



Recent Federal Developments September 15, 2006

Henry M. Jacoby Joins Bergeson & Campbell, P.C. Law Firm And The Acta Group, L.L.C. And The Acta Group, EU, Ltd. Consulting Practices -- Bergeson & Campbell, P.C. (B&C) is pleased to announce that Henry M. Jacoby, MS, former Branch Chief of the U.S. Environmental Protection Agency's (EPA) Environmental Fate and Ground Water Branch, has joined B&C and its consulting affiliates, The Acta Group, L.L.C. (Acta) and The Acta Group, EU, Ltd. (Acta EU). Mr. Jacoby has over 34 years of experience in assisting pesticide, insecticide, herbicide, fungicide, antimicrobial, wood preservation, and antifouling paint manufacturers and formulators in the area of environmental science and applications for federal and state pesticide registrations and tolerance petitions. Twenty-five years of his experience were gained at EPA, where he worked in the Office of Pesticide Programs (OPP) as a Chemist, Product Manager, Senior Staff Member, and Branch Chief. Upon retiring from EPA, Mr. Jacoby joined the consultant firm of Charles, Conn & van Gemert, LLC as Director of Environmental Affairs. In 2001, Mr. Jacoby established his own regulatory consultant business. Mr. Jacoby holds an undergraduate degree in Chemistry from St. Norbert College and an M.S. in Management from Frostburg State University.

TSCA/FIFRA/EPCRA/NTP

EPA Issues Final Pesticide Container Rule Custom Blending Policy Guidance -- On August 16, 2006, EPA issued a final rule establishing requirements for pesticide container design and procedures, standards, and label language to facilitate removal of pesticides from containers prior to disposal or recycling as well as guidance on custom blending. 71 Fed. Reg. 47330. The final rule also establishes requirements for containment of stationary pesticide containers and procedures for container refilling operations. The rule is effective **October 16, 2006**. In the preamble to the rule, EPA provides additional guidance on its policy for "custom blenders" -- companies that provide the services of mixing certain registered pesticides to customers' specifications. EPA's 1982 Custom Blending Policy states that a "custom blender," a term which EPA has defined in 40 C.F.R. Section 167.3 for purposes of establishment registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), need not register a blend of a registered pesticide and other ingredients when it meets certain conditions. In the August 16, 2006, rule, EPA provides guidance intended to clarify its position that its custom blending policy applies to situations when a blend is diluted.

Under the rule, EPA, in part, exempts custom blending from the repackaging requirements, although custom blenders of agricultural pesticides are subject to certain containment regulations. In addition, EPA addresses the issue of whether the 1982 Custom Blending Policy applies when a pesticide is mixed with water or other diluents. EPA states it is "appropriate to clarify our position on diluting custom blends" because various offices and regions within EPA, as well as the states, "have not had a consistent policy about whether custom blends can be diluted with water or another diluent."



NAC/AEGL Committee Announces Notice Of A Public Meeting -- On August 18, 2006, the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee) announced the scheduling of a public meeting on September 6-8, 2006, in Bethesda, Maryland. 71 Fed. Reg. 47809. The NAC/AEGL Committee will address, as time permits, the various aspects of the acute toxicity and the development of AEGLs for the following chemicals: 1,2,3-trimethylbenzene; 1,2,4-trimethylbenzene; 1,3,5-trimethylbenzene; 2-ethylhexyl chloroformate; benzyl chloroformate; chlorobenzene; dibromoethane; ethylbenzene; ethylene oxide; hexafluoropropylene; phenyl chloroformate; phenyl mercaptan; propargyl alcohol; tetrafluoroethylene; and trifluorochloroethylene. Please consult the *Federal Register* for additional information.

EPA Issues TSCA PAIR And Health And Safety Data Reporting Rules -- On August 16, 2006, EPA issued two rules under the Toxic Substances Control Act (TSCA), one Preliminary Assessment Information Reporting (PAIR) rule under TSCA Section 8(a), 71 Fed. Reg. 47122, and the other under TSCA Section 8(d), 71 Fed. Reg. 47130, for 243 so-called High Production Volume (HPV) “orphan” chemicals. These chemicals are referred to as orphans because no entity claimed responsibility for them under the HPV Challenge Program launched in 2000. Under the PAIR rule, chemical manufacturers, including importers, must submit a one-time report on general production, importation, end use, and exposure related information to EPA. On September 15, 2006, EPA published a *Federal Register* notice revising the effective dates of these rules from September 15, 2006, to **September 29, 2006**. 71 Fed. Reg. 54434. The effect of this revision of the rules’ effective dates is that the listed chemicals will not be subject to the reporting requirements until **September 29, 2006**. PAIR forms are due by **November 28, 2006**. Under the TSCA Section 8(d) rule, manufacturers must submit certain unpublished health and safety data to EPA by **November 28, 2006**. EPA revised the effective dates of the rules to ensure that all requests for withdrawal submitted to EPA by August 30, 2006, have been accounted for and addressed.

Court Affirms Decision In Tolerance Reassessment Case -- On August 22, 2006, the U.S. Court of Appeals for the Second Circuit affirmed the U.S. District Court for the Southern District of New York’s decision to dismiss a complaint filed by a coalition of public interest groups against EPA. *NRDC v. EPA*, Docket No. 04-5337-cv. The coalition, led by the Natural Resources Defense Council (NRDC), challenged EPA’s tolerance reassessments for several pesticides, claiming that EPA failed to take into account scientific data demonstrating serious safety risks, or that it otherwise acted in the absence of “reliable data” when it left certain existing tolerances in place without applying the 10x safety factor required under the Food Quality Protection Act (FQPA) to account for potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. The lower court, in its July 29, 2004, decision, granted motions by EPA and Intervenor-Defendant CropLife America, Inc. to dismiss NRDC’s complaint for lack of subject matter jurisdiction. On appeal, NRDC argued that Section 408(h) of the Federal Food, Drug, and Cosmetic Act (FFDCA)



governs judicial review only of EPA decisions to establish, modify, or revoke tolerances and that decisions to leave tolerances in effect are reviewable in the district courts pursuant to the Administrative Procedure Act (APA). The court rejected NRDC's argument and affirmed the lower court's decision.

After affirming that EPA's tolerance reassessments represent final agency action, the court analyzed whether FFDCA precludes judicial review under the APA. The court concluded: "Despite the absence of an overarching judicial review provision, both the language and the statutory scheme of Section 346a indicate that the district court lacked jurisdiction to adjudicate actions such as those brought by the NRDC Appellants." According to the court, NRDC could have filed a petition to modify or revoke the tolerances. Because NRDC failed to do so, the court concludes that NRDC is precluded from obtaining judicial review under the APA.

NRDC argued that, even if the FFDCA precluded their claims, FIFRA Section 16a provides an alternative ground for jurisdiction because, according to NRDC, EPA "used a confidential computer model to conduct pesticide exposure assessments even though under FIFRA such a model must 'be available for disclosure to the public.'" The court concluded, however, that NRDC's claims are reviewable "only in the courts of appeals, and only after they have exhausted the statutory provisions for administrative review."

National Toxicology Program Seeks Comment On Proposed Changes To Carcinogens Report

-- On August 17, 2006, the National Toxicology Program (NTP) announced its desire to consider changing the process by which it will develop its periodic *Report on Carcinogens*. 71 Fed. Reg. 47507. The proposed changes apparently result from the NTP's review of its procedures and processes, its implementation of Information Quality Guidance, and recommendations from the Office of Management and Budget (OMB) in 2004 to increase NTP's transparency. NTP's notice describes two elements in the proposed *Report on Carcinogens* review process. First, NTP would hold a public peer review of draft documents it would use to understand a potentially carcinogenic hazard. Second, the NTP's independent advisory panel, the Board of Scientific Counselors, would peer review draft profiles developed by NTP staff to describe a substance's potential to cause human cancer. Public comment on the proposed changes will be accepted through **September 18, 2006**.

EPA Makes Minor Amendments To TSCA Inventory Update Rule

-- On September 6, 2006, EPA published a direct final rule that makes minor amendments, summarized below, to the TSCA Inventory Update Reporting (IUR) regulations. 71 Fed. Reg. 52494. The rule will be effective on **November 6, 2006**, unless EPA receives adverse comments by **October 6, 2006**. EPA states in the preamble to the rule that if adverse comments are received, EPA will withdraw the part of the rule related to the adverse comment and allow the remainder of the rule to take effect. In a related notice issued on September 11, 2006, EPA announced the 2006 reporting period to IUR. 71 Fed. Reg. 53335. The period is from **August 25, 2006**, to **December 23,**



2006. With the direct final rule, EPA makes several changes to 40 C.F.R. Part 710. EPA is updating information in the regulations regarding: how to obtain reporting forms, software, guidance, and other documents from EPA and how to submit required information to EPA, citing the publication *Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database*. EPA also specifically states in the regulatory language that it “encourages reporting sites . . . to submit the required information to EPA electronically.” Acceptable submission methods include electronic ones (*i.e.*, over the Internet using the Central Data Exchange or on CD ROM), as well as in hard copy.

Previously, EPA required reporting of the following company information: “the name of a person who will serve as technical contact for the submitter company and who will be able to answer questions about the information submitted by the company to EPA, **the parent company name** and Dun and Bradstreet Number, the contact person’s full mailing address, the contact person’s telephone number and the contact person’s e-mail address.” EPA states in the preamble that the use of the term “parent company” has created confusion. EPA consequently is changing the language to state just “company” to indicate that submitters are to report the company name associated with the manufacturing site and that identifying further corporate lineage is unnecessary. EPA also makes corrections to some cross references and section headings. For more information relevant to the 2006 IUR, please refer to our earlier memoranda available at <http://www.lawbc.com/updates/020403-tsca.pdf>, <http://www.lawbc.com/updates/122005-tsca.pdf>, and <http://www.lawbc.com/updates/080706-tsca.pdf>.

RCRA/CERCLA

Reportable Quantity For Isophorone Diisocyanate -- On September 11, 2006, EPA proposed to adjust the reportable quantity (RQ) for isophorone diisocyanate. RQs for many of the Extremely Hazardous Substances (EHS) under the Emergency Planning and Community Right-to-Know Act (EPCRA) were adjusted to their threshold planning quantities (TPQ) in a final rule on May 7, 1996. On September 8, 2003, EPA modified the TPQ for isophorone diisocyanate to 500 pounds. EPA inadvertently omitted an RQ adjustment for this substance. Therefore, EPA is now proposing to adjust the RQ for isophorone diisocyanate to be 500 pounds. Comments are due on or before **October 11, 2006**.

EPA Issues New Manifest Form -- On September 5, 2006, EPA made available a new hazardous waste manifest form that all hazardous waste generators and treatment, storage, and disposal facilities must use. The new standardized form will, according to EPA, save waste handlers and regulators time and money. In general, the new standardized form reduces or eliminates many of the variables in state requirements. EPA’s new manifest form also provides check boxes and adds fields that allow for better tracking of complicated shipments, such as container residues, rejected wastes, and interstate shipments. EPA has ensured uniformity by authorizing printers and providing them with precise specifications. Each standardized form



carries a unique preprinted manifest tracking number. The standardized form also allows multistate waste handlers to register and use their own manifest forms everywhere they do business.

Information on the Standardized Manifest Form is available at <http://www.epa.gov/epaoswer/hazwaste/gener/manifest/>. A list of EPA-approved printers for the forms is available at <http://www.epa.gov/epaoswer/hazwaste/gener/manifest/registry/printers.htm>.

EPA Adjusts RQs For Carbamates -- On August 16, 2006, EPA revised the RQ amounts under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) for 28 individual carbamates and five carbamate-related hazardous waste streams and for the inorganic chemical manufacturing process waste K178 from their statutory one-pound RQs. 71 Fed. Reg. 47106. Under CERCLA, in the absence of a substance specific RQ, a one-pound default value applies, which means releases of one pound or more in any 24-hour period are reportable to the National Response Center and other agencies. EPA has adjusted the one-pound value based on chemical-specific information, up to, in a few cases, 5000 pounds. Please see the notice for details. The rule is effective on **September 15, 2006**.

NANOTECHNOLOGY

PEN Releases Report And Database On Anticipated Applications Of Nanotechnology In Agriculture And Food Production -- On September 7, 2006, the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars released a report entitled *Nanotechnology in Agriculture and Food Production: Anticipated Applications*. The report provides an analysis of a newly created database of publicly available nanotechnology food- and agriculture-related research, and predicts potential directions of products and applications in both the food and agriculture sectors. The report is available at http://www.nanotechproject.org/file_download/94. The database is available online at <http://www.nanotechproject.org/50>, and PEN and the researchers “welcome comments and collaborations with others.”

According to the report, the current number of nanotechnology food products available to consumers “appears to be relatively small,” although governments and industry are spending millions of dollars to apply nanotechnologies in areas such as food processing, food safety and packaging, and agricultural production. Before more nanotechnology agrifood products enter the market, the public and stakeholders should be engaged in a dialogue about the use of nanotechnology in food and agriculture. Key questions include: when will the research result in large numbers of nanotechnology food products appearing on the market; who will be affected; what are the potential benefits and risks; and how can consumers be engaged early on.



As of April 2006, the database contained 160 projects, of which 146 were “clearly connected to food and agriculture applications of nanotechnology” and 14 “had enough connections to warrant their inclusion.” Most of the entries are from information provided by the U.S. Department of Agriculture (USDA), EPA, National Science Foundation (NSF), and other agencies that have funded similar work, including the National Institutes of Health, Department of Defense, Department of Energy, Department of Homeland Security, and Food and Drug Administration (FDA). Total spending from all agencies between 2000 and Fall 2005 was \$15.2 million, with most provided by USDA. During the same time period, the NSF provided \$3.5 million and EPA \$780,000 for similar projects.

According to the report, more than 30 of the projects “could produce a commercially viable application in five years or less, and most of the others have the potential to generate a commercial product in the next 15 years.” The majority of projects are focused on the food industry. Projects include using nanomaterials to improve food packaging or to enhance the biological activity of dietary supplements.

NIOSH Nanotechnology Developments -- On August 8, 2006, the National Institute for Occupational Safety and Health (NIOSH) posted an updated version of its October 2005 document entitled *Approaches to Safe Nanotechnology: An Information Exchange with NIOSH*. NIOSH intends the document to review what is currently known about nanoparticle toxicity and control, but notes that it “is only a starting point.” According to NIOSH, the document serves as a request from NIOSH to occupational safety and health practitioners, researchers, product innovators and manufacturers, employers, workers, interest group members, and the general public “to exchange information that will ensure that no worker suffers material impairment of safety or health as nanotechnology develops. Opportunities to provide feedback and information are available throughout this document.” The document is available on the Internet at http://www.cdc.gov/niosh/topics/nanotech/safenano/pdfs/approaches_to_safe_nanotechnology.pdf.

EPA Authorizes Access To NIOSH On CBI Data -- On August 18, 2006, EPA published a notice announcing it has authorized access to NIOSH to information, including confidential business information (CBI), submitted to EPA under TSCA. 71 Fed. Reg. 47807. According to the notice, NIOSH needs access to this information “to meet its obligations to conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health.” The notice states: “Specifically, in response to its authorities and stakeholder requests, NIOSH is pursuing a nanotechnology research program including a strategic mix of laboratory studies, field studies, and support for extramural studies. To assist in these activities, NIOSH is seeking information on nano-substances and other materials in the possession of EPA.” EPA will provide NIOSH access to these CBI materials “on a need-to-know basis only.”



Clearance for access to TSCA CBI information under this arrangement may continue until **August 1, 2016**.

AIR/WATER

EPA Proposes PSD Rule -- On September 14, 2006, EPA proposed revisions to the regulations governing the major New Source Review (NSR) programs required under Title 1 of the Clean Air Act (CAA). 71 Fed. Reg. 54235. EPA has proposed changes that would clarify and codify its policy when emissions increases from multiple projects are to be aggregated together to determine NSR applicability. The proposed rule also clarifies how emissions decreases from a project may be included in the calculation to determine if a significant emissions increase will result from a project. Finally, EPA proposes to change how emissions from emissions units upstream or downstream from the unit undergoing a physical change or change in the method of operation are included in the calculation of an emissions increase for the project. Comments on this important rulemaking are due on or before **November 13, 2006**.

FDA DEVELOPMENTS

Use Of Recycled Plastics In Food Packaging -- The FDA's Center for Food Safety and Applied Nutrition (CFSAN) published an August 2006 updated guidance for industry entitled "Use of Recycled Plastics in Food Packaging: Chemistry Considerations." The guidance is available at <http://www.cfsan.fda.gov/~dms/opa2cg3b.html>.

The guidance discusses different methodologies by which plastic packaging may be recycled, addresses issues and concerns relating to contaminant residues relating to each, and recommends approaches for estimating the maximum level of a chemical contaminant in the recycled material that would result in an estimated daily intake (EDI) that does not exceed 0.5 part per billion (ppb) in the diet, the level FDA would generally consider to be of negligible risk for a contaminant migrating from recycled plastic. The guidance recommends a protocol for developing chemistry data that demonstrates that the recycling process is adequate for removing chemical contaminants. The guidance is considerably expanded from the December 1992 guidance and makes several substantive changes to the recommended testing protocol and evaluation procedures.

FDA notes that the testing protocol and evaluation procedures recommended in this revised guidance may change as new knowledge is acquired. FDA recommends that all analyses be validated as discussed in the "Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations," available at <http://www.cfsan.fda.gov/~dms/opa2pmnc.html>. Further, FDA notes that testing protocols may be submitted to the Office of Food Additive Safety for comment before any contamination studies are done. As always, the guidance does not establish legally enforceable responsibilities,



but rather describes FDA's current thinking, and should be viewed as providing recommendations.

LEGISLATIVE DEVELOPMENTS

E-Manifest Bill Introduced -- EPA would be authorized to have a computer vendor pay the up-front costs of developing an electronic system to track hazardous waste shipments under a bill Senator John Thune (R-S.D.) introduced September 7, 2006. The Hazardous Waste Electronic Manifest Establishment Act, S. 3871, would create a revolving fund at the Treasury Department to be used "to pay costs incurred in developing, operating, maintaining, and upgrading the system." Waste handlers choosing to use the computerized system rather than paper forms would pay user fees that would reimburse the vendor, as well as pay EPA's overhead costs. As of September 5, 2006, hazardous waste generators and haulers were required to begin using EPA's standardized manifest form to keep track of shipments, which is a necessary step in converting the paper system to an electronic one. The bill, which would amend the Solid Waste Disposal Act, would require the electronic system to be in operation three years after the bill is enacted. It is co-sponsored by Senators James Inhofe (R-OK) and James Jeffords (I-VT).

Bill Would Impose Penalties On Sources In Areas With Serious Air Quality Problems -- Senator James Inhofe (R-OK) introduced legislation on September 7, 2006, that would impose monetary penalties on major stationary sources in areas that are in serious nonattainment of the federal air quality standard for ozone and fine particles. As drafted, S. 3868 would affect only areas in California, because other states do not have serious ozone nonattainment areas. On September 11, 2006, however, Inhofe announced that he was pulling the legislation from the agenda for a Committee markup set for September 13, 2006. There is speculation that Senator Inhofe's introduction of the bill was an attempt to retaliate against California for controlling greenhouse gases, an effort Inhofe opposes.

House Approves Bill Limiting Imports Of Foreign Waste -- The House of Representatives approved a bill on September 6, 2006, that would allow states to limit the amount of international waste they accept. Representative Paul Gillmor (R-OH) sponsored the International Solid Waste Importation and Management Act (H.R. 4291). According to Gillmor, Canada ships nearly four million tons of trash into the United States each year, mostly into Michigan. Other states such as New York and Washington also receive some international waste.

H.R. 2491 would direct EPA to publish within 24 months regulations implementing the Agreement Between the Government of Canada and the Government of the United States of America Concerning the Transboundary Movement of Hazardous Waste. The agreement requires those who intend to export waste to provide specific information, including the types and quantities of waste, where the waste will cross the border, and the name of the facility to receive the waste. The bill would allow states to limit the receipt and disposal of foreign



municipal solid waste until federal regulations are issued to implement the U.S.-Canadian agreement.

A companion bill, S. 1198, is pending in the Senate. The last action on the Senate bill was in June 2005 when it was referred to the Committee on Environment and Public Works.

House Approves Conservation Program Bill -- The House of Representatives approved by voice vote September 12, 2006, a bill to reauthorize a national wetlands conservation program at \$375 million over five years. H.R. 5539 would reauthorize the North American Wetlands Conservation Act at \$75 million a year from fiscal 2007 through fiscal 2011. A companion Senate measure (S. 3617), introduced on June 30, 2006, by Senator James Inhofe (R-OK), gained Senate Environmental and Public Works Committee approval on September 13, 2006.

Committee Approves Abandoned Mine Cleanup Bill -- A bill promoting voluntary cleanup of abandoned hardrock mines by exempting compliance with federal and state laws cleared the Senate Environment and Public Works Committee on September 13, 2006. The Committee approved by voice vote a substitute version of S. 1848, the Cleanup of Inactive and Abandoned Mines Act, to send to the Senate floor. Offered by Senator James Inhofe (R-OK), the Committee's Chair, the substitute S. 1848 bill would require permits from appropriate state, federal, and tribal agencies for volunteers or "good Samaritans" who offer to conduct complete or partial cleanups of abandoned hardrock mines. In exchange, federal and state permitting agencies would grant these volunteers potential liability waivers under the Clean Water Act (CWA), TSCA, the Resource Conservation and Recovery Act (RCRA), CERCLA, and "applicable" state and tribal environmental laws and ordinances. If enacted, the bill would prohibit permitting agencies from allowing remediation at abandoned mines that already are considered Superfund sites. The bill also would prohibit mining activities other than the reprocessing of mine tailings collected during cleanup of those sites. According to EPA estimates, there are more than half a million abandoned mines nationwide, most of which are former hardrock mines located in the West. Abandoned mines are among the largest sources of pollution degrading water quality.

Bill Would Require Notification Of Radioactive Substance Releases -- A bill that would require nuclear power plant operators to notify state and local officials within 24 hours if an unintentional release of a radioactive substance occurs cleared a Senate panel on September 13, 2006. The Senate Environment and Public Works Committee approved by voice vote the Nuclear Release Act of 2006 (S. 2348). Offered by Senators Barack Obama (D-IL), James Inhofe (R-OK), and James Jeffords (I-VT), the bill would require the Nuclear Regulatory Commission (NRC) to promulgate rules within two years of enactment that would require licensed nuclear plant owners to notify state, county, and NRC officials of any "unplanned releases" of radioactive material within 24 hours of the event. It is a substitute version of the



original bill, introduced in March 2006 by Obama and Senator Richard Durbin (R-IL), which would have required immediate notification.

MISCELLANEOUS

OSHA Issues ANPR On GHS -- On September 12, 2006, the Occupational Safety and Health Administration (OSHA) issued an advance notice of proposed rulemaking (ANPR) on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). 71 Fed. Reg. 53617. The GHS has been adopted by the United Nations and there is an international goal for as many countries as possible to implement the GHS by 2008. The GHS includes harmonized provisions for classification of chemicals for the health, physical, and environmental effects, as well as for labels on containers and safety data sheets (SDS). OSHA seeks comment from the public on a number of implementation issues related to the GHS. OSHA also announced the issuance of a new guidance document on its web page at <http://www.osha.gov> that describes the GHS. Comments on the ANPR are due on **November 13, 2006**.

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