



Recent Federal Developments November 15, 2006

TSCA/FIFRA/EPCRA/NTP

EPA Makes Available Risk Framework For Assessing Exposures To Children -- On October 13, 2006, the U.S. Environmental Protection Agency (EPA) announced the availability of *A Framework for Assessing Health Risks of Environmental Exposures to Children*. 71 Fed. Reg. 60514. The document, which was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development (ORD), provides an overarching framework for a complete and transparent assessment of exposure of environmental agents to children and resulting potential health risks within EPA's risk assessment paradigm. The document is available at <http://www.epa.gov/ncea>.

EPA Releases 2010/15 PFOA Stewardship Program Reporting Guidance -- EPA issued a final guidance document, entitled *2010/15 PFOA Stewardship Program: Guidance on Reporting Emissions and Product Content*, which includes guidance on reporting emissions and product content. Under EPA's 2010/15 PFOA Stewardship Program, participating companies committed to reducing PFOA and related chemicals from facility emissions and in product content by 95% no later than 2010, and to work toward eliminating PFOA from emissions and in product content no later than 2015. Participating companies were required to submit by October 31, 2006, their year 2000 baseline numbers for emissions and product content. According to EPA, it will post the submissions in early November at <http://www.epa.gov/opptintr/pfoa/pubs/pfoastewardship.htm>. More information is available in the docket at <http://www.regulations.gov>, under docket number EPA-HQ-OPPT-2006-0621.

Revised Guidance On Pesticide Label Warranty Statements -- On October 20, 2006, EPA's Office of Pesticide Programs (OPP) issued revised guidance addressing the type of language it wants registrants to incorporate in the warranty and disclaimer statements that appear on the labeling for registered pesticides. A copy of the guidance document, which reviewers are instructed to consult when determining if a pesticide label is acceptable under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is available at <http://www.epa.gov/pesticides/regulating/labels/warranty.pdf>.

This marks the first time since 1997 that EPA has revisited its pesticide label warranty guidance. The stated impetus for these revisions is OPP's concern that some warranty and disclaimer language found on existing labels is overbroad or potentially misleading to consumers in obscuring the full extent of the relief that may be available to them against a manufacturer under state law for injury or damage resulting from the use of a pesticide product. These concerns are a result of the Supreme Court's decision last year in *Bates v. Dow Agrosciences*, which considerably narrowed the scope of the common law or other state law claims preempted under FIFRA. The *Bates v. Dow* Court narrowly interpreted the preemptive effect of FIFRA on "labeling or packaging" claims by construing those terms to exclude claims based on defective design, defective manufacture, negligent testing, or breach of the express warranty that a



manufacturer elects to provide. Subsequent lower court decisions have broadened the impact of *Bates v. Dow* even further.

EPA's active oversight of the warranty portions of pesticide labels, which predated *Bates v. Dow*, has stepped up even more assertively in its wake, reflecting OPP's concern that manufacturers now have a stronger incentive to limit their express warranty provisions as far as possible. According to EPA, it is authorized to undertake such oversight -- and to refuse to approve labeling that fails to meet the specifics of the OPP guidance -- because non-complying labels render a pesticide product "misbranded," in violation of a core provision of FIFRA. The breadth of FIFRA's "misbranding" provision lends some support to EPA's position, although it does not answer the threshold question of whether EPA properly has involved itself in what are matters of commercial and consumer law.

EPA's ability to withhold its approval of a given label or label amendment, however, makes issues of authority somewhat academic for manufacturers trying to bring a product to market by a date certain. The examples of both recommended language and unacceptable wording contained in the recently-issued guidance document are quite specific and allow for only limited flexibility on the part of individual reviewers. This raises the issue of whether the guidance document is in effect a rule dressed in "policy" clothing, which should have been subject to notice and an opportunity for public comment under the Administrative Procedure Act (APA) before it could be implemented -- not an unprecedented shortcoming. Whether, or when, this vulnerability might translate into a successful challenge to the warranty guidance is still in the realm of conjecture. As matters now stand, pesticide registrants should consult with counsel in preparing language that is sufficiently protective under commercial law principles while satisfying the revised guidance, as applied by OPP's reviewers.

OPP Releases Draft Inert Ingredients Document And Labeling Materials -- EPA OPP released a draft document regarding inert ingredients and materials regarding labeling consistency. The October 31, 2006, draft document on inert ingredients is entitled "Tips for Inert Ingredients." It describes what an inert ingredient is, how to find inert ingredients that are approved for use in pesticide products, what to put on a confidential statement of formula for inert ingredients, and how to contact OPP's Inert Ingredient Assessment Branch (IIAB). The draft document is available at <http://www.epa.gov/opprd001/inerts/tips.pdf>. The labeling consistency materials include a response to comments on "For Use Only By," a request for comments, which are due by **December 11, 2006**, on the issue of whether product labels can establish minimum use rates for any purpose other than risk reduction or efficacy, and a pesticide labeling consistency question and answer (Q&A) web page. The labeling documents and a link to the Q&A are available on the Internet at http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm.



EPA Issues Final Amendments To TSCA Export Notification Reporting Requirements -- On November 14, 2006, EPA promulgated long awaited amendments to the Toxic Substances Control Act (TSCA) Section 12(b) export notification regulations at Subpart D of 40 C.F.R. Part 707. 71 Fed. Reg. 66234. The amendments diminish, but do not eliminate, the burden imposed under the TSCA Section 12(b) export notification program, long regarded by many as an unnecessary and overly burdensome reporting requirement. The amendments change the current annual notification requirement to a one-time requirement for exporters of chemical substances or mixtures for which certain actions have been taken under TSCA and change the current requirement that EPA notify foreign governments annually after EPA's receipt of export notifications from exporters to a requirement that EPA notify foreign governments once after it receives the first export notification from an exporter. Significantly, EPA reversed its previous guidance by adopting *de minimis* concentration levels below which notification will not be required for the export of any chemical for which export notification under TSCA Section 12(b) is otherwise required, as well as other minor amendments. The amendments take effect **January 16, 2007**.

REACH

The REACH Legislative Process Is Nearing Completion -- While the Registration, Evaluation, and Authorization of Chemicals' (REACH) legislative process is nearing completion, many critical issues remain unresolved. These unresolved issues are a major component of the REACH progress in the European Union (EU).

The major institutions involved in the EU legislative process are the European Commission (EC or the Commission), the European Parliament (EP or Parliament), and the Council of the EU (Council). Within the EP, most of the key legislative work is done by parliamentary committees, of which there are currently 20. The most prominent parliamentary committee with respect to REACH has been the EP's Environment, Public Health and Food Safety Committee (Environment Committee).

The REACH legislation, proposed by the EC in November 2003, is coming close to fruition, with an estimated Entry Into Force date of April 2007. The EP completed its first reading of the legislation in November 2005, and the Council formally adopted its Common Position on June 27, 2006. Shortly thereafter, the Common Position was forwarded to the EP, which is now engaged in its second reading. At this late juncture, there are still many unresolved issues.

According to trade press reports, the European Parliament intends to modify its position on the proposed REACH chemicals legislation to find agreement with other EU institutions. Under the compromise, Parliament would allow authorization of toxic substances classified as carcinogenic, damaging to reproductive systems, or very bioaccumulative if no alternative is available and if producers can demonstrate adequate safeguards are in place. The next and last



meeting of the so-called inter-instituted group is **November 27, 2006**. The Parliament is scheduled to meet on **December 13, 2006**.

NANOTECHNOLOGY

EPA OPP Presentation On Nanotechnology -- On November 9, 2006, OPP's Pesticide Program Dialogue Committee (PPDC) convened its first discussion on nanotechnology. The PPDC is an advisory committee that provides feedback to the OPP on pesticide regulatory, policy, and program implementation issues. Jack Housenger, Associate Director of the Health Effects Division, and Betty Shackelford, Associate Director of the Antimicrobials Division, lead the discussion.

Housenger's remarks track closely the written presentation, the majority of which provided an overview of nanotechnology and what the federal government and EPA program offices, most particularly the Office of Pollution Prevention and Toxics, are doing in the nano area. In his remarks, Housenger stated that OPP is not aware of any currently registered nanopesticides and, to its knowledge, has yet to receive a FIFRA registration application for a nanopesticide. Housenger confirmed that OPP has formed a nanotechnology workgroup chaired by himself and Shackelford, and comprised of representatives from the various OPP Divisions and EPA's Office of General Counsel. Housenger encouraged industry and the public to share information and concerns with the workgroup.

Dr. Jennifer Sass, Natural Resources Defense Council (NRDC) and member of the PPDC, expressed NRDC's strong and often repeated view that EPA's nanotechnology budget is inadequate. In response to another of Dr. Sass' points, Jim Jones, OPP Director, stressed OPP's desire to be ready for the first nanopesticide registration application, which OPP believes may be coming in the not too distant future.

ICON Issues Survey Of Nanotechnology Practices -- On November 13, 2006, the International Council on Nanotechnology (ICON) released a report entitled *A Survey of Current Practices in the Nanotechnology Workplace*, which presents the findings of an international survey of current environmental health and safety (EHS) and product stewardship practices in the global nanotechnology industry. Of the 337 organizations that were invited to participate, 64 companies, research labs, and university labs from four continents responded. ICON administered the survey between June and September 2006, through telephone interviews and written and web-based surveys. ICON inquired about current practices related to research, use, and manufacture of nanomaterials in the following areas: EHS training; use of engineering controls; personal protective equipment (PPE) and clothing recommendations; exposure monitoring; waste disposal; product stewardship practices; and risk characterization. In general, surveyed organizations reported that they believe there are special risks related to the nanomaterials they work with, that they are implementing nano-specific EHS programs, and that



they are actively seeking additional information on how best to handle nanomaterials. According to the survey, actual reported EHS practices, including selection of engineering controls, PPE, cleanup methods, and waste management, do not significantly depart from conventional safety practices for handling chemicals. Additionally, few organizations reported monitoring the workplace for nanoparticles or providing formal guidance to downstream users on the safe disposal of nanomaterials. When asked, organizations generally recommended disposal of nano-products as hazardous waste, though they did not frequently report conveying this information to their customers. Reported practices in the handling of nanomaterials, with some exceptions, are based on criteria unrelated to any perceived risks stemming specifically from working with nano-scale materials. Most organizations said that the biggest impediment to improving their nano-specific EHS program is a lack of information, and nearly half of the organizations implementing a nano-specific EHS program described it as a precaution against unknown hazards. Organizations reported seeking new information from scientific literature and governmental guidelines for help in assessing the risks related to their nanomaterials and the appropriate steps that should be taken to address them. The report is available on the Internet at http://icon.rice.edu/projects.cfm?doc_id=4388.

AIR/WATER

EPA Requests Nominations Of Drinking Water Contaminants For The Contaminant Candidate List -- On October 16, 2006, EPA requested nominations of chemical and microbial contaminants for possible inclusion in the third drinking water Contaminant Candidate List (CCL 3). 71 Fed. Reg. 60704. EPA is also requesting information that shows the nominated contaminant may have an adverse health effect on people and that the contaminant occurs or is likely to occur in public water systems. Nominations must be received on or before **December 15, 2006**.

LEGISLATIVE DEVELOPMENTS

Congressional Turnover -- Congressional business other than environmental legislation received the bulk of attention in the rush preceding Congress's 2006 election recess, which began on the morning of September 30, allowing many legislators to head for their home states and districts to focus their energy on mid-term election campaigns. The results of the mid-term elections, however, portend a number of significant Congressional changes.

First, with the Democrats in control, there will be a surge in the oversight of all federal environmental activities among the various Senate and House Committees. For example, Representative Henry Waxman (D-CA) will chair the House Government Reform Committee and will have a staff of approximately 60 "investigators" with jurisdiction over the entire U.S. Government. In the Senate, Joe Lieberman (I-CT), functionally again a Democrat, will lead an equivalent Committee with a similarly large staff of investigators. Lieberman has a history of



interest in pesticide and chemical regulation. EPA senior management will likely be initially overwhelmed by a deluge of information requests, threatened subpoenas, and the need to prepare for program oversight and legislative hearings. As a result, EPA's ability to conduct new and continuing business will be limited, and that impact might be felt starting early in 2007.

Second, with Democrats in control, stalled environmental legislation will regain attention and consideration. For example, with the election of a Democratic Congress, passage of legislation to control emissions of greenhouse gases blamed for global warming moves from being almost unthinkable to being a strong possibility. In part, the possibilities for this and other legislation will be brought about by the new Chairs of Committees with relevant jurisdiction. In the 110th Congress, in all likelihood, Jeff Bingaman (D-NM) will chair the Senate Energy and Natural Resources Committee, and Barbara Boxer (D-CA) will chair the Senate Environment and Public Works Committee. Boxer has stated, "As the new Chair of the EPW Committee, I am already planning for vigorous oversight and legislation to make sure that the U.S. Senate is once again an environmental leader in protecting the health of our families and our children and addressing pressing concerns like global warming." A number of other Senate bills may also gain traction. Senators Bingaman, Boxer, Dianne Feinstein (D-CA), John McCain (R-AZ), and Joseph Lieberman (I-CT) all have climate change-related proposals. Senator Tom Carper (D-DE) is the author of legislation (S. 843) that would reduce carbon dioxide emissions to 2006 levels in 2010 and 2001 levels in 2015 using emissions trading. Also, incoming Senate Commerce Committee Chair Daniel Inouye (D-HI) is a co-sponsor of legislation (S. 3543) to require an increase in corporate average fuel economy (CAFE) requirements on automobiles and light trucks. Senator Tom Harkin (D-IA) is expected to chair the Senate Committee on Agriculture, Nutrition, and Forestry.

In the House, while energy and climate issues are "high priority issues" for Representative Nancy Pelosi (D-CA), who is expected to be the House Speaker in January 2007, the outlook is less clear on energy legislation. Representative John Dingell (D-MI), the incoming Chair of the House Energy and Commerce Committee, has indicated support for energy legislation as long as it does not disproportionately shift the burden to the United States. Nevertheless, the change in House leadership will bring renewed attention to climate change legislation, including various Democratic proposals that would place a mandatory cap on U.S. greenhouse gas emissions. Representative Henry Waxman (D-CA) is likely to press for his proposal to freeze total U.S. greenhouse gas emissions at 2009 levels beginning in 2010, followed by 2 percent annual reductions through 2020. This proposal, introduced in June 2006, has to this point garnered 110 co-sponsors.

Representative Colin Peterson (D-MN) will chair the House Committee on Agriculture. Representative Nick Rahall (D-WV) is expected to take over control of the House Resources Committee in the next Congress, while leadership on the minority side remains unclear after the defeat of Chair Richard Pombo (R-CA). Rahall could face a challenge from Representative



Edward J. Markey (D-MA), a senior member of the Resources Committee who also is in line for key posts in other Committees.

The Democratic takeover of Congress will also result in leadership changes among the five House Resources Subcommittees. It is likely that Representative Frank Pallone, Jr. (D-NJ) will run the Fisheries and Oceans Subcommittee and Representative Grace Napolitano (D-CA) will lead the Water and Power Subcommittee. Representative Tom Udall (D-NM) is in line to chair the Forests and Forest Health Subcommittee and Representative Raul Grijalva (D-AZ) is the senior Democratic member of the Energy and Mineral Resources Subcommittee.

Representative Bart Gordon (D-TN) is expected to chair the House Science Committee. Representative David Wu (D-OR) will likely chair the House Environment, Technology, and Standards subcommittee.

MISCELLANEOUS

ATSDR Makes Available Draft Toxicological Profiles -- On October 18, 2006, the Department of Health and Human Services announced the availability of the 20th set of toxicological profiles, which consists of one new draft and six updated drafts, prepared by the Agency for Toxic Substances and Disease Registry (ATSDR) for review and comment. 71 Fed. Reg. 61479. Comments on these draft toxicological profiles must be received on or before **February 26, 2007**. Comments received after the close of the public comment period will be considered at the discretion of ATSDR on the basis of what is deemed to be in the best interest of the general public.

EPA Announces Meeting Of NAC/AEGL -- On November 14, 2006, EPA's National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) announced that it will convene a meeting from December 12 to December 14, 2006, in Alexandria Virginia. 71 Fed. Reg. 66327. AEGLs under consideration are: allyl alcohol, carbon disulfide, carbonyl fluoride, ethyl benzene, mercury vapor, methacrylaldehyde, methyl vinyl ketone, N,N-dimethylformamide, oxygen difluoride, phosphorus trichloride, propargyl alcohol, selenium hexafluoride, stibine, sulfur dioxide, and thionyl chloride. In addition, proposed AEGL chemicals listed for public comment in the October 12, 2006, *Federal Register* will be considered for elevation from Proposed to Interim AEGL chemicals. 71 Fed. Reg. 60141. Please consult the *Federal Register* for meeting details.

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