and Disease Registry (ATSDR) to establish an asbestos-related disease registry and to require the National Institutes of Health (NIH) to establish an asbestos-related disease research treatment network.

Senate Committee Approves Farm Bill Funds -- The Senate Finance Committee approved approximately \$12.6 billion in additional funding for Farm Bill-related programs, including \$5.1 billion for a permanent disaster aid program. The legislation, approved October 4, 2007, seeks to provide \$5.4 billion in funding for conservation programs, \$2.1 billion for various agricultural provisions, and \$30 million for various energy programs. The spending figures are based on FY 2008 to FY 2012, which runs with the expected life of the 2007 Farm Bill.

House Bill Would Reinstate Superfund Money Via Corporate Taxes -- Representatives Earl Blumenauer (D-OR) and Frank Pallone, Jr. (D-NJ) offered legislation on September 24, 2007, that would reinstate corporate taxes to pay for the cleanup of Superfund sites. The Superfund Reinvestment Act of 2007 (H.R. 3636) would amend the Internal Revenue Code of 1986 to replenish the Superfund Trust Fund by reinstating three taxes: a corporate income tax, an excise tax, and a chemical feed stocks excise tax on 42 listed chemicals. Specifically, H.R. 3636 would take the tax rate that existed between December 31, 1986, and January 1, 1996, and reinstate it for the taxable years beginning with the date of enactment until January 1, 2018. The taxes primarily would be imposed on the petroleum and chemical industries. The Bush Administration opposes reinstating the taxes.

Senate Committee Approves Increase To Oil Spill Liability Tax -- The Senate Finance Committee approved a measure on September 21, 2007, that would double an oil spill liability tax and use the increased revenue for highway funding. The American Infrastructure Investment and Improvement Act includes a provision that would increase the Oil Spill Financing Liability



Trust Fund financing rate from 5 cents per barrel to 10 cents per barrel. The provision also would extend the oil spill tax through December 31, 2017, and repeal the requirement that the tax be suspended when the cleanup Fund's unobligated balance exceeds \$2.7 billion. The oil spill tax is paid by refiners on all petroleum produced in or imported to the United States. It was established to pay cleanup costs and damages not paid for by responsible parties due to liability limits or other factors. The Fund also pays costs associated with spills for which there is no identified responsible party. If the legislation clears the Senate, it would have to be reconciled with the House bill (H.R. 2881) on aviation and highway funding programs, which does not include the oil spill tax provision.

Senate Approves Defense Spending Bill Requiring Climate Assessments -- The Senate passed a FY 2008 defense authorization bill on October 1, 2007, that would require the Defense Department to assess the effects of climate change on current and future missions of the U.S. Armed Forces and to revise various defense plans based on those assessments. The climate assessment provision would direct the Defense Department to assess the risks of projected climate change to the current and future missions of the U.S. Armed Forces. It also would direct the Department to work with U.S. allies on strategies for mitigating the effects of climate change and for conducting related research and development. The assessment also would examine the capabilities of U.S. forces in responding to the effects of climate change and its preparedness for natural disasters from extreme weather events that might require the use of those forces either in the United States or overseas. The climate study requirement is also in the House version of the defense authorization bill (H.R. 1585), which the House approved on May 17, 2007.

Senate Committee Approves Ballast Water Bill -- The Senate Commerce, Science, and Transportation Committee approved a bill on September 27, 2007, that would set national standards for ballast water in an attempt to prevent invasive species from entering U.S. waters. During markup of the Ballast Water Management Act of 2007 (S. 1578), Committee Chair Daniel Inouye (D-HI) agreed to continue discussion with Senator Barbara Boxer (D-CA) to resolve the issue of which federal agency should have lead authority over ballast water. Currently, the bill would direct the Department of Homeland Security (DHS), in consultation with EPA and other agencies, to set the standards.

Conference Report Authorizing Corps Projects Faces Veto Threat -- On September 24, 2007, the Senate approved the conference report to the water resources bill that would authorize the U.S. Army Corps of Engineers to carry out \$23.2 billion worth of flood control, navigation, and environmental restoration projects across the United States. The Water Resources Development Act of 2007 (H.R. 1495) conference report would authorize the Corps to carry out roughly 940 projects pertaining to flood control, navigation, water supply, environmental restoration, and infrastructure across the nation. A significant portion of these projects are related to hurricane damage along the Gulf of Mexico, including roughly \$7 billion for coastal restoration along the Louisiana coast. It also includes \$30 million for the Washington, D.C.-based Blue Plains



Wastewater Treatment Plant to install nutrient removal technology to comply with the stringent limits. President Bush has indicated that he would veto the conference legislation.

Tax Credits Approved For Easements And Habitat Protections -- On September 21, 2007, the Senate Finance Committee approved a bill that would give farmers, ranchers, and landowners tax incentives for establishing conservation easements and protecting the habitat for endangered species. The Habitat and Land Conservation Act of 2007 would provide for \$3.182 billion in tax benefits. The allowable credit amount for habitat protection agreements is 100 percent of costs paid or incurred and the loss in value to property pursuant to qualified perpetual habitat protection agreements; 75 percent of costs paid or incurred and the loss in value to property pursuant to qualified 30-year habitat protection agreements; and 50 percent of costs paid or incurred pursuant to a qualified habitat protection agreement. A \$630 million three-year extension of expensing of brownfields remediation costs was also in the bill, along with a \$55 million provision that would provide an exclusion for certain payments and programs relating to fish and wildlife.

Bills Would Address Sewage Overflows -- Senator Frank Lautenberg (D-NJ) introduced two bills that would help communities curb sanitary and combined sewer overflows and would tighten public notification policies when overflows occur. The Water Quality Investment Act of 2007 (S. 836) would authorize EPA to distribute \$1.8 billion in grants to local communities to upgrade aging wastewater treatment and collection systems that are unable to prevent overflows from both sanitary and combined sewer systems. The bill is intended to assist communities in response to the Bush Administration having chosen to reduce funding for the Clean Water State Revolving Fund (SRF) in its fiscal 2008 budget.

Senator Lautenberg also introduced the Sewage Overflow Right-to-Know Act of 2007 (S. 820), which would require public notification within 24 hours of sewer overflows discharging waste into their local waterways. Under S. 820, sewage treatment operators would be required: to monitor their systems for sewage overflows by using a management program or technology that will alert them of sewer overflows in a timely manner; to notify the public, public health officials, and other affected downstream entities, including drinking water suppliers, of any sewer overflows that endanger human health; to report to the state or EPA all sewer overflows within 24 hours of becoming aware of the overflow and follow up with a written report explaining the duration and volume of the overflow and steps taken to mitigate the overflow; and to make monitoring and notification eligible for funding through the SRF.

Bill Would Establish Commission To Develop National Water Strategy -- The House Natural Resources Committee approved a bill on October 10, 2007, that would establish a water commission to study federal, state, local, and private water management programs for the purpose of recommending a national water management strategy. Representative John Linder (R-GA) sponsored the Twenty First Century Water Policy Commission Act of 2007 (H.R. 135),



which would authorize \$9 million for the commission to develop the strategy within three years of its first meeting. Under the bill, the nine-member commission would look at existing water assessments, conduct additional assessments if deemed necessary, study current water management programs, and develop recommendations after meeting with representatives of water agencies at all levels to ensure the national strategy is consistent with laws, treaties, decrees, and interstate water use compacts. The commission would be comprised of nine water experts, five of whom would be appointed by the President, two by the House speaker in consultation with the minority leader, and two by the Senate majority leader in consultation with the Senate minority leader. Representative Linder introduced similar legislation in the 108th and 109th congressional sessions, but the Senate did not act on the legislation.

MISCELLANEOUS

Environmental Fact Sheets For Older Adults Available In 11 Languages -- As the U.S. population continues to become more diverse, EPA is taking steps to inform minority older adults and their caregivers about simple actions they can take to reduce environmental health hazards. EPA's Aging Initiative has developed six fact sheets on the health impacts of air pollution, water contaminants, pesticides, and extreme heat on the most common chronic health conditions that can be worsened by environmental contaminants. The fact sheets outline simple preventative steps to reduce exposure to environmental hazards and have been translated into 11 languages, including Spanish, Portuguese, Chinese, Japanese, Korean, Haitian Creole, Italian, French, Arabic, Russian, and Vietnamese. The fact sheets address chronic conditions such as heart disease, stroke, and asthma, as well as health issues that can arise from exposure to environmental hazards such as drinking water contaminants or pesticides. "*It's Too Darn Hot: Planning for Excessive Heat Events*" describes ways for older adults to reduce exposure to excessive heat and measures local governments can take to prepare for periods of excessive heat. "*Environmental Hazards Weigh Heavy on the Heart*" describes the environmental hazards that can worsen these diseases, including indoor and outdoor air pollution, smoke from tobacco, household products, extreme heat, and lead, and arsenic in drinking water. "*Age Healthier, Breathe Easier*" outlines simple steps that older adults with respiratory diseases can take to reduce and control the frequency of their symptoms. "*Safe Steps to Rid Your Home and Garden of Pests*" discusses responsible pesticide use across generations. Older adults who may be more susceptible to the effects of pesticide exposure can also play an important role in keeping grandchildren safe from pesticides. "*Water Works*" discusses water contaminants such as microbes, lead, and arsenic and what to do after a flood. "*Diabetes and Environmental Hazards*" describes how exposure to environmental hazards, such as air pollution and extreme heat can worsen the health of persons living with diabetes. The fact sheets are available at <http://www.epa.gov/aging/index.htm>.



EPA Revises Procedure For Implementing NEPA And Assessing Environmental Effects Abroad Of EPA Actions -- On September 19, 2007, EPA issued final amendments to its procedures for implementing the requirements of the National Environmental Policy Act of 1969 (NEPA). 72 Fed. Reg. 53652. The rule amends EPA's NEPA implementing procedures by: consolidating and standardizing the procedural provisions and requirements of EPA's environmental review process under NEPA; clarifying the general procedures associated with categorical exclusions, consolidating the categories of actions subject to categorical exclusion, and amending existing and adding new categorical exclusions; consolidating and amending existing and adding new extraordinary circumstances; consolidating and amending the listing of actions that generally require an environmental impact statement; clarifying the procedural requirements for consideration of applicable environmental review laws and executive orders; and incorporating other revisions consistent with the Council on Environmental Quality's regulations (CEQ Regulations). For more information on NEPA, go to <http://www.epa.gov/compliance/nepa/>. This final rule is effective on **October 19, 2007**.

EPA Releases Draft Framework For Determining Mutagenic MOA For Carcinogenicity -- On September 27, 2007, EPA announced the availability of an external review draft of a document entitled *Framework for Determining a Mutagenic Mode of Action for Carcinogenicity: Using EPA's 2005 Cancer Guidelines and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (Draft Framework). 72 Fed. Reg. 54910. EPA states that it is releasing the Draft Framework "solely for the purpose of seeking public comment prior to external peer review." Following the public comment period, an external panel of experts will review the Draft Framework. EPA will publish a *Federal Register* notice announcing the date and other details about the external review. EPA will consider both the public and the external peer review comments when revising the Draft Framework. The purpose of the Draft Framework is to "expand and clarify" discussions found in the *Cancer Guidelines* and *Supplemental Guidance* on characteristics to be evaluated for a chemical's potential for a mutagenic mode of action (MOA). EPA states that the Draft Framework is "not a prescriptive guide on how any particular type of assessment should be conducted within an EPA program or regional office. Rather, it is a science-based document that is intended to help EPA's risk assessors determine whether data support a finding of a mutagenic MOA for carcinogenicity." The Draft Framework discusses mutagenicity only within the context of a mutagenic MOA for carcinogenicity, and not for other adverse endpoints that involve mutations.

EPA's *Cancer Guidelines* emphasize using MOA information in interpreting and quantifying the potential cancer risk to humans. The *Supplemental Guidance* discusses the use of age-dependent adjustment factors (ADAF) with the derived cancer slope factors (and appropriate age-specific estimates of exposure) in the development of risk estimates if the weight of evidence supports a mutagenic MOA. EPA notes: "This default approach is used only when appropriate chemical-specific data are not available on susceptibility from early-life exposures."



The Risk Assessment Forum prepared the Draft Framework in response to requests from numerous stakeholders following EPA's release of the *Supplemental Guidance* in 2005. The Draft Framework expands and clarifies characteristics used to determine a chemical's potential for a mutagenic MOA for carcinogenicity. EPA states that this determination affects consideration of adjusting cancer potencies via the ADAFs when exposures of these carcinogens occur to children. EPA intends the Draft Framework to complement its 2005 *Cancer Guidelines* and *Supplemental Guidance*. To use the Draft Framework properly, according to EPA, "the chemical of interest must already have a weight-of-evidence determination for carcinogenicity." The Draft Framework does not provide an approach to hazard identification. Instead, it provides information EPA believes is useful to determining whether MOAs by which the chemical causes cancer include mutagenicity as an early key event. The Draft Framework is available at <http://www.epa.gov/osa/mmoaframework>. Comments are due **November 26, 2007**.

OMB Withdraws 2006 Draft Risk Assessment Bulletin And Issues Updated Principles For Risk Analysis -- On September 19, 2007, the Office of Management and Budget (OMB) and the Office of Science Technology and Policy (OSTP) issued a memorandum that withdraws OMB's January 9, 2006, proposed bulletin on risk assessment and outlines principles for conducting analyses of health, safety, and environmental risk (Updated Principles for Risk Analysis). OMB stated that the Updated Principles for Risk Analysis "reaffirms risk analysis principles previously released by OMB in 1995 and reinforces them with more recent guidance from the scientific community, Congress, and the Executive Branch." According to OMB, the Updated Principles for Risk Analysis "reflects the recommendation by the National Academy of Science [(NAS)] that OMB outline goals and general principles to increase the quality, objectivity, and utility of Agency risk analyses. This update will make it easier for agencies to adhere to these well-established principles." The Updated Principles for Risk Analysis are available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf>.

OECA Announces Enforcement Priorities -- On October 12, 2007, EPA announced the triennial national enforcement and compliance assurance priorities to be addressed for FYs 2008-2010. 72 Fed. Reg. 58084. EPA has incorporated the final priority selections into Office of Enforcement and Compliance Assurance (OECA) guidance providing national program direction for all EPA regional offices. The national priorities are:

- CWA -- Stormwater;
- CWA -- Combined Sewer Overflow;
- CWA -- Sanitary Sewer Overflow;
- CWA -- Concentrated Animal Feeding Operations;



- CAA -- New Source Review/Prevention of Significant Deterioration;
- CAA -- Air Toxics;
- RCRA and CERCLA -- Financial Assurance;
- RCRA -- Mineral Processing; and
- Indian Country.

The FY 2005-2007 Petroleum Refining priority will not continue into FY 2008-2010 as a national priority. According to EPA, the priority has met its primary goal of addressing 80 percent of the national refining capacity and was returned to the core program at the end of FY 2006. For each of the national priority areas, EPA has developed a strategy intended to achieve specific goals. The strategy summaries include a description of the environmental problem or noncompliance problem; why OECA is addressing the problem; how the problem will be addressed; and, highlights the progress made by the priorities for FY 2005-2007. The strategy summaries are available at <http://www.epa.gov/compliance/data/planning/priorities/index.html>. Annual results information for FY 2007 will be available on **November 16, 2007**.

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