

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

Vol. 6, No. 2

February 2005

CHAIRPERSON'S CORNER

Lawrence Cullen
Arnold & Porter

We are looking forward to a busy beginning to 2005 for the Committee. We have numerous programs planned or in the works. Here are some of the highlights:

- Vice Chair Ken Weinstein is planning to hold two Pesticide Law Half-Day Meetings in the Winter and Spring months in 2005. The first two of these quarterly events will be **February 22, 2005**, and **June 7, 2005**. These half-day meetings generally feature panel discussions and individual speakers and focus primarily on issues related to U.S. Environmental Protection Agency's (EPA) regulation of pesticides.
- Vice Chairs Herb Estreicher, Jim Chen and I plan to hold day-long meetings in Washington, D.C., that feature panel discussions and individual speakers, and focus primarily on emerging legal issues that are unique to EPA's regulation of pesticide products that are considered to be either biopesticide or antimicrobial products. The dates are being arranged with EPA staff who probably will participate, but a Spring session is likely.

- The Committee is cosponsoring with the Agricultural Management Committee an event that likely will be held during **March 2005** in which Vice Chair Lynn Bergeson will moderate a conference call with the U.S. Department of Agriculture General Counsel (and former Committee member) Nancy Bryson.

TENDING THE FIELDS: STATE AND FEDERAL ROLES IN THE OVERSIGHT OF GENETICALLY MODIFIED CROPS (PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, DECEMBER 2004)

Lawrence Cullen
Arnold & Porter

In December 2004, the Pew Initiative on Food and Biotechnology published a report entitled *Tending the Fields: State and Federal Roles in the Oversight of Genetically Modified Crops*. (The report is available at <http://pewagbiotech.org/research/fields/report.pdf>.) The Pew Initiative on Food and Biotechnology was established in 2001 and is intended to be an independent source of credible and objective information about agricultural biotechnology for the public, media and policymakers. The December 2004 report analyzes how state regulators have responded to agricultural

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biotechnology and the legal framework in which state and federal authorities collectively attempt to ensure food safety and environmental protection, in light of such biotechnology. The report is based upon interviews with biotechnology stakeholders across the country and targeted data from 17 states. The report does not include any policy recommendations, but makes several findings, as set forth in more detail below.

In general, the report found that agricultural biotechnology issues are extremely important to those states with prominent agricultural sectors, such as California and North Carolina. Indeed, these states seek to capture the economic benefits arising out of new technologies related to traditionally low-priced commodity crops. Officials from these states acknowledge, however, that economic benefits related to such technologies might be threatened if there is public anxiety about conventional crops or if market access to these crops is jeopardized. Because of such competing concerns, states have a vested interest in exercising effective oversight of agricultural biotechnology; and, although officials in such states tend to defer to federal regulatory authorities on certain issues, they nonetheless desire to be partners with federal authorities to ensure that state issues are addressed adequately.

When preparing the report, the Pew Initiative contacted numerous "stakeholders," including agricultural producers, representatives of commodity and trade groups, federal and state government employees, and environmental advocates. As discussed in the report, one consistent concern among these stakeholders is whether state governments have the resources necessary to oversee agricultural biotechnology and to address issues that arise at the local level. Indeed, there was broad sentiment among those interviewed for the report that many states lack the technical expertise and financial resources necessary to partner effectively with federal regulators.

Moreover, the report noted that certain aspects of the legal framework that supports federal regulation of biotechnology prevent certain state regulation. For example, applicants for federal permits often seek to withhold certain information as confidential business information (CBI). These claims of CBI effectively prevent federal authorities from disclosing this information to state regulators, yet this information often includes information concerning the identity of the genetically modified organism at issue. As a result, states may lack an adequate basis upon which to make an independent determination about the safety of such introductions before the introduction takes place.

In addition to these concerns, according to the report, most officials and stakeholders agree that state regulation of agricultural biotechnology should address local concerns, while federal regulation should assume primary responsibility for human health and environmental protection. Despite this consensus, states differed with respect to which issues they believed are encompassed within “local concerns.”

Finally, the report noted that while some states are struggling to find an approach to manage conflicts between state and federal regulatory authorities, others are responding to such challenges in innovative manners. For example, Colorado has developed a public participation process for the consideration of “pharmaceutical” crops, and North Carolina has developed identity preservation criteria for genetically engineered and conventional tobacco.

The report also sets forth issues that underlie the role of state oversight of biotech crops and foods. These include the priority and relative importance of biotechnology, issues that are appropriate for state control or oversight, the role states should play in health and environmental issues, the role states should play in economic and social issues, the necessity of

new legal tools for states, the manner in which states seek appropriate expertise, the responsibility for costs associated with state oversight, ways to improve interactions between state and federal regulators, and preparation for potential future incidents related to agricultural biotechnology.

**A GROWING CONCERN: PROTECTING
THE FOOD SUPPLY IN AN ERA OF
PHARMACEUTICAL AND INDUSTRIAL
CROPS (UNION OF CONCERNED
SCIENTISTS, DECEMBER 2004)**

**Lawrence Cullen
Arnold & Porter**

In December 2004, the Union of Concerned Scientists (UCS) released a report entitled *A Growing Concern: Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops*. (The UCS report is available at http://www.ucsusa.org/documents/Pharma_fullreport.pdf.) The UCS is an independent nonprofit alliance of more than 100,000 concerned citizens and scientists that seek to “build a cleaner, healthier environment and a safer world.”

The report notes that food crops, primarily corn and soybeans, are being genetically engineered to produce pharmaceuticals and industrial agents. For purposes of the report and this summary, these products are collectively referred to as “pharma crops.” The report identifies both physical mixing and pollen as sources of contamination of commodity crops by pharmaceutical and industrial transgenes and states that, unless substantial changes are made to the commodity production and management practices applied to genetically engineered pharmaceutical and industrial crops (pharma crops), corn and soybean cannot be used as pharma crops while preventing contamination of the food supply. Thus, the report recommends that the U.S. Department of

Agriculture (USDA) stop outdoor production of pharma crops immediately, until a new system for producing drugs and industrial substances without endangering the food system can be put in place.

After highlighting the problems and risks associated with using corn and soybeans as pharma crops, the report discusses alternative crops that might be used as pharma crops. Generally, the UCS recommends that USDA lead a major campaign to encourage and fund such alternatives to food and feed crops. The report identifies five desirable characteristics for pharma crops: the crop should have little use as food or a feed crop, the crop should lack sexual reproductive organs or be amenable to pollen and seed dispersal restrictions, the organ or tissue in which the pharmaceutical compound is produced should be easily stored and purified, appropriate production infrastructure should exist, and the molecular information and tools needed to direct the production of pharma compounds as intended should be available. After identifying these characteristics, the report analyzes several crops and compares their potential value as crops used for production of pharmaceutical and industrial compounds. Based upon this analysis, the report concludes that “[o]verall, tobacco is the best prospect for an alternative pharma crop.”

**PESTICIDES, CHEMICAL
REGULATION, AND
RIGHT-TO-KNOW
COMMITTEE NEWSLETTER**

BACK ISSUES

Back issues of this Newsletter can be viewed on the Pesticides, Chemical Regulation, and Right-to-Know Committee Web page at <http://www.abanet.org/envIRON/committees/pesticides/newsletter/archive.html>.

**NEW GROUNDS IN
TOXIC SUBSTANCES CONTROL ACT
SECTION 8(E) REPORTING?**

Lynn L. Bergeson

Lisa R. Burchi

Bergeson & Campbell, P.C.

The U.S. Environmental Protection Agency's (EPA) recent enforcement actions against E.I. du Pont de Nemours and Company (DuPont) under Toxic Substances Control Act (TSCA) Section 8(e) (Complaints) break new ground on several fronts and may be troubling to chemical companies generally. (The First Complaint includes one violation of the Resource Conservation and Recovery Act (RCRA). EPA alleges that DuPont's failure to submit toxicological information it obtained regarding perfluorooctanoic acid (PFOA) used in the manufacturing process for fluoropolymers at its Washington Works facility in West Virginia violates provisions in the Company's RCRA Corrective Action Permit.) Among the concerns raised by EPA's actions are:

- How an adverse effect is defined for purposes of TSCA Section 8(e) reporting obligations; and
- The potential liability a company might face for establishing a voluntary internal standard.

Legal Background – TSCA Section 8(e)

Under TSCA Section 8(e), any person who manufactures, imports, processes or distributes a chemical substance or mixture and who obtains information which reasonably supports the conclusion that the chemical substance or mixture poses a substantial risk of injury to human beings or the environment must provide the information to EPA immediately. TSCA § 8(e), 15 U.S.C. § 2607(e). EPA has not promulgated regulations implementing TSCA Section 8(e). Instead, in 1978, EPA issued a

Statement of Interpretation and Enforcement Policy regarding TSCA Section 8(e). 43 Fed. Reg. 11110 (Mar. 16, 1978). EPA also released a Reporting Guide in 1991 to assist companies in determining their obligations under TSCA Section 8(e). EPA, *TSCA Section 8(e) Reporting Guide* (June 1991) at 11 (Reporting Guide).

On June 20, 1991, EPA suspended the applicability of TSCA Section 8(e) reporting requirements for “widespread and previously unsuspected distribution in environmental media” and “emergency incidents of environmental contamination.” 56 Fed. Reg. 28458 (June 20, 1991). EPA reinstated these provisions in 2003 when it released its Revised Policy and provided additional guidance to assist companies in determining when this type of reporting would be reportable. 68 Fed. Reg. 33129 (June 3, 2003). EPA issued corrections and clarifications to its Revised Policy on Jan. 12, 2005, as well as releasing additional questions and answers guidance. 70 Fed. Reg. 2162 (Jan. 12, 2005). The new Q&A document can be found at <http://www.epa.gov/oppt/tsca8e/doc/q&atscanew.htm>.

Under EPA’s Revised Policy, two types of reportable information – human health effect information and environmental contamination – are now addressed. EPA’s Revised Policy on TSCA Section 8(e) reporting identifies the human health effects that warrant reporting as follows:

The Agency considers effects for which substantial-risk information should be reported to include the following.

(a) *Human health effects.* (1) Any instance of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one (or a few) chemical(s) is strongly implicated.

(2) Any pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation.

68 Fed. Reg. at 33138.

EPA identifies in its Revised Policy the non-emergency situations involving environmental contamination that warrant reporting (EPA requirements governing emergency incidents of environmental contamination are not addressed here):

The Agency considers effects for which substantial-risk information should be reported to include the following. . . .

(b) *Non-emergency situations involving environmental contamination; environmental effects – (1) Non-emergency situations of chemical contamination involving humans and/or the environment.* Information that pertains to widespread and previously unsuspected distribution in environmental media of a chemical substance or mixture known to cause serious adverse effects, when coupled with information that widespread or significant exposure to humans or non-human organisms has occurred or that there is a substantial likelihood that such exposure will occur, is subject to reporting. The mere presence of a chemical in an environmental media, absent the additional information noted above, would not trigger reporting under section 8(e). Information concerning the detection of chemical substances contained within appropriate disposal facilities such as treatment, storage and disposal facilities permitted under [the Resource Conservation and Recovery Act] RCRA should not be reported under this part.

(2) *Environmental effects.* Measurements and indicators of pronounced bioaccumulation heretofore unknown to the Administrator (including bioaccumulation in fish beyond 5,000 times water concentration in a 30-day exposure or having an n-octanol/water partition coefficient greater than 25,000) should be reported when coupled with potential for widespread exposure and any non-trivial adverse effect.

(3) *Environmental effects.* Any non-trivial adverse effect, heretofore unknown to the Administrator, associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media, should be reported.

(4) *Environmental effects.* Ecologically significant changes in species' interrelationships; that is, changes in population behavior, growth, survival, etc. that in turn affect other species' behavior, growth, or survival, should be reported. Examples include: (i) Excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems. (ii) Interference with critical biogeochemical cycles, such as the nitrogen cycle.

(5) *Environmental effects.* Facile transformation or degradation to a chemical having an unacceptable risk as defined above should be reported.

68 Fed. Reg. at 33138.

EPA's TSCA Section 8(e) guidance provides that "immediately" in terms of the reporting

deadline means within thirty (30) calendar days of a person obtaining the information. *Id.* If a company becomes aware of an emergency incident involving a chemical substance or mixture known to be a serious human or environmental toxicant, the information must be reported "as soon as reasonably possible" after the company obtains such information. Reporting Guide at 11.

EPA has the authority to seek a penalty of \$25,000 per day for each TSCA and RCRA violation occurring before Jan. 30, 1997, and up to \$27,500 per day for each violation occurring between then and March 15, 2004, and \$32,500 per day for each violation occurring after March 15, 2004.

EPA's Allegations and DuPont's Response

On July 8, 2004, EPA issued a complaint against DuPont alleging two violations of the reporting requirements imposed by TSCA Section 8(e) (and one violation of RCRA). *In the Matter of E.I. du Pont de Nemours and Company*, TSCA-HQ-2004-0016, RCRA-HQ-2004-0016, Complaint and Notice of Opportunity for Hearing (July 8, 2004), available at <http://www.epa.gov/compliance/resources/complaints/civil/mm/dupont-pfoa-complaint.pdf> (First Complaint). DuPont filed its response to the first EPA complaint on Aug. 11, 2004. *In the Matter of E.I. du Pont de Nemours and Company*, TSCA-HQ-2004-0016, RCRA-HQ-2004-0016, Answer and Request for Hearing (Aug. 11, 2004), available at http://ww1.dupont.com/dupontglobal/corp/documents/US/en_US/news/releases/pdf/answer_and_request_for_hearing.pdf (DuPont Response). EPA issued a second complaint, on Dec. 6, 2004, that alleges an additional TSCA Section 8(e) violation. *In the Matter of E.I. du Pont de Nemours and Company*, TSCA-HQ-2005-5001, Complaint and Notice of Opportunity for hearing (Dec. 6, 2004), available at <http://www.epa.gov/compliance/resources/complaints/civil/mm/dupont2-pfoa-complaint.pdf> (Second Complaint).

All would, if upheld, potentially set a new standard for Section 8(e) reporting. All of the alleged violations relate to data relating to PFOA, which has been the subject of significant attention since data were released showing a general background level of 5 parts per billion (ppb) in the blood of the U.S. population. EPA did not propose a specific penalty in its Complaints, but reportedly may seek one of the largest fines EPA has ever proposed.

The specific TSCA Section 8(e) allegations are:

Transfer of PFOA from Blood of Mother to Fetus of Female Worker (First Complaint):

EPA claims that under TSCA Section 8(e), DuPont should have reported to EPA in 1981 the results of a single blood sample that suggested that a trace amount of PFOA could cross the human placenta if it is present in the maternal blood. DuPont asserts that EPA's scientists knew in 1981 that a chemical like PFOA would travel through the placenta, and in 1982, DuPont provided to EPA the results of an animal study confirming that PFOA would cross the placenta. DuPont states that the TSCA Section 8(e) reporting requirement is triggered "only when the information reasonably supports the conclusion that exposure to a chemical actually presents a 'substantial risk to human health.'" Based on the testing that has been done, DuPont claims that prenatal exposure to PFOA does not cause such a risk, and thus there was no "substantial risk" to trigger reporting requirements. DuPont further states that TSCA Section 8(e) does not require a company to report information if EPA is already "on notice" of the information.

Presence of PFOA in Public Water Supplies at Levels above Voluntary Internal Standard (First Complaint):

Perhaps the most controversial allegation of the Complaint is EPA's claim that DuPont should have reported the results of water sampling that found levels of PFOA in excess of DuPont's voluntary internal guideline, even though that guideline was below

regulatory requirements. DuPont's response questions the legal basis for this assertion, and claims that EPA "seeks to punish DuPont for establishing a level of safety that exceeds EPA's requirements and sends a message to the regulated community that it should never set a voluntary goal for an unregulated chemical for fear that EPA will label any exceedance of that goal a 'substantial risk' that must be reported to the Agency." DuPont cites EPA's own guidance on TSCA Section 8(e) reporting, which states that when EPA sets an acceptable level in drinking water, a company that detects the chemical in drinking water at concentrations below that level does not have an obligation to report under TSCA Section 8(e). DuPont states that it undertook a program of minimizing its plant emissions to reach a self-imposed goal of reducing the PFOA level in drinking water so that there would be a 3,000-fold margin of safety. DuPont also notes that the levels that EPA claims DuPont failed to report – 0.8 to 3.9 ppb – are 38 to 185 times lower than the 150 ppb drinking water level that the C8 Assessment of Toxicity Team (CAT Team), a multi-agency panel of scientists, including several from EPA, concluded in 2002 poses "no risk of deleterious effects" to human health. DuPont further argues that any enforcement action by EPA relating to these data is contrary to the agreement reached between DuPont and EPA under the Compliance Audit Program (CAP). EPA developed CAP to allow companies to audit their files and submit reportable information under TSCA Section 8(e) with a limit of liability. DuPont argues that under its CAP agreement, EPA "agreed that it would not bring a TSCA § 8(e) enforcement action arising out of water sampling data at issue . . ." DuPont Response at 28.

Presence of Blood Levels above Background Level in Community Exposed Through Drinking Water (Second Complaint):

According to EPA's Second Complaint, DuPont performed a blood serum analysis in July 2004 of 12 members of the

general population living near DuPont's Washington Works Facility in West Virginia. The Second Complaint states that each of the individuals tested was exposed to PFOA through drinking water provided by the Lubeck Public Service District where, according to DuPont, the level of PFOA in the drinking water averaged approximately 0.5 ppb over the last several years. All of the individuals tested claim to have stopped using the contaminated public drinking water as their primary source of drinking water approximately three years ago. The Second Complaint states: "Human serum sample levels of PFOA for these 12 individuals were reported to range from 15.7 ppb to 128 ppb, with a mean of 67 ppb. The median value is in the range of 60 ppb PFOA. . . . the average background serum level of PFOA in individuals residing in the United States is estimated to be approximately 5 ppb." The Second Complaint further states:

The human serum sampling data are particularly useful because they represent an attempt to associate body burden in the general population with a specific exposure pathway and a source of exposure. This data is information that reasonably supports the conclusion that PFOA presents a substantial risk of injury to human health that the Administrator was not already adequately informed about at the time the information was obtained by DuPont or at any time prior to the date EPA received the data.

. . . The Agency considers the human serum sampling information to reasonably support the conclusion of a substantial risk of injury to health or the environment.

DuPont has not yet filed a formal response to this second complaint. Many believe, however, that DuPont may include in its response assertions that there was no substantial risk as that term is defined under TSCA Section 8(e), the exposure levels reported are below

occupational exposure levels, and that, in any event, EPA was aware of the information at issue. Statement from E. I. du Pont de Nemours and Company, Response to: EPA Claim Regarding PFOA Information (Dec. 6, 2004), available at http://www1.dupont.com/dupont_global/corp/documents/US/en_US/news/releases/pdf/120604response.pdf.

Implications

The case raises important legal issues that could have far reaching implications for the chemical community and others subject to TSCA.

- EPA is apparently taking the position that information that shows an exceedence of a company-set exposure guideline can be reportable under TSCA Section 8(e) even if the information does not show an exceedence of a government-set exposure standard and even when small or minor exceedences of government-set standards may generally not be reportable. 68 Fed. Reg. at 33138 (noting that EPA "establishes concentrations of various substances in different media that trigger a regulatory response or establish levels that are presumed to present no risk to human health or the environment" and that, for purposes of 8(e) reporting, "information about contamination found at or below these kinds of benchmarks would not be reportable"); EPA, *Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA* (Feb. 20, 2003) at 16 ("EPA believes the use of such benchmarks as RfD's, MCL's, RCRA action levels, etc., is reasonable in the section 8(e) decision making process").

The concern that many have expressed with EPA's position is that it could discourage the development of internal health and safety standards that are more restrictive than government-established standards. EPA's

position also may arguably be contrary to EPA's own stated guidance that reporting under TSCA Section 8(e) is not warranted when information indicates the presence of a substance at or below benchmark concentrations that EPA has established (*i.e.*, reference doses (RfD), reference concentrations (RfC)).

- EPA's recent Questions and Answers (Q&A) on the reporting of information on chemical releases to the environment provides interesting guidance that may affect the reportability of DuPont's water sampling data. That Q&A provides:

Q. 1. Analysis of soil or groundwater samples provides new information about the extent of contamination at a site known to be contaminated. Is this information "previously unsuspected"?

A. 1. New information about the presence of a substance or mixture in soil or groundwater (or other environmental media) at a site known to be contaminated with that substance or mixture would be "previously unsuspected" if it materially added to or changed the understanding of the amount, extent and/or pattern (e.g., groundwater in addition to previous evidence in soil) of site contamination.

EPA, *New Questions and Answers about TSCA Section 8(e)* (lasted updated Jan. 5, 2005), available at <http://www.epa.gov/oppt/tsca8e/doc/q&atscanew.htm>.

Based on the foregoing, EPA clarifies that if the presence of a substance in an environmental media is known as to amount, extent, and/or pattern, it is not "previously unsuspected" and thus not reportable.

- The allegation regarding the placental transfer of PFOA raises new issues regarding traditional interpretations of what

constitutes a "significant adverse effect" for purposes of TSCA Section 8(e) reporting, and when information is already known to EPA.

- EPA's Second Complaint raises troubling issues concerning the circumstances under which the mere presence of a chemical human blood might be considered to require a report under TSCA Section 8(e), when no effect other than presence has been asserted. The Complaint alleges facts that tie the presence in blood to the defined dose determined in the drinking water of those whose blood samples were at issue. It could signal a possible future new approach to determining the reportability of biomonitoring data and what constitutes a significant adverse effect.

Conclusion

EPA's assertions against DuPont, although specifically related to a controversial chemical product that might have spawned such assertions where another, less controversial product might not have, nevertheless should be watched with great concern by the chemical industry. The precedents that potentially could be set in this case could dramatically change the interpretation of what is and is not reportable under TSCA Section 8(e) and could change significantly the product stewardship programs of companies that use voluntary internal standards to go above and beyond what they are required to do. These issues will become even more important as the collection and release of biomonitoring data becomes more widespread, a result that is widely expected to become reality in the coming years.

SUPREME COURT HEARS FIFRA PREEMPTION CASE

Ken Weinstein
Latham & Watkins

On Jan. 10, 2005, the U.S. Supreme Court conducted a spirited oral argument in the important case of *Bates v. Dow Agrosciences*, which raises the issue of whether the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 24(b) preempts certain state tort claims against pesticide manufacturers for crop damage. The case has wide-ranging implications for many federal statutes that contain preemption provisions.

While FIFRA Section 24(a) provides that states may regulate the sale and use of pesticides, Section 24(b) declares that a state shall not impose labeling requirements in addition to, or different from, those required by the U.S. Environmental Protection Agency (EPA). One of the key issues in the case was whether state tort law judgments constitute labeling “requirements.”

The Fifth Circuit Court of Appeals concluded that the tort claims at issue in *Bates* were expressly preempted by FIFRA Section 24(b). The Fifth Circuit found, as had most federal courts of appeals, that “failure to warn” claims were preempted by FIFRA because a jury verdict in such a case would, in effect, impose “labeling requirements” on the manufacturer. In *Bates*, however, the plaintiff farmers had alleged several types of claims, including negligence, design defect, deceptive trade practices, breach of contract, and express and implied warranty. The Court of Appeals held that these allegations were “disguised” failure to warn claims because a judgment against Dow would “induce” it to change the product label.

In the oral argument, the farmers’ counsel opined that there was nothing in the legislative history of FIFRA that indicates that Congress

intended to abolish a long history of common law tort claims by enacting Section 24(b). He contended that the scope of the preemption provision is limited narrowly to actual state statutes and regulations – or “positive law” – that would impose pesticide labeling requirements, and that preexisting state law remedies were not intended to be displaced. Moreover, he claimed that EPA had asked Congress for the authority to “waive” the review of the effectiveness of pesticides, and that part of EPA’s rationale for this waiver was the fact that state tort law remedies would serve to regulate this subject matter. In addition, counsel contended that to the extent that state tort suits result in non-uniformity, and different rules apply in different states, this can be accommodated through supplemental labeling containing provisions specific to the states. He received relatively “light” questioning from the justices for most of his premises.

Counsel for Dow, as well as the solicitor general, argued that allowing state tort claims would result in a “crazy-quilt” of state requirements for labeling, and that the purpose of FIFRA Section 24(b) was to create labeling “uniformity” to avoid this precise problem. Justice Souter asked whether the “uniformity” notion was intended to apply to subjects that EPA does regulate, rather than to areas such as pesticide efficacy issues, where EPA has waived regulation. Justice Ginsberg, as well, asked about the significance of the fact that EPA is not regulating the types of claims that the plaintiffs had brought.

Justice O’Connor asked about the plaintiffs’ claim alleging that the product had not been adequately field-tested. She questioned why such a claim should be considered to constitute a labeling requirement and asked whether this type of claim ought not to be allowed. Dow counsel replied that this was only a subset of failure to warn type claims. Moreover, he noted, allowing defective design claims also would impeach the product label. Justice Souter,

however, observed that under that theory, virtually any claim would always result in impeaching the label.

Justice Breyer raised a question about the plaintiffs' argument that the label is allegedly misbranded. He asked whether such a misbranding claim would not impose a "different" requirement than EPA imposed, because if the label were misbranded, the law would require that it be corrected anyway. Justice Ginsberg noted that private tort plaintiffs such as the farmers would not have a direct right of action under FIFRA to enforce the misbranding provisions.



Justice Stevens picked up on the misbranding issue by asking if a product is misbranded because of a defect in its composition, that situation could not be remedied without resorting to changing the label – rather, he suggested, the manufacturer could address the misbranding problem by changing the composition.

Justice Souter asked whether there should not be a distinction between a "real" failure to warn and label statements that are false and misbranded – should not these situations be dealt with differently? Should not the preemption provision be read narrowly to cover only the former situation? Government counsel responded that this would destroy Congress' purpose of achieving uniformity of labeling.

Justice Scalia injected that this preemption case was controlled by the "clear statement" rule – that an indication of Congressional intent to preempt must be "clear." Since the government has changed its position on the interpretation of FIFRA Section 24(b) and formerly took the position that preemption did not apply, Justice Scalia asked whether this indicated that the statutory preemption provision did not express a clear intent to preempt state tort law. He noted that Congress could have been more clear if it had intended to endorse the position that state

tort claims that resulted in an "implied inducement" to change the label were to be preempted. He stated that FIFRA Section 24(a) did authorize the states to impose requirements on pesticides, and that FIFRA Section 24(b) must be read in conjunction with this provision. Justice Breyer pointed out that EPA can establish what actions are preempted though regulation. In addition, Justice Souter asked how, if EPA had not regulated in this area, could preemption be found. In her final question, Justice Ginsberg asked whether Congress could have intended thousands of tort suits to be "wiped out" by its adoption of FIFRA Section 24(b).

The one thing that was clear from this argument was that nearly all of the justices were interested in and engaged by the issues, as evidenced by the vigorous questioning and lively debate. We are always admonished that one cannot make predictions of the outcome of a case based on the questions that are asked in oral argument. It does seem likely, however, that the Court will issue a decision that will provide much more extensive guidance on the scope of express and implied regulatory preemption clauses.



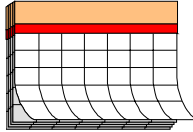
Pesticides, Chemical Regulation,
and Right-to-Know
Committee Newsletter

LIKE TO WRITE?

The Pesticides, Chemical Regulation, and Right-to-Know Committee welcomes the participation of members who are interested in preparing this Newsletter. If you would like to lend a hand by writing, editing, identifying authors, or identifying issues, please contact the editor, Lynn Bergeson, at 202/557-3801 or lbergeson@lawbc.com.

**AMERICAN BAR ASSOCIATION
SECTION OF ENVIRONMENT, ENERGY, AND RESOURCES**

Calendar of Section Events



23rd Annual Water Law Conference

Feb. 24-25, 2005
San Diego

34th Annual Conference on Environmental Law

March 10-13, 2005
Keystone, Colorado

Key Environmental Issues in Region 4

April 22, 2005
Atlanta

Key Environmental Issues in Region 6

May 26, 2005
Dallas

Wetlands Law and Regulation

June 8-10, 2005
Washington, D.C.
(Cosponsored with ALI-ABA and ELI, for information see www.ali-aba.org.)

ABA Annual Meeting

Aug. 4-9, 2005
Chicago

13th Section Fall Meeting

Sept. 21-25, 2005
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