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# *The* Tozzi *Decision: Another Arrow in Manufacturers' Quiver in Product Defense Wars*

**by**

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On November 23, 2001, the United States Court of Appeals for the D.C. Circuit gave parties aggrieved by flawed government characterizations of chemical products reason to cheer. In *Tozzi v. Department of Health and Human Services*,[1] the court rejected the government's argument that a medical plastic tubing manufacturer lacked Article III standing to sue the U.S. Department of Health and Human Services (DHHS) for the National Toxicology Program's (NTP) final decision to upgrade dioxin, a contaminant formed during the incineration of hospital waste, from the "reasonably anticipated" to be a human carcinogen category to the "known" category. The court also found that NTP's decision had legal effect and was thus judicially reviewable.

While the court affirmed the District Court's ruling on the merits that DHHS's decision was not arbitrary and capricious in violation of the Administrative Procedure Act (APA), *Tozzi* is nonetheless significant because it expressly holds that parties have standing to sue NTP listing decisions. The decision also provides needed leverage to stakeholders when engaged in advocacy with NTP on the scientific and procedural merit of NTP's determinations, as well as other agency determinations regarding the toxicological characterization of chemicals and the products in which those chemicals are included. This article provides a background on the NTP listing process and analyzes the implications of the case.

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### The NTP Listing Process

Federal and state government agencies engage in countless hazard and risk reviews of chemicals. The outcomes of such reviews have a profound impact on the regulatory status of the molecule under scrutiny and thus its fate in the market place. In today's exceedingly chemaphobic society, even a modest addition of "adverse effects" baggage to a molecule's profile results in diminished market share. This is especially true for chemicals with use applications in consumer markets. This is due to the powerful forces of product deselection. It is a fundamental principal that victory in the market place belongs to those with the least regulatory encumbrances imposed on their products. Since the trigger for additional regulatory controls—and the often dramatic and far-reaching commercial effect of those controls—is many times a finding that a chemical poses or may pose an adverse health effect, the toxicological characterization of a molecule by a government agency is critically important.

The review process in *Tozzi* concerns the NTP listing process. In 1978, Congress amended the Public Health Service Act (PHSA) to require the DHHS Secretary to publish a list of known and suspected carcinogens.[2] NTP lists chemicals "known to be human carcinogens" or "reasonably anticipated to be human carcinogens" in a report entitled the *Report on Carcinogens* (*RoC*). The *RoC* lists agents, substances, mixtures, or exposure circumstances that are "known to be human carcinogens," or are "reasonably anticipated to be human carcinogens."[3] An agent or substance is listed in the "known to be human carcinogen" category where there is "sufficient evidence" of

carcinogenicity from studies in humans that indicates a causal relationship between "exposure to the agent, substance or mixture and human cancer."[4] Materials fall into the "reasonably anticipated to be human carcinogens" category if they meet one of several listing criteria, including whether effects were seen in multiple species, whether effects were seen in multiple routes of exposures, and related factors.[5]

The NTP listing process nominally is public, transparent, and participatory. Many believe, however, that in reality the process falls far short of these standards. The process starts with a nomination, typically offered by government agencies (including NTP), the general public, and others, that provides a rationale for listing an agent, substance, mixture, or exposure circumstance as a "known human carcinogen" or a "reasonably anticipated human carcinogen."[6] Nominated chemicals are almost always the subject of prior NTP testing initiatives. NTP testing includes, among other tests, long-term bioassays designed to assess the cancer potency of the test chemical. NTP publishes the results of these bioassays, in draft and in final, as "Technical Reports." Interested parties are provided an opportunity to comment upon draft Technical Reports.

Upon receipt of a chemical nomination for inclusion in the *RoC*, NTP will publish a notice in the *Federal Register*, trade journals, and NTP publications announcing the nomination and soliciting public comment. NTP claims to identify, to the extent possible, key scientific issues for each nomination, and communicate these issues to the public at the time of announcement of the nominations.[7] Stakeholders have opportunities to provide written comments addressing pertinent issues and to identify any additional issues.[8]

After a lengthy review process spanning several years, NTP publishes in the *Federal Register*, trade journals, and NTP publications the nominated agents recommended for listing, and solicits final public comment. The NTP Executive Committee has responsibility for reviewing the recommendations of various NTP groups, along with the public comments, and providing its comments and recommendations to the NTP Director.

After completion of the final draft of the *RoC*, the NTP Director submits the document to the DHHS Secretary for review and final approval.[9] The DHHS Secretary has the responsibility for submitting the final *RoC* to the U.S. Congress as a final document. NTP also publishes in the *Federal Register*, trade journals, and NTP publications a notice of the publication and availability of the *RoC*.

Although the listing process is nominally participatory, NTP has been severely criticized in years past for a host of substantive and procedural deficits. These deficits relate specifically to the listing process, but go well beyond this aspect of the NTP program. Key among them are alleged deficiencies in the NTP process for selecting chemicals for NTP testing. In that a positive finding in an NTP cancer bioassay renders the test chemical a potential, if not likely, candidate for *RoC* listing consideration, how NTP goes about selecting chemicals for testing and how these tests are actually conducted are critically important inquiries. NTP has for years been harshly criticized for significant and far-reaching scientific deficiencies in its chemical testing program and a serious lack of transparency in its chemical nomination process. Scientific and technical flaws that have been the subject of criticism include, among many others, rodent strain selection (some strains are known to produce spontaneously very high numbers of tumors in certain target organs); maximum tolerated dose (MTD) selection; and related science policy issues.

### Implications of *RoC* Listing

There are significant regulatory, marketing, and product liability implications resulting from an NTP decision to conduct chemical testing and any subsequent NTP classification or *RoC* listing determination. None of them is good.

Under the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard, for example, manufacturers of NTP tested chemicals must include material safety data sheet (MSDS) notations when test results exhibit positive evidence that a chemical may be a carcinogen.[10] The inclusion of such information on MSDSs almost certainly makes the chemical

 

more susceptible to product deselection considerations by formulators and processors who purchase the chemical. The thinking is: why take a chance with something that has adverse toxicological data, even when experts believe those data are spurious, if a substitute without these adverse data can be used. This logic applies even when that substitute has not been tested.

NTP classifications invite increased regulatory scrutiny under Resource Conservation and Recovery Act (RCRA) implementing regulations. Under RCRA's Land Disposal Restrictions (LDR) rules, for example, disposal restrictions are more onerous for chemicals classified as carcinogens. Under EPA's RCRA hazardous waste listing criteria, chemicals with cancer potencies are reviewed more critically and subjected to more onerous regulations as listed hazardous wastes when disposed. Similar enhanced regulatory scrutiny arises under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Clean Air Act (CAA), Safe Drinking Water Act (SDWA), and Clean Water Act (CWA) regulatory programs.

NTP decisions also materially affect state regulatory programs. Key among such programs is the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) interpretation and implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986, more commonly known as Proposition 65.[11] A chemical listed as a carcinogen or reproductive toxin under Proposition 65 triggers significant warning and labeling requirements, each of which has a distinctly chilling effect on the marketing of Proposition 65 listed products. Allegations of noncompliance with Proposition 65 invite expensive and well-publicized enforcement action brought by the State and a growing legion of "bounty hunters" authorized to pursue enforcement actions under Proposition 65.

Under Proposition 65, OEHHA may list chemicals known to cause cancer or reproductive toxicity by several mechanisms.[12] Of relevance here is the mechanism by which a chemical has been "formally identified" as causing cancer by a body considered "authoritative" by the State. This procedure is called the authoritative bodies mechanism. NTP is among the government bodies determined by the State of California to be authoritative for purposes of the identification of chemicals believed to cause cancer. OEHHA considers draft and final NTP Technical Reports as a "formal identification" for purposes of triggering the authoritative body mechanism. Most chemicals that have been identified as Proposition 65 cancer causing chemicals pursuant to the authoritative body mechanism and reliant upon an NTP Technical Report (either draft or final) have been listed under Proposition 65.

Finally, the likelihood of product liability claims increases exponentially, particularly when a product enjoys consumer applications, once NTP labels a chemical as a carcinogen. The public's tendency to overreact to even the slightest association of any product with cancer is felt profoundly in the product liability area, and chemical manufacturers and processors must be especially vigilent in anticipating the implications of chemical testing for this reason alone. The advent of "voluntary" chemical testing initiatives, such as the High Production Volume (HPV) Challenge Program, the International Council of Chemical Associations (HPV/ICCA) chemical testing initiative, and the Voluntary Children's Chemical Evaluation Program (VCCEP), have elevated considerably the significance and relevance of NTP testing initiatives.[13] These newer initiatives have both heightened the general public's awareness of chemicals in the environment and the adverse health effects some are believed to cause, making product liability claims all the more probable. They also have hastened the development and global circulation of basic screening level chemical test data on thousands of chemicals. In many respects, these voluntary initiatives are a promising and efficient means to a reasonable end. They also, however, have served to elevate the stakes considerably in product defense wars as the global community is vastly more attuned to appreciating the implications of chemical testing and immediately making market adjustments in response to new testing data.

It is these and other concerns that drive chemical product manufacturers and manufacturers of products with significant chemical components to track closely NTP chemical testing and NTP listing processes and to participate actively in NTP

 

deliberations. They appreciate that NTP actions almost certainly will bear materially upon the continued economic viability of their chemical products. Failure to do so can mean the demise of entire product lines.

### The *Tozzi* Litigation

Plaintiffs in the District Court proceeding included Jim Tozzi, President of Multinational Business Service, a Washington, D.C. consulting firm, Brevet Industries and Brevet Inc. (Brevet), makers of medical tubing connectors that use polyvinyl chloride (PVC) plastic, and others. Plaintiffs filed suit in the United States District Court for the District of Columbia pursuant to APA Section 706 claiming that the DHHS Secretary acted arbitrarily and capriciously by upgrading dioxin without sufficient epidemiological evidence that it causes cancer in humans.[14] The District Court found the Secretary's interpretation of the criteria "eminently reasonable" and granted summary judgment for DHHS.

On appeal, the D.C. Circuit Court began its *de novo* review with an analysis of two threshold issues: whether the appellants had standing to challenge the dioxin upgrade and whether the NTP listing decision was reviewable. As to Article III standing, the court defined the standard as whether the plaintiff demonstrated an actual or immediate "injury-in-fact" traceable to the challenged conduct and amenable to redress by a favorable judicial decision. The court concluded that Brevet demonstrated actual or immediate injury. The court cited an affidavit submitted by Brevet's President that over 95% of company sales depended on the continued use of PVC plastic by medical establishment customers. The court also found compelling the passage by three California municipalities of resolutions encouraging healthcare institutions to eliminate the use of PVC plastic in medical devices.[15] Finally, the record revealed that large commercial purchasers of medical supplies serviced by Brevet had announced that they would cease purchasing PVC products in the future, resulting in greatly diminished revenue to Brevet.

The court found these economic injuries not at all speculative, and further concluded that Brevet's declining profits were "fairly traceable" to the dioxin upgrade. The court stated that where "as here, the alleged injury flows not directly from the challenged agency action, but rather from independent actions of third parties, we have required only a showing that the 'agency action is at least a substantial factor motivating the third parties' actions."[16] The *Tozzi* court expressed "little doubt" that the dioxin upgrade was a substantial factor in the decisions of state and local agencies to regulate products containing dioxin and in healthcare companies' decisions to reduce or end purchases of PVC plastics.

The court found equally meritless DHHS's contention that Brevet's injury was not "redressable." According to the court, nothing in the record indicated that any other federal agency had yet labeled dioxin a known carcinogen. Were it to set aside the Secretary's upgrade decision, the court stated, regulators undertaking dioxin activities could no longer point to an authoritative determination by the United States government that dioxin is known to cause cancer in humans. The court also stated its belief that state and local governments would be less likely to regulate dioxin, and healthcare companies would, in turn, be less likely to stop using PVC plastic. In short, reclassification of dioxin would, according to the court, redress at least some of Brevet's economic injury.[17]

The court's analysis regarding reviewability is especially compelling. Reviewability of a listing under the APA hinges upon whether that listing has "'legal effect, which in turn is a function of the agency's intention to bind either itself or regulated parties.'"[18] In making this determination, the court looked to "'the agency's own characterization of its action" and to "publication or the lack thereof in the *Federal Register* or the *Code of Federal Regulations.*'"[19] DHHS argued that the listing was unreviewable under these two indicia of reviewability. It pointed out that the NTP Report's preamble states that it is "for informational purposes only" and that the Secretary never published the entire Report in the *Federal Register*.

The court disagreed. It found that although the final Report was not published in the *Federal Register,* the Secretary published a notice

 

proposing a dioxin upgrade and, once issued in final, a summary of the decision. Equally important, the court disagreed with the contention that a listing has no "binding effect," even though the Secretary took no action pursuant to the listing "Listing a substance as a human carcinogen triggers obligations under OSHA, Department of Labor and state regulations. . . . Additional evidence of a listing's 'legal effect' comes from the fact that in order to remove a substance from either category, the Secretary must undertake the same elaborate procedure—including notice and comment—required for an initial listing."[20]

Unfortunately, appellants fared less well on the merits. The court fairly summarily dismissed the challenges on the merits by stating that since Brevet was challenging only the Secretary's interpretation of the criteria, the court was constrained to afford NTP's interpretation the substantial deference that controlling precedent requires. The court thus based its decision largely on the presumption that NTP's interpretation of very technical matters in dispute deserved the substantial deference the court afforded NTP.

Judge Silberman, in his concurring opinion, raised the possibility, however, that had Brevet differently framed its challenge, the court may have reviewed it differently. He stated: "I concur with all parts of the court's opinion including the portion dealing with reviewability. But it is an interesting question how one should categorize the agency's action that we review. It might be thought to be an informal adjudication—a specific application of the regulation—but because it has only a future effect, I think it is accurately described as an interpretive rule. . . . In this case, the agency authoritatively proclaims which substances qualify as known carcinogens, which is why I think it is properly described as an interpretive rule."[21]

### What Does *Tozzi* Mean?

*Tozzi* is important for several reasons. First, *Tozzi* can be cited as support that stakeholders with clear interests in *RoC* chemicals have standing to challenge NTP listing decisions. *Tozzi* is the first appellate decision to do so.

Second, the decision offers clear guidance on how successfully to satisfy the "substantial factor" standard in determining whether the injury alleged is "fairly traceable" to the action complained of. In *Tozzi*, the court found that Brevet demonstrated actual or immediate injury through diminished sales data, and the fact that the diminished sales were plainly traceable to the dioxin upgrade. The court found indisputable the statement that the three California resolutions were directly traceable to the *RoC* as each cited the initial Review Committee's preliminary determination for the proposition that dioxin is a known human carcinogen.

On the question of whether the court's decision would redress the injury, *Tozzi* is probably somewhat unique. According to the court, there was nothing in the record indicating that any other federal agency had labeled dioxin as a carcinogen and were the court to set aside the Secretary's upgrade decision, the court noted that dioxin activists could "no longer point to an authoritative determination by the United States government that dioxin is 'known' to cause cancer in humans."[22] Based on this, it is questionable whether the court would have so ruled had another U.S. agency determined independently of DHHS that dioxin is believed to cause cancer in humans.

As is often the case with highly tested chemicals, other government agencies, most notably EPA through its Office of Pesticide Programs, or other international authoritative bodies, such as the International Agency for the Review of Carcinogens (IARC), determine the cancer potency of a molecule. Had this been the case in *Tozzi*, and had such information been included in the record, the court may have been constrained to conclude that by setting aside the Department's decision, the court would not be able meaningfully to redress Brevet's economic injury. It would seem then that the redressability standard only be met when *RoC* upgrade decisions are ones of first impression for a chemical and no other United States federal authoritative body has classified the molecule as a known or suspected human carcinogen, except in reliance on the NTP decision.

Third, *Tozzi* offers an appellate ruling that NTP decisions, at least decisions with facts similar to those presented in *Tozzi*, are reviewable for purposes of APA Section 704. In this regard,

 

*Tozzi* is consistent with earlier District Court precedent. In *Synthetic Organic Chemical Manufacturers Ass'n v. Secretary, Dep't of Health & Human Services*,[23] the Western District of Louisiana court held that the *Annual Report on Carcinogens* (the designation given the *RoC* in 1989) was reviewable agency action. The court so ruled because of its determination that certain agency actions merit review even when they are informational and impose no sanctions or obligations.[24]

Fourth, aside from the judicial value of *Tozzi*, the fact that the parties alleging injury were found to have standing to sue and the decision was determined to be reviewable, the ruling offers considerable leverage in conducting advocacy with NTP throughout the long process leading up to an *RoC* listing. Almost certainly, government attorneys will be mindful of the fact that *RoC* listings have been judicially determined, at least by one federal appellate court, to inspire immediate injury that may be redressable by a court and that, for this reason, companies have standing to sue. At the least, this may help make NTP more receptive to heeding the comment, technical advice, and other advocacy offerings of business stakeholders in the NTP listing process. Historically, many in industry believe the chemical community's comments have been given short shrift and that NTP staff generally have been unreceptive to the thoughts and comments of industry stakeholders offered in connection with virtually all phases of public comment on NTP Technical Reports, as well on the *RoC* listing process.

What *Tozzi* does not do is help define how industry stakeholders can demonstrate that the decisions of the NTP, or other government agency, are arbitrary and capricious within the meaning of the APA. According to the court, Brevet fell "far short" of meeting the "substantial deference" standard. There is little discussion of the merits of the case and it is not clear if the parties simply failed to make a compelling case or if the *Tozzi* court, like so many others, was reluctant to disturb the findings of a government agency when, as in *Tozzi*, those findings are highly technical in nature.

What is interesting in this regard is Judge Silberman's concurring opinion, which indicates that the agency action under review in *Tozzi* should be regarded as an "interpretative rule." Presumably, since the Secretary's decision to upgrade was not afforded all the administrative bells and whistles of a rulemaking, Brevet may have been more successful in challenging the upgrade decision itself as a rule—one that was issued without required administrative process—rather than merely challenging as arbitrary and capricious the Secretary's interpretation of its own listing criteria as applied to dioxin.

Resolution of this issue in favor of Brevet would have been good. Such was not the case, however, and industry will need to find another promising opportunity to push the envelope even further to blunt judicially the many science policy sins that are forgiven under the substantial deference standard. Nonetheless, *Tozzi* is a positive development, and provides industry with reason to cheer.

 

## Notes

[1] No. 00-5364 (D.C. Cir. Nov. 23, 2001), available on the Internet at http://pacer.cadc.uscourts.gov/common/opinions/200111/00-5364a.txt.

[2] Biomedical Research and Research Training Amendments, Pub. L. No. 95-622, Tit. II Section 262, 92 Stat. 3412, 3435-36 (1978) (amending 42 U.S.C. § 241).

[3] NTP, *Call for Nominations*, available on the Internet at http://ntp-server.niehs.nih.gov/NewHomeRoc/CallforNoms.html (*Call for Nominations*). NTP has also stated that the Tenth *RoC* is "in the final stages of review." *See* NTP, *Q's & A's on the RoC*, available at http://ntp-server.niehs.nih.gov/NewHomeRoC/RoCQA.html.

[4] *Call for Nominations*.

[5] *Id*. The criteria are there is "limited evidence" of carcinogenicity from studies in humans which indicates that causal interpretation is credible but that alternative explanations such as chance, bias, or confounding factors could not adequately be excluded; or there is "sufficient evidence" of carcinogenicity from studies in experimental animals which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors: (1) in multiple species, or at multiple tissue sites; or (2) by multiple routes of exposure; or (3) to an unusual degree with regard to incidence, site, or type of tumor or age at onset; or there is "less than sufficient evidence" of carcinogenicity in humans or laboratory animals, but the agent, substance, or mixture belongs to a well defined, structurally-related class of substances whose members are listed in a previous *RoC* as either "known to be a human carcinogen," or "reasonably anticipated to be a human carcinogen," or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans. Not surprisingly, there is considerable debate on the application of these criteria to particular fact patterns.

[6] *See* NTP, *Listing and Delisting Procedures*, available on the Internet at http://ntp-server.niehs.nih.gov/NewHomeRoC/ListDelistProc.html.

[7] *See* NTP, *Response to Public Comments and Discussion on the Preparation and Review of the Report of Carcinogens*, available on the Internet at http://ntp-server.niehs.nih.gov/NewHomeRoc/ResponsePub.html.

[8] *Id.*

[9] NTP will provide all the public comments to the NTP Executive Committee and the NTP Director, including comments submitted to the RoC Subcommittee after the RoC Subcommittee deadline. *See id.* NTP provides a summary of stakeholder opinion to the Secretary. *See id.*

[10] This requirement assumes that at least one bioassay demonstrates that a chemical has statistically significant finding. *See* OSHA Instruction CPL - 2.38C.

[11] In California, an initiative statute is a law placed on the general election ballot by citizen petition and adopted by a majority of California voters. CAL. CONST. Art. 2, §§ 8, 10. Section 2 of Proposition 65, which contains the Act's core substantive provisions, is encoded in Cal. Health & Safety Code §§ 25249.5-13.

[12] For a more detailed review of Proposition 65 and the authoritative body listing mechanism, *see* R. Bozof, "State of California's Implementation of the Authoritative Bodies Procedure for Listing Carcinogens Under Proposition 65: The Need for Use of Sound Science and Conformance with Statutory and Regulatory Purpose," *EPA Administrative Law Reporter*, Vol. 17, Nos. 4 and 5, April and May 2001.

[13] The HPV Challenge Program was unveiled in 1998 as a cooperative program among the American Chemistry Council (formerly the Chemical Manufacturers Association), Environmental Defense (formerly Environmental Defense Fund, Inc.), and EPA. HPV Challenge

 

Program testing targets approximately 2,800 chemicals. This listing is based on the TSCA 1990 Inventory Update Rule (IUR). Testing began in 1999, and is expected to be completed by the end of 2004, with various provisions to ensure progress. The chemical industry is projected to spend approximately $500 million on voluntary HPV testing. The ICCA launched its Global Initiative to seek sponsors to make available data on 1,000 HPV chemicals by 2004. The VCCEP is an initiative resulting from President Clinton's 1997 Executive Order 13045 entitled *Protection for Children from Environmental Health Risks and Safety* Risks. The Order requires federal agencies to assign a high priority to addressing health and safety risks to children to coordinate research priorities on children's health issues, and to ensure that regulatory standards reflect special risks to children. EPA rolled out its pilot VCCEP in 2001, seeking data on 23 chemicals. Many producers of the listed chemicals volunteered to participate in the Program.

[14] APA Section 706 provides that the reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be," *inter alia*:

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ;
>
> (D) without observance of procedure required by law;
>
> (E) unsupported by substantial evidence in a case subject to sections 556 and 557 . . .; or
>
> (F) unwarranted by the facts to the extent that the facts are subject to trial *de novo* by the reviewing court.

[15] San Francisco, Oakland, and Berkley adopted resolutions along these lines. Elsewhere state and local agencies in Connecticut, North Carolina, and Washington had also held hearings regarding the elimination of PVC plastic use in medical applications.

[16] *See Tozzi v. Department of Health and Human Services* at 7 (Internet version).

[17] *Id.* at 8.

[18] *Id.* at 8-9 (citation omitted).

[19] *Id*. at 9 (citation omitted).

[20] *Id*. (citations omitted).

[21] *Id*. at 11-12.

[22] *Id*. at 8.

[23] 720 F. Supp. 1244 (W.D. La. 1989).

[24] *Id*. at 1249.

 