

Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter

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CHAIRPERSON'S CORNER

Lawrence Cullen

The 2004-2005 year is going to be very busy for the Pesticides, Chemical Regulation and Right-to-Know Committee. As always, the Committee will be following closely international, federal and state matters affecting pesticides, chemicals and the "right-to-know." Pesticide, chemical, and right-to-know legal issues are exciting and interesting because they involve the intersection of law and science, and affect all environmental media (air, soil and water). There are a number of legal issues that the Committee hopes to follow closely this year:

Nanotechnology – Consideration of efforts to explore the necessity for government oversight of this emerging technology that blends issues of regulatory chemistry and micro-technologies.

Endangered Species Act (ESA) and Pesticides – How public interest group litigants, the courts, and the U.S. Environmental Protection Agency (EPA) are responding to ESA lawsuits concerning the use and releases of pesticide products.

Right-to-Know and Homeland Security – EPA's efforts to address homeland security concerns through new and existing authorities, including its right-to-know authorities.

Clean Water Act and Pesticides – Litigation concerning EPA's adoption of total maximum daily loads (TMDL) for pesticides; proper roles of EPA and states; possible water permitting for inadvertent dispersal of pesticides over bodies of water.

Human Testing Policy – Status of litigation and National Academy of Sciences' review of EPA policy on human testing.

Protection of the Public Health – EPA's efforts to test antimicrobial products and confirm their efficacy and take enforcement actions when failures occur.

The Committee members have planned the following activities during 2004-2005:

12th Section Fall Meeting on Oct. 6-10, 2004 – At the Section Fall Meeting in San Antonio, Vice-Chair Herb Estreicher moderated a panel on "Homeland Security Measures and Their Impact on Infrastructure Owners and Operators." Also at the meeting, Vice-Chair Ken Weinstein and Claudia O'Brien coordinated a panel on "Jurisdictional Issues under the Clean Water Act Arising from Pesticide Application."

Pesticide Law Half-Day Meetings – Vice Chair Ken Weinstein will hold quarterly half-day meetings that feature panel discussions and individual speakers and focus primarily on issues related to EPA's regulation of pesticides.

**Pesticides, Chemical Regulation, and
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Vol. 6, No. 1, November 2004
Lynn L. Bergeson, Editor**

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Chemical Regulation Meetings – Vice Chairs Herb Estreicher and Jim Chen and I plan to hold two half-day meetings in Washington, D.C., that feature panel discussions and individual speakers and focus primarily on issues related to EPA's regulation of consumer and chemical products subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA) and the Emergency Planning and Community Right-to-Know Act (EPCRA).

Additional Programs – Committee Vice Chair Lynn Bergeson will hold a program on nanotechnology and federal regulatory initiatives and other Committee members are considering holding brown bag seminars or potentially other half-day meetings to address new developments.

Public Service – In conjunction with the Public Service Task Force and EPA, Public Service Vice Chair Patricia Sims will lead the Committee in its continued support of the successful Earth Day public service program in public and private schools.

**ENDANGERED SPECIES ACT CASES
PROLIFERATE RAISING CONCERNS OF
INTRUSION ON EPA'S
PRIMARY JURISDICTION**

**Ken Weinstein, Janice M. Schneider
and Elizabeth Kronk
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As forecast in the June 2003 edition of this newsletter, Endangered Species Act (ESA) lawsuits continue to be filed alleging that the Environmental Protection Agency (EPA) has failed to consult as required under the ESA over the potential effects of pesticide use on threatened and endangered species. Ken Weinstein and Janice Schneider, *Endangered Species Act Compliance Results in a Rapidly Changing Landscape for Pesticide Regulation*,

4 Pesticides, Chemical Regulation and Right-to-Know Committee Newsletter 3 (June 2003), available at <http://www.abanet.org/enviro/committees/pesticides/newsletter/june03/pesticideregulation/> (June 2003 Newsletter). These suits continue to ask federal judges to order consultation based on the plaintiffs' allegations of harm to various listed species and to enjoin pesticide use while the consultation is pending. See, e.g., *Natural Resources Defense Council v. EPA*, Civ. No. 1:03-CV-2444-RDB (D. Md.) (claiming that the herbicide atrazine jeopardizes 21 listed species across approximately two-thirds of the United States); *Center for Biological Diversity v. Leavitt*, Civ. No. 1:04-CV-126-CKK (D.D.C.) (alleging that six pesticides threaten the Barton Springs salamander in Texas). Including the currently pending suit alleging harm to the California red-legged frog from pesticide use in the Northern District of California, over 60 pesticides are at issue in these three cases alone, and more litigation is expected to be filed. *Center for Biological Diversity v. Leavitt*, Civ. No. C-02-1580-JW (N.D. Ca.); see also 60-day Notice Letter from Patti Goldman, Earthjustice, to Michael Leavitt, EPA Administrator (July 26, 2004) (alleging that the "no effect" determinations made by EPA pursuant to the *Washington Toxics Coalition v. EPA*, Civ. No. C01-132C, court decree are arbitrary and capricious and arguing that consultation is required). Cf. *Washington Toxics Coalition, et al. v. Department of Interior, et al.*, Complaint for Declaratory and Injunctive Relief (W.D. Wash.) (filed Sept. 23, 2004) (alleging that the counterpart regulations recently adopted to increase the efficiency and effectiveness of ESA consultations resulting from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulatory actions violate ESA Section 7 and are arbitrary, capricious, and contrary to the best available scientific information).

Despite EPA's extensive ecological assessment of pesticides and their impact on

wildlife under FIFRA (7 U.S.C. §§ 136-136y), plaintiffs in these cases allege the pesticides at issue harm species listed under the ESA and, accordingly, EPA should have engaged in consultations before allowing the use of these pesticides. As a general proposition, requiring EPA to consult would go beyond the power of the courts, which are not empowered to make substantive effects determinations for agencies. One district court, however, in a case that is currently on appeal to the Ninth Circuit Court of Appeals, seems to have engaged in such a substantive determination. On July 2, 2002, a district judge held that EPA violated Section 7(a)(2) of the ESA, finding that "despite competent scientific evidence addressing the effects of pesticides on salmonids and their habitat, EPA has failed to initiate section 7(a)(2) consultation with respect to its pesticide registrations. . . . Such consultation is mandatory and not subject to unbridled agency discretion." *Washington Toxics Coalition v. EPA*, Civ. No. C01-132C, July 2, 2002, Order at 15. The court then ordered EPA to "initiate and complete section 7(a)(2) consultation with [the National Marine Fisheries Service] regarding the effects of pesticides on threatened and endangered salmonids" on 54 pesticides. *Id.* at 17 (requiring EPA to make effects determinations and consult, as appropriate, on a schedule proposed by the federal government and endorsed by the plaintiffs). Subsequently, the court ordered injunctive relief in the form of pesticide-application buffer zones and additional mandatory point of sale notifications for the sale of pesticides in urban areas "to prevent potential adverse effects of certain pesticide active ingredients on threatened and endangered salmonids. . . ." *Washington Toxics Coalition v. EPA*, Civ. No. C01-0132C (W.D. Wash.), Jan. 22, 2004, Order at 4, 11.

The *Washington Toxics* court's substantive effects determination raises a concern regarding the proper role of the courts in cases contending that EPA should have consulted under the ESA during many of its FIFRA

regulatory actions. It may be argued that a court decision ordering EPA to consult infringes EPA's primary jurisdiction over the decision of whether consultation is needed. In such cases, even if the Agency were to be found to have violated its duty to make an effects decision, the proper remedy is not for the court to usurp EPA's function and make the effects decision in EPA's place, but rather to require EPA to make effects determination. Congress delegated to EPA, not the courts, the exclusive authority under the ESA and FIFRA to determine when EPA's pesticide regulatory actions may affect a listed species and trigger consultation requirements. See, e.g., 50 C.F.R. § 402.42. For a court to engage in a weighing of the scientific evidence, make an effects determination, and order EPA to consult is to preempt the Agency's authority to make a consultation decision within its primary jurisdiction.

The decision of whether a pesticide may affect an endangered species involves scientific issues beyond the conventional competence of courts, and uniquely within the expertise of EPA, as was recognized by the recently promulgated counterpart regulations developed to help federal agencies conduct ESA consultations for regulatory actions under FIFRA. 69 Fed. Reg. 47732 (Aug. 5, 2004). (The Counterpart Regulations modify 50 C.F.R. Part 402 and put EPA squarely in the driver's seat for consultations involving FIFRA. One alternative modifies the process for EPA to conduct informal consultation with the Services for those FIFRA actions that EPA determines are "not likely to adversely affect" any listed species or critical habitat. 50 C.F.R. § 402.42(a)(2). The other alternative permits the Services to conduct formal consultation in a manner that more effectively takes advantage of EPA's substantial expertise in evaluating ecological effects of FIFRA regulatory actions on listed species and critical habitats. 50 C.F.R. § 402.46.) Accordingly, courts should defer to EPA's primary jurisdiction over ESA decisions

involving FIFRA regulatory actions. See *United States v. Western Pacific R.R.*, 352 U.S. 59 (1956) (holding that the court should defer to an agency decision on whether or not napalm should be considered fuel or an "incendiary bomb" for purposes of shipment on the railroad and stating that the "primary jurisdiction doctrine is properly invoked whenever enforcement of the claims requires the resolution of issues which ... have been placed within the special competence of an administrative body; in such a case the judicial process is suspended pending referral of such issues to the administrative body for its views."); *Far East Conference v. United States*, 342 U.S. 570, 574 (1952) (holding that the court should defer the question of whether a shipping dual-rate scheme violated antitrust laws to the Federal Maritime Board, which had primary jurisdiction over the matter and stating that "in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over"); *U.S. v. 43.47 Acres of Land*, 45 F.Supp.2d 187, 191 (D. Conn. 1999) (holding that trial on the issue of tribal status was premature because the doctrine of primary jurisdiction indicates that resolution of the issue should be first deferred to the Bureau of Indian Affairs); see also *Johnson v. Nyack Hospital*, 964 F.2d 116, 122 (2nd Cir. 1992) (deferring to state medical agency on primary jurisdiction grounds). Because EPA has extensive knowledge and experience in determining whether pesticide registrations issued under FIFRA may affect listed species, the courts should consider the application of the doctrine of primary jurisdiction in these cases. *MFS Securities Corp. v. New York Stock Exchange*, 277 F.3d 613, 621 (2d Cir. 2002) (remanding to the district court to stay proceedings until the Securities and Exchange Commission, which had primary jurisdiction in the matter, could address several questions because it was in a better position to answer many of the questions before the court stepped in).

In addition to deferring to the EPA's primary jurisdiction over the "may affect" determination, courts should also recognize that judicial review is often limited in instances involving agency discretion. Specifically, judicial review is constrained in instances where "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). As neither the ESA nor FIFRA provides a specific timeline for the "may affect" determination, "review is not to be had if the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion. In such a case, the statute ("law") can be taken to have committed the decisionmaking to the agency's judgment absolutely." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). In these cases, a court's deference to EPA's "may affect" determination on a FIFRA regulatory action is consistent with previous decisions addressing similar questions. "[C]ourts generally will defer to an agency's construction of the statute it is charged with implementing, and to the procedures it adopts for implementing that statute." *Id.* at 832 (citing *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 543 (1978); *Train v. Natural Resources Defense Council, Inc.*, 421 U.S. 60, 87 (1975)).

Should courts opt to intercede, however, they should only act to establish a deadline by which EPA should make its effects determination, rather than making an actual determination or requiring consultation. An actual effects determination made by a court would violate both EPA's primary jurisdiction over the matter and the deference the Agency should receive in making decisions under the ESA. In recognition of the deference agencies are to receive, courts have refrained from making such determinations in previous cases, instead imposing deadlines on the agencies. See *Potomac Elec. Power Co. v. ICC*, 702 F.2d 1026, 1035 (D.C. Cir. 1983) (holding initially that the Interstate Commerce Commission (ICC) must make a decision on railroad haulage

charges within 60 days of the court's order, while recognizing that the ICC has discretion to make the final decision); *Public Citizen Health Research Group v. Aucter*, 702 F.2d 1150, 1153 (D.C. Cir. 1983) (holding that the district court impermissibly substituted its decision that an emergency rule regarding a safe exposure to ethylene oxide was warranted for that of Occupational Safety and Health Administration (OSHA); rather OSHA would only be required to perform an expedited review under normal (non-emergency) rulemaking procedures that it had already engaged); *MCI Telecommunications Corp. v. FCC*, 627 F.2d 322 (D.C. Cir. 1980) (remanding and requiring the Federal Communications Commission (FCC) to submit a feasible schedule within 30 days of the court's opinion for completion of rate proceedings); *Nader v. FCC*, 520 F.2d 182, 207 (D.C. Cir. 1975) (same; ultimately allowing 17 months to complete process).

In pending ESA lawsuits, the courts should follow precedent, allowing EPA to make effects determinations, rather than attempting to intercede and preempt the Agency's primary jurisdiction.

GET READY FOR THE EXPANDED IUR!

John R. Wheeler

2005 will be remembered by chemical manufacturers and importers (and their counsel!) as the first year for which expanded information must be collected for reporting under the TSCA Inventory Update Rule (IUR). Since 1986 the U.S. EPA has collected limited data every four years from hundreds of companies; and although some companies which reported previously will no longer be subject to the IUR requirement, those which must report will be required to provide EPA with substantially more information.

Previous Requirements

Beginning in 1986, and every four years thereafter through 2002, chemical manufacturers and importers were required to report information on chemical identity, production volume, plant site identity, whether the substance is manufactured or imported and site-limited status (“site-limited status” refers to whether a chemical substance is manufactured and processed only within a plant site, or whether it is distributed for commercial purposes outside the plant site) for certain chemical substances on the TSCA Inventory. Generally, manufacturers and importers were required to report if they manufactured or imported for commercial purposes 10,000 pounds or more of a “reportable substance” at any manufacturing or importing site at any time during the most recent complete corporate fiscal year preceding Aug. 25, 1986, and preceding Aug. 25 at four-year intervals thereafter. A “reportable substance” was any chemical substance which was on the TSCA Inventory as of Aug. 25, except for those categories of substances that were specifically excluded.

The New Requirements

On Jan. 7, 2003, the U.S. EPA published significant Inventory Update Rule Amendments (IURA) applicable to IUR reporting commencing with the 2006 submission period. (40 C.F.R. §§ 710.1-710.59; 68 FR 847, Jan. 7, 2003.) The 2003 IURA changed the annual period for which data are required to be collected from the most recent complete corporate *fiscal year* preceding Aug. 25, 2006 to *calendar year* 2005 and *calendar years* at four-year intervals thereafter.) The threshold for reporting was increased from 10,000 pounds of production to 25,000 pounds; however, commencing in 2006 chemical manufacturers and importers who are subject to the IUR must report, in addition to the information required in prior years: (1) the total number of workers reasonably likely to be

exposed to the chemical substance at the site of manufacture; (2) the physical form(s) in which the chemical substance is sent off-site (or, if the chemical substance is site-limited, the physical form(s) at the time that the substance is reacted on-site to produce a different chemical substance); (3) the percentage of the total production volume associated with each physical form; and (4) the maximum concentration of the chemical substance at the time it leaves the IUR Report submitter’s manufacturing site (or, if the chemical substance is site-limited, the maximum concentration at the time that it is reacted on-site to produce a different chemical substance). Such information is required to be reported to the extent “known to or reasonably ascertainable” (40 C.F.R. § 710.52) by the submitter.

Additionally, manufacturers and importers of reportable substances with production of 300,000 pounds or more, must report (in addition to the data described above) detailed exposure-related information concerning the processing and use of those chemicals at sites that receive the substance from the IUR reporting site. These reporting requirements apply whether or not the recipient site(s) are controlled by the IUR submitter site, and whether or not receipt of the chemical substance is directly from the submitter, or indirectly through a broker, distributor, customer, etc. The required substantial “processing and use information” is set forth at 40 C.F.R. § 710.52(c)(4), and must be reported only to the extent that it is “readily obtainable” (*id.*) by the IUR Report submitter.

Exemptions from Reporting

Certain limited exemptions from reporting are enjoyed by small manufacturers and manufacturers of inorganic chemical substances; however, the EPA is phasing in reporting for inorganic substances, with partial reporting required in 2006. Limited exemptions from reporting also apply to some petroleum process streams, certain chemicals of “low

current interest” to EPA, specified polymers, microorganisms, some forms of natural gas, and naturally occurring chemical substances.

The time to help your clients is now. The “Expanded IUR” will require significant effort by chemical manufacturers and importers to ensure that they collect all required information during 2005 for reporting in 2006.

John R. Wheeler is associate general counsel of Occidental Chemical Corporation, and the editor of the TSCA Compliance Guide and OnLine Service from which this article is extracted (www.TSCA.info). Copyright ©2004 by Environment Books, Inc.

ANSI ESTABLISHES NANOTECHNOLOGY STANDARDS PANEL

Lynn L. Bergeson

In August, the American National Standards Institute (ANSI) announced the formation of the Nanotechnology Standards Panel (NSP) to facilitate the development of standards on the area of nanotechnology. This article summarizes briefly the purpose of the NSP, and explains why standardization is important.

The Nanotechnology Explosion

Over the past year or so, media attention on and public interest in nanotechnology has grown exponentially. There has been a notable proliferation of meetings and conferences on nanotechnology – what it is, what nanotechnology offers, and the risks and benefits nanotechnology and nanostructures offer. The interest is global, and involves an exceedingly diverse community of stakeholders in many different industry sectors and scientific disciplines.

With all the “nano-speak” around, it is no wonder Dr. John Marburger, science advisor to the

President and director of the Office of Science and Technology Policy (OSTP), asked ANSI this past June to consider “coordinating the development of standards, including nomenclature, in the area of nanotechnology.” The request reflects a keen awareness of the fact that the “language of nanotechnology” is by no means clear, and that universally recognized standards for nanotechnology – particularly in the area of terminology and nomenclature– are needed. ANSI quickly affirmatively responded to the request, and announced its plans to convene an “initial steering committee to develop a recommendation on how best to coordinate the development of standards in this area.”

ANSI

ANSI provides a uniquely well-suited framework to coordinate the development of standards. Institutionally, ANSI is a non-government umbrella organization for the United States voluntary consensus standards community. It is a private-sector lead and public-sector supported not-for-profit organization. In this context, a “standard” is a document, established by consensus and approved by a recognized body. A standard is not a technical regulation. ANSI does not develop standards itself.

The ANSI process generally involves five critical elements: openness, balance, transparency, due process, and consensus. OSTP asked ANSI to consider serving in the role that it is serving for two reasons. First, ANSI offers a process that ensures integrity in the standards development process. Second, ANSI has significant experience in this area. In the 1990s, ANSI convened the Information Infrastructure Standards Panel (IISP) to assist in the rapid development of cross-sectoral standards facilitating the growth of the Internet. More recently, ANSI convened the Homeland Security Standards Panel (HSSP) to facilitate the development and rapid deployment of standards supporting homeland security and first responders.

ANSI-NSP

The ANSI-NSP is lead by three co-chairs: Dr. E. Clayton Teague, Director, National Nanotechnology Coordination Office (NNCO); Dr. Vicki Colvin, professor of Chemistry at Rice University and director of the Center for Biological and Environmental Nanotechnology, Rice University; and Dr. David Bishop, vice president of Nanotechnology Research, Lucent Technologies, and president of the New Jersey Nanotechnology Consortium. Steering Committee members represent a broad cross-section of stakeholders – government standards development organizations, academia, legal, international, and industry representatives. Importantly, two out of the four representatives from the “legal” community are ABA Section of Environment, Energy, and Resources leaders: Tracy Hester, Vice Chair of the Environmental Enforcement and Crimes Committee, and Lynn Bergeson, Section Chair-elect and Vice Chair of the Pesticide, Chemical Regulation and Right-to-Know Committee. The Steering Committee is the NSP’s planning group, and represents virtually all relevant nanotechnology stakeholder categories.

The mission of the NSP is to serve as a cross-sector coordinating body to facilitate the development of standards in the area of nanotechnology. The September workshop focused on nomenclature and terminology standards. Other standards included with the scope of the NSP include materials properties, testing, measurement and characterization procedures, environmental, health and safety, and metrology, including dimensional, mechanical and electrical.

The first meeting of the NSP was convened on Sept. 29-30, following a Sept. 28 Steering Committee meeting. Approximately 90 people registered for the plenary meeting. The initial meeting was hosted by the National Institute of Standards and Technology in Gaithersburg, Maryland.

The discussion at the plenary meeting focused on nomenclature (specific means to describe nanomaterials), terminology (general names for nanomaterials), nomenclature issues to certain specific types of materials such as inorganic nanomaterials and carbon nanostructures, testing and measurement issues, and related concerns. Breakout sessions were convened on five topics: morphological, geometrical and general terminology; metallic, semi-conducting and insulating nanostructures; carbon nanostructures; organic nanostructures; and hybrid nanostructures. These sessions yielded specific recommendations in the area of nomenclature and terminology. The materials from the plenary meeting sessions, and the recommendations, will be posted shortly on the ANSI Web site at http://www.ansi.org/standards_activities/standards_boards_panels/nsp/overview.aspx?

Next steps include refinement of the recommendations coming from the plenary meeting and ANSI’s identification of suitable standard-setting organizations to participate in the development of consensus-based standards for specific issues. Among the organizations that are well-suited to assist are the Institute of Electrical and Electronics Engineers, Inc. (IEEE) and the American Society for Testing and Materials (ASTM).

The Steering Committee is scheduled to meet again in early 2005 to continue the work that was initiated at the September plenary meeting. For further information, please consult the ANSI-NSP Web site at <http://www.ansi.org/nsp>.

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