



## Recent Federal Developments September 15, 2007

---

### TSCA/FIFRA/EPCRA/NTP

---

***EPA Grants TSCA Section 21 Petition On Nonylphenol And Nonylphenol Ethoxylates*** -- On September 5, 2007, the U.S. Environmental Protection Agency (EPA) issued its response to the Toxic Substances Control Act (TSCA) Section 21 petition submitted by the Sierra Club, the Environmental Law and Policy Center, the Pacific Coast Federation of Fishermen's Associations, the Washington Toxics Coalition, Physicians for Social Responsibility, and UNITE HERE on June 6, 2007. The petitioners requested that EPA require manufacturers and importers to conduct certain health and safety studies under TSCA Section 4; and also require, under TSCA Section 6(a), labeling on all products containing nonylphenol (NP) and nonylphenol ethoxylates (NPE), and limit the use of NP and NPEs where the use of these substances presents an unreasonable risk to public health and the environment. 72 Fed. Reg. 50954. EPA announced that it is granting the petitioners' request to initiate a proceeding for chronic aquatic toxicity testing under TSCA Section 4 and will also request comment on potential additional testing related to certain of the petitioners' requests. EPA denied the petition in regard to TSCA Section 6 and to the remaining specific TSCA Section 4 requests. EPA denied the other request in the petition claiming that petitioners failed to meet their TSCA burden.

***TERA Cooperation Agreement Expires*** -- On August 31, 2007, the cooperative agreement between EPA and Toxicology Excellence for Risk Assessment (TERA), which has provided funding to TERA for peer consultations, including those for the Voluntary Children's Chemical Evaluation (VCCEP) pilot program, ended. Because not all of the VCCEP submissions on the EPA pilot list have been completed, TERA has reportedly been in contact with EPA and with the sponsors of the non-completed chemicals to ask about their future plans. At the present time, TERA reports that no schedule is in place for peer consultations for the outstanding VCCEP chemicals, although some of the sponsors have indicated that they are completing their submissions and want them to undergo a peer consultation.

***EPA Releases List Of High Production Volume Chemicals*** -- On September 10, 2007, EPA released the first set of Hazard Characterizations on 101 High Production Volume (HPV) chemicals. These characterizations reportedly are based on EPA's scientific review of the screening-level hazard, or toxicity, data that were submitted by the U.S. chemical industry through EPA's HPV Challenge Program or other information previously collected by the Agency. The HPV Challenge Program challenged companies to provide the public with basic health and safety data on chemicals that are manufactured in excess of a million pounds a year. The hazard characterizations include a summary of the data submitted, EPA's evaluation of the quality and completeness of the data, and an assessment of the potential hazards that a chemical or chemical category may pose. EPA will combine this information with human and environmental exposure information collected from EPA's Inventory Update Reporting (IUR) maintained under TSCA Section 8, to develop a risk characterization and, based on that review,



determine if additional action is needed to ensure the safety of the HPV chemicals' manufacture and use.

EPA intends to use this approach to assess risks and identify and take needed action on 3,000 HPV chemicals by 2012. This was one of the elements of the North American chemical cooperation commitment announced by the U.S., Canada, and Mexico at the Security and Prosperity Partnership North American Leaders' Summit in Canada in August. For additional information on this announcement, visit the HPV Challenge Program website at <http://www.epa.gov/hpv>. EPA will continue to prepare and periodically post additional HPV chemical hazard characterizations as they are developed. EPA also intends to post risk characterizations on chemicals when they are developed and completed, beginning later this year. The first set of hazard characterizations is available at [http://iaspub.epa.gov/opthpv/hpv\\_hc\\_characterization.get\\_report](http://iaspub.epa.gov/opthpv/hpv_hc_characterization.get_report).

#### **CAA/CWA/SDWA/ESA**

---

***EPA Proposes Revisions To Consolidated Federal Air Rule*** -- On August 27, 2007, EPA proposed to revise the General Provisions for Consolidated Federal Air Rule. 72 Fed. Reg. 48953. On May 16, 2007, EPA published a final rule that revised the General Provisions for Standards of Performance for New Stationary Sources, for National Emission Standards for Hazardous Air Pollutants, and for National Emission Standards for Hazardous Air Pollutants for Source Categories to allow extensions to the deadline imposed for source owners and operators to conduct initial or other required performance tests in certain specified force majeure circumstances. EPA recently realized that it should have also revised the Consolidated Federal Air Rule to allow similar extensions. Comments must be received by **September 26, 2007**.

***EPA Updates Website On Endangered Species*** -- EPA announced on August 28, 2007, that it has updated its website for its Endangered Species Protection Program. According to EPA, the website includes a more streamlined interface and more visible and useful links on the home page. Information on the website includes pesticide use limitations in particular counties to protect endangered species, a description of how EPA evaluates potential risks to endangered species from pesticides, assessments of various pesticides' potential effects on endangered species, and detailed information about specific types of endangered species.

***EPA Proposes Amendments To NESHAP For Petroleum Refineries*** -- On September 4, 2007, EPA proposed amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) from petroleum refineries to address the risk remaining after application of the 1995 standards. 72 Fed. Reg. 50716. The proposal also provides the results of EPA's eight-year review of developments in practices, processes, and control technologies that have occurred since the time EPA adopted the emissions standards. Based on the results of the residual risk and technology review, EPA proposed two options for wastewater treatment systems and storage



vessels. For wastewater treatment systems, the first option would not require any additional controls as necessary to address residual risk or under the technology review. The second option would require refineries to apply new or additional requirements for wastewater treatment systems. For storage vessels, the first option would also not require any additional controls as necessary to address residual risk or under the technology review and the second option would require refineries to apply new or additional requirements for storage vessels. Finally, EPA also proposed two options for amendment to add emissions standards for cooling towers. Comments must be received on or before **November 5, 2007**.

***EPA Publishes Groundwater Guidance For Systems At Risk For Microbial Pollutants*** -- On August 21, 2007, EPA issued guidance on protecting groundwater systems believed to be at risk for microbial pollutants. Entitled *Ground Water Rule Source Water Monitoring Guidance Manual*, the document summarizes EPA's Final Groundwater Rule and lists requirements for monitoring source water. The guidance document is one of three issued on August 21, 2007, pertaining to the Final Groundwater Rule. The guidance describes the eight components of a water system that must be regularly monitored: source; treatment; distribution system; finished water storage; pumps, pump facilities, and controls; monitoring, reporting, and data verification; system management and operation; and operator compliance with state requirements.

The second guidance document, the *Consecutive System Guide for the Ground Water Rule*, describes the regulatory requirements of the rule as it applies to wholesale systems that supply groundwater and to the water systems that receive and distribute that groundwater supply. The third document, *Complying with the Ground Water Rule: Small Entity Compliance Guide*, is designed for owners and operators of public water systems serving fewer than 10,000 people that must comply with the Final Groundwater Rule. The three groundwater compliance documents are available at <http://www.epa.gov/safewater/disinfection/gwr/compliancehelp.html>.

***EPA Issues Technical Amendments To Continuous Instrumental Test Methods*** -- On September 7, 2007, EPA issued a direct final rule amending five instrumental test methods published on May 15, 2006. 72 Fed. Reg. 51365. The amendments contained inadvertent errors and provisions that need to be clarified. EPA is correcting errors and clarifying portions of the amendments to reflect the intent of the rule and to make them more understandable by affected parties. This rule is effective on **November 6, 2007**, without further notice, unless EPA receives adverse comment by **October 9, 2007**. If EPA receives adverse comment, EPA will publish a timely withdrawal in the *Federal Register* informing the public that this rule will not take effect. EPA issued a proposed rule on the same day. 72 Fed. Reg. 51392. Comments are due by **October 9, 2007**.



## **NANOTECHNOLOGY**

---

***U.K. Report Lists Government Agencies Working On Nanotechnology Applications*** -- In August 2007, the United Kingdom's Technology Transfer Center published a report entitled *Government Policy and Initiatives in Nanotechnology Worldwide 2007*, which lists government agencies throughout the world that are working with and/or funding divergent applications of nanotechnologies and the research institutes they support. The report, which costs \$4,000, lists the governmental and/or research institutions that have received money, and the types of research being conducted. A 12-page table of contents is available at <http://www.mindbranch.com/product/Government-Policies-Initiatives-R3404-16>.

***European Commission Issues Opinion On Risk Assessment Of Nanoparticles*** -- On August 8, 2007, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) issued an opinion suggesting that traditional risk assessment methods may need to be revised to assess nanoparticles. The report, *Opinion on the Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for New and Existing Substances for Assessing the Risks of Nanomaterials*, notes that nanoparticles may act in ways that differ from larger molecules, so risks need to be assessed on a "case-by-case basis." The opinion is available at [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihp/docs/scenihp\\_o-010.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihp/docs/scenihp_o-010.pdf).

***NNI Seeks Comment On Federal Priorities For Research On Nanoscale Materials*** -- On August 16, 2007, the National Nanotechnology Coordination Office (NNCO) identified a list of federal priorities for research designed to address environmental, health, and safety (EHS) questions raised by engineered nanoscale materials. The document, *Prioritization of Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials*, was developed by a dozen federal agencies that are part of the Nanoscale Science, Engineering, and Technology Subcommittee of the Committee on Technology within the National Science and Technology Council. NNCO acts as the secretariat for these interagency groups. The report lists criteria the federal agencies used to prepare their respective lists of proposed priority research. The five research areas involved instrumentation, measurement, and analytical methods; nanomaterials and human health; nanomaterials and the environment; health and environmental exposure assessment; and risk management methods. Within those areas, the federal agencies identified 25 research priorities, including the need to: develop methods to detect nanomaterials in biological matrices, such as cells, the environment, and the workplace; develop methods to quantify and characterize exposure to nanomaterials and fully describe them within biological matrices, such as cells; understand the effects of engineered nanomaterials in individuals of a species and the applicability of testing schemes to measure effects; characterize exposures among workers; and understand and develop best workplace practices, processes, and environmental exposure controls.



After public comment has been obtained, the Nanotechnology Environmental and Health Implications (NEHI) Working Group, an interagency committee that oversees EHS issues, will complete a gap analysis to identify whether high-priority research is being conducted or whether some additional priority studies should be conducted or funded. Comments are due by **September 17, 2007**. The report and related documents along with a link to provide comments are available at [http://www.nano.gov/html/society/ehs\\_priorities](http://www.nano.gov/html/society/ehs_priorities).

*Canada Publishes Proposed Regulatory Framework For Nanomaterials Under CEPA --* Environment Canada (EC) and Health Canada (HC) have released a document entitled *Proposed Regulatory Framework for Nanomaterials Under the Canadian Environmental Protection Act, 1999* (Proposed Framework). EC/HC will hold a public workshop for stakeholders regarding the Proposed Framework on **September 27, 2007**, in Toronto. At the workshop, EC/HC will gather comments from participating stakeholders through discussion groups and plenary sessions. EC/HC will invite all stakeholders to provide additional written comments the weeks following the meeting.

The document notes that at present there is no definitive system of nomenclature for nanomaterials. The Proposed Framework states that Canada will be working with other countries under the auspices of the International Organization for Standardization (ISO) over the next year to develop a nomenclature system specific to nanomaterials. Once in place, according to the Proposed Framework, this nomenclature system will simplify the task of determining whether a particular nanomaterial is new or existing under CEPA.

Until a nomenclature system is established, Canada has issued an advisory note describing new and existing nanomaterials under the current regulations, which is available at [http://www.ec.gc.ca/substances/nsb/eng/a200706\\_e.shtml](http://www.ec.gc.ca/substances/nsb/eng/a200706_e.shtml). Substances listed on the Domestic Substances List (DSL) whose nanoscale forms do not have unique structures or molecular arrangements are considered “existing.” The nanoscale form of a substance on the DSL is considered a “new” substance if it has unique structures or molecular arrangements.

The Proposed Framework states that nanomaterials present challenges to the current regulatory framework because their novel properties may give rise to new effects and behaviors which may lead to impacts on human health and the environment. According to the Proposed Framework, the current data requirements for “traditional” chemicals and polymers may not be appropriate to permit adequate risk assessments of nanomaterials. Therefore, EC and HC have proposed an approach for the development of a regulatory framework for nanomaterials under CEPA which is set forth in the document.

The Proposed Framework states that the development of an effective regulatory framework “will make use of the outcomes of international efforts and collaboration with industry. Information gathering initiatives will be developed in conjunction with industry and the public through multi-



stakeholder consultations.” According to the Proposed Framework, this will be the first substantive step toward enabling the appropriate risk assessment and risk management of nanomaterials. EC and HC intend to obtain feedback from stakeholders:

The Proposed Framework states that EC and HC may hold future consultations on other aspects of the federal government’s approach to regulating nanomaterials “to ensure that the needs of both industry and the public are met through an open and transparent process.” EC and HC invite stakeholders to provide written comments on the Proposed Framework and the options for information gathering.

## **FDA**

***FDA Releases Proposed Rule Regarding Sunscreens*** -- On August 27, 2007, the Food and Drug Administration (FDA) proposed to amend the final monograph (FM) for over-the-counter (OTC) sunscreen drug products as part of FDA’s ongoing review of OTC drug products. 72 Fed. Reg. 49070. The proposed rule addresses formulation, labeling, and testing requirements for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection, would introduce a four-star rating system for the level of UVA protection, and would require a warning statement. FDA previously delayed regulations concerning UVA protection until reliable testing methodologies could be developed. The proposed rule specifically solicits comment on “the safety and effectiveness of sunscreen ingredients formulated in particle sizes as small as a few nanometers.” Comments on the proposed rule are due on or before **November 26, 2007**. More information is available at <http://www.fda.gov/cder/drug/infopage/sunscreen/default.htm>.

***NCI Alliance For Nanotechnology In Cancer*** -- FDA recently added to its nanotechnology home page a link to the website of the National Cancer Institute Alliance for Nanotechnology in Cancer (NCI Alliance). FDA indicates that the site is a source of additional information on nanotechnology. The NCI site is of interest for a number of reasons. First, it is an example of a serious, concentrated effort to conduct directed research utilizing nanotechnology to provide patient benefit now, and not at some indefinite time in the future. Next, the site is interesting because it does not dwell on the possible negative effects of using nanomaterials, but only on the gains that might be made. Third, the site contains a wealth of information on studies utilizing many forms of nanomaterials that have not been widely discussed in the literature. Lastly, several members of the Cancer Nanotechnology Working Group (CNWG) that coordinates the work being done or sponsored by NCI are FDA employees, two of who are members of the FDA Nanotechnology Task Force engaged in the shaping of FDA policy on nanotechnology.

The mission of the NCI Alliance since the development of an action plan, the Cancer Nanotechnology Plan or CNPlan, in July 2004 has been to change radically the way that cancer is diagnosed, treated, and prevented. NCI states that it has the technological power and tools to help scientists turn molecular discoveries into patient benefits. NCI cites from the CNPlan the



following goals for accomplishing its mission: research tools to identify new biological targets; agents to monitor predictive molecular changes and prevent precancerous cells from becoming malignant; imaging agents and diagnostics to detect cancer in the earliest, most easily treatable, pre-symptomatic stage; multi-functional targeted devices to deliver multiple therapeutic agents directly to cancer cells; systems to provide real-time assessments of therapeutic and surgical efficacy; and novel methods to manage symptoms that reduce quality of life.

NCI states that it is supporting targeted discovery and development in six key areas that offer great chances for making advances in the short and middle term. In the description of these areas, NCI mentions the use of nanoscale materials, many of which are described in abstracts and study reports listed elsewhere on the site.

The site contains an extensive “Scientific Biography” that lists hundreds of abstracts dealing with nanomaterials, and other articles on a variety of related topics. There is also a section entitled “Nanotech News” with both very recent publications, and an archive of previous postings. The articles address a wide variety of materials, including quantum dots, nanotubes, nanoshells, nanotweezers, nano chips, fullerenes, porous nanocontainers, nanoclusters, and magnetic nanoparticles.

Four FDA employees serve on the CNWG, which coordinates the work of the NCI Alliance on the CNPlan. Two of those individuals, Dr. Nakissa Sadrieh and Dr. Paul Howard, are members of the FDA Nanotechnology Task Force. Another employee, Dr. William Allaben, is Assistant Director of the National Center for Toxicological Research at FDA.

## **LEGISLATIVE DEVELOPMENTS**

---

***Legislation Intended To Promote And Coordinate Green Chemistry Efforts*** -- After returning from its scheduled August 2007 recess, the House of Representatives passed legislation on September 4, 2007, that would establish a federal interagency program to promote and coordinate “green chemistry” research and development. The bill (H.R. 2850) would establish a coordinated research program using existing authorized accounts at EPA, the National Science Foundation (NSF), the National Institute of Standards and Technology, and the Department of Energy. H.R. 2850 also would authorize these entities to spend as much as \$51 million in fiscal year 2008, \$55 million in fiscal year 2009, and \$59 million in fiscal year 2010 on green chemistry. The legislation would establish an interagency working group to oversee the planning and management of all federal green chemistry research programs. The NSF Director and EPA Assistant Administrator for Research and Development would oversee the group. The bill also would establish grant programs to create green chemistry science curricula at colleges and universities at the undergraduate and graduate levels, as well as set up partnerships between companies and academic institutions to re-train chemists and chemical engineers. The House



passed similar legislation in its 2004 session and again in 2006, but the Senate never took up the legislation.

**Senate Passes Spending Bill** -- The Senate passed the fiscal year 2008 transportation and housing spending bill on September 12, 2007. The bill would direct \$10 million for brownfields redevelopment, an increase of \$100,000 over the level for the current fiscal year. The brownfields funding is for competitive economic development grants, provided in conjunction with loan guarantees for qualified brownfields projects under Section 108 of the Housing and Community Development Act. Funding would be available through September 30, 2009. The Bush Administration has said it opposes “lower performing” programs such as Section 108 loan guarantees, brownfields, and rural housing. The Administration recommended no funding for the brownfields or loan guarantee programs in its proposed budget. The House passed its version of the spending bill on July 24, 2007, which included \$9.9 million for brownfields redevelopment through September 30, 2009. The Senate and House bills also would provide approximately \$27 million for hazardous materials transportation safety programs.

**MISCELLANEOUS**

**EC/HC Publish Third Batch Of Substances For Priority Risk Assessment** -- On August 18, 2007, EC and HC released the technical documentation pertinent to 19 substances included in the third batch of substances considered likely to be toxic. The government also released notices of its intent to develop a similar plan for an additional 18 substances. The chemicals included in the third batch are drawn from the DSL under CEPA. The government also outlined its plans for additional action on the substances, including identification of commercial best management practices, collection of release and exposure information, and related risk mitigation measures. The 19 substances are:

CAS No.	Substance Name
81-68-5*	Benzenesulfonamide, N-(4-amino-9,10-dihydro-3-methoxy-9,10-dioxo-1-anthracenyl)-4-methyl-
1594-08-7	9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]phenyl]amino]-
2425-85-6	2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]-
2814-77-9	2-Naphthalenol, 1-[(2-chloro-4-nitrophenyl)azo]-
3468-63-1	2-Naphthalenol, 1-[(2,4-dinitrophenyl)azo]-
4395-65-7*	9,10-Anthracenedione, 1-amino-4-(phenylamino)-
6410-09-9*	2-Naphthalenol, 1-[(2-nitrophenyl)azo]-
6410-13-5*	2-Naphthalenol, 1-[(4-chloro-2-nitrophenyl)azo]-
6410-41-9*	2-Naphthalenecarboxamide, N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]azo]-3-hydroxy-



CAS No.	Substance Name
6471-01-8*	2-Anthracenesulfonic acid, 4,4'-[(1-methylethylidene)bis(4,1-phenyleneimino)]bis[1-amino-9,10-dihydro-9,10-dioxo-, disodium salt
20241-76-3	9,10-Anthracenedione, 1,8-dihydroxy-4-nitro-5-(phenylamino)-
25155-25-3	Peroxide, [1,3(or 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl)
60352-98-9	1-Propanaminium, 3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]-N,N,N-trimethyl-, methylsulfate
72243-90-4	Benzenesulfonic acid, 3-[[4-amino-9,10-dihydro-9,10-dioxo-3-[sulfo-4-(1,1,3,3-tetramethylbutyl)phenoxy]-1-anthracenyl]amino]-2,4,6-trimethyl-, disodium salt
74336-60-0*	9,10-Anthracenedione, 1-[(5,7-dichloro-1,9-dihydro-2-methyl-9-oxopyrazolo[5,1- <i>b</i> ]quinazolin-3-yl)azo]-
110-49-6	Ethanol, 2-methoxy-, acetate
111-15-9	Ethanol, 2-ethoxy-, acetate
111-77-3	Ethanol, 2-(2-methoxyethoxy)-
1589-47-5	1-Propanol, 2-methoxy-

New information is due by **February 19, 2008**, and a 60-day comment period will begin on **August 23, 2008**.

**Greenpeace Releases Activists' Guide To REACH** -- On August 30, 2007, Greenpeace International (Greenpeace) issued a report entitled *Navigating REACH: An Activists' Guide To Using and Improving the New EU Chemicals Legislation* (Guide), which is intended to explain how the European Union's (EU) Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation will work, what main issues are at stake, and how the law will be implemented. The Guide highlights provisions that non-governmental organizations and citizens can use to promote safer chemicals and lead ultimately to better protection of human health and the environment from the adverse impact of hazardous chemicals. The Guide notes loopholes and flaws that Greenpeace believes need to be avoided as activists work to spark strong policy reforms in other regions of the world. The Guide is available on the Internet at <http://www.greenpeace.org/raw/content/eu-unit/press-centre/reports/navigating-reach.pdf>.

**Report Of The Import Safety Working Group** -- On September 10, 2007, the federal government's Interagency Working Group on Import Safety presented its initial report, entitled *Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety*, to President Bush. The group is composed of twelve Department Secretaries and Agency Heads. The report lists a number of immediate steps to take, including collaboration with manufacturers and the importing community, to develop best practices. It also describes the building blocks to a more effective system for identifying potential product



hazards, and invites public comments and recommendations. The Working Group indicates in the report that a follow-on Action Plan will be presented to the President by mid-November, after the Working Group has considered all the comments filed. The report is available at <http://www.importsafety.gov/report/index.html>.

This Update is provided as a complimentary service to our clients and is for informational purposes. This Update may be copied or quoted, provided proper attribution is given. The contents are not intended and cannot be considered as legal advice.