News

Toxic Substances

Federal Court Affirms HHS Classification Of Dioxin as 'Known' Human Carcinogen

The Department of Health and Human Services acted reasonably in upgrading dioxin from a "reasonably anticipated" to a "known" human carcinogen in the National Toxicology Program list, a federal appeals court ruled Nov. 23 (*Tozzi v. HHS*, D.C. Cir., No. 00-5364, 11/23/01).

The U.S. Court of Appeals for the District of Columbia Circuit affirmed a lower-court decision that found HHS's reclassification of dioxin in May 2000 was not arbitrary or capricious (*Tozzi v. HHS*, 51 ERC 1893 (D.D.C. 2000); 200 DEN A-3, 10/16/00).

The decision is expected to have major implications for the Environmental Protection Agency's ongoing reassessment of the risks of dioxin. The agency hopes to complete its final reassessment early in 2002 (196 DEN A-11, 10/12/01).

Further, although the petitioners in the case failed in their effort to block the redesignation of dioxin, the ruling was hailed as a precedent-setting decision for entities seeking standing to legally challenge government statements on health issues.

The Public Health Service Act requires HHS to compile a list of suspected and known human carcinogens in consumer products. The list is prepared biennially by the NTP, an HHS agency, and is titled the *Report on Carcinogens*.

State and federal agencies, among other organizations, use the report in many ways, including to determine whether exposure to a substance should be reduced or prevented altogether.

The NTP's *Ninth Report on Carcinogens* issued May 15, 2000, upgraded dioxin from a "reasonably anticipated human carcinogen" to a "known human carcinogen" (95 DEN AA-1, 5/16/00).

Dioxin is a chemical produced as a byproduct of paper and pulp bleaching and emitted during incineration of chlorine-containing materials such as polyvinyl chloride plastic.

Plaintiffs Jim J. Tozzi, an individual restaurant, a trade association of restaurants, and Brevet Inc., a manufacturer of medical products that release dioxins when incinerated, filed suit May 14, 1999, in the U.S. District Court for the District of Columbia challenging the findings of the *Ninth Report*. Tozzi is a consultant and a former White House Office of Management and Budget official.

They claimed, that according to its own regulations, HHS must rely upon epidemiological studies in evaluating whether a chemical is a "known" carcinogen.

1982 Regulations. The original 1982 HHS regulations governing classification of both "reasonably anticipated" and "known" carcinogens required that epidemiological studies were required to establish carcinogenicity. These regulations were revised in 1996 to allow for mechanistic evaluations in addition to epidemiological evaluations in establishing carcinogenicity.

The plaintiffs argued that the revisions applied only to the "reasonably anticipated" section of evaluation criteria immediately preceding the new methods. HHS interpreted the regulations as applying to both preceding sections of criteria.

The appeals court ruled that HHS did not act arbitrarily and capriciously in interpreting its regulations on establishing carcinogenicity in the NTP listings. The court found that at most there was inconsistency in the formatting of the regulations and the text of the "known" criteria, but that the resolution by HHS of that contradiction was reasonable and not contradicted by the plain language of the regulations.

Regarding the plaintiffs' right to sue, the court found that Brevet Inc. suffered an injury in fact that was fairly traceable to the dioxin upgrade and, therefore, had standing to challenge the HHS decision.

The court also found that the listing has binding legal effects and, therefore, is reviewable by the court.

Plaintiff Responds. In a Nov. 23 statement, the industry-supported Center for Regulatory Effectiveness, on whose board Tozzi serves, said, "Notwithstanding the court's deference to an agency's interpretation of its own rules, the opinion sets a major precedent on both a governmentwide basis and for EPA's upcoming dioxin reassessment in particular."

Tozzi added, "While we are disappointed with the court's decision on the merits of the case and obviously disagree with it, at the same time, the court's willingness to decide this issue is important and a significant development. It sets a very positive precedent for the Data Quality Law."

The court's interpretation will help corporations because "it expands the universe of agency statements" subject to lawsuit, he told BNA.

The scope of the ruling goes way beyond defining what is a carcinogen," Tozzi continued. Specifically, "when a federal agency issues a pejorative statement about a corporation, product, or person you no longer have to wait until it is incorporated into a final rule," before filing a lawsuit, he said.

The Data Quality Act was aimed at governing the quality of information the government issues in press releases, on the Internet, and in other sources outside the scope of federal rules, Tozzi said.

"Before this decision, you had to have injury in fact, which is 'fairly traceable to final agency action,' " he added. "This case expands those terms and what they apply to."

R. Craig Lawrence, assistant U.S. attorney representing HHS, told BNA that the regulatory impact of the case is not readily discernible.

It may have a significant impact on certain segments of the chemical industry, while others could feel little or

no impact from the court's decision, he said. At this point, it is hard to tell what the full impacts will be, he said.

The plaintiff-appellants were represented by Charles J. Fromm, of Multinational Legal Services, in Washington, D.C. HHS was represented by the U.S. Attorney's office in Washington.

By John H. Stam and Linda Roeder

Text of the appellate court's decision is available at http://pacer.cadc.uscourts.gov/common/opinions/200111/00-5364a.txt on the World Wide Web.