

counsel and representation to clients in international trade matters and in administrative and regulatory matters before federal and state governmental agencies. Plaintiff Empire State Restaurant & Tavern Association is a trade organization representing approximately 20,000 New York establishments, most of which sell to the public cooked food containing meat, poultry, dairy products, and fish. Plaintiff Greenbaum & Giloolley's is a member of the Empire State Restaurant & Tavern Association that is well known for its steak and seafood preparations. Finally, plaintiff Brevet Industries and Brevet, Inc. makes medical tubing connectors that use polyvinyl chloride (PVC) plastic.¹

Defendants are the United States Department of Health and Human Services (HHS), Donna Shalala, the Secretary of HHS Kenneth Olden, Director of the National Institute of Environmental Health Sciences (NIEHS) and of the National Toxicology Program (NTP), and George Lucier, Director of the Environmental Toxicology Program (ETP).

II. 9th Report on Carcinogens

The RoCs are prepared by the agency by congressional mandate.² The RoCs have two purposes: 1) to provide the general public with information on substances in their environment that cause, or might cause, cancer; 2) to urge individuals and regulatory agencies to make choices that reduce or eradicate human exposure to carcinogens. The RoCs are publicized widely, including on the Internet, and receive a great deal of media attention. See, e.g., Cindy Skrzycki and Joby Warrick, *EPA Links Dioxin to Cancer*, Washington Post, May 17, 2000.

Dioxin is a contaminant formed during incineration of municipal, toxic, and hospital wastes, and has been found as a contaminant of herbicides and pesticides.³ Plaintiffs allege that defendants contravened the Administrative Procedure Act 9 ("APA") , 5 U.S.C. § 706 *et seq.*, in upgrading dioxin from "reasonably anticipated to be a human carcinogen" to "known to be a human carcinogen" in the 9th Report on Carcinogens (RoC).

¹Plaintiff BeDuCi, a Washington, D.C. restaurant, voluntarily withdrew from this case during the pendency of this motion.

²Public Law 95-622, the "Community Mental Health Centers Extension Act of 1978," Title II, § 262(b)(4), 92 Stat. 3435-36, amended § 301 of the Public Health Service Act, now codified at 42 U.S.C. § 241(b)(4), and ordered the Secretary of the Department of Health and Human Services to prepare an annual report to include, inter alia, "a list of all substances W which either are known to be carcinogens or may reasonably be anticipated to be carcinogens"

³ According to the defendants' filing of the proposed language for a dioxin listing under the "known" category, "[m]ore than 90% of the dioxins found in humans in the general population are due to consumption of meat including poultry, dairy products, and fish."

The 9th RoC was published May 15, 2000. As part of the 9th RoC the Secretary approved dioxin for listing as a "known" human carcinogen, upgrading it from its previous listing as "reasonably anticipated to be a human carcinogen." In the present version of the report, any mention of dioxin is trailed by an asterisk and a statement that "This substance has been proposed for upgrade to the 'Known To Be A Human Carcinogen' category."

Discussion

I. Standing

Defendants move to dismiss on the grounds that plaintiffs do not have standing to bring this action, and that it therefore should be dismissed under Rules 12 (b) (1) and 12 (b) (6) . The elements for standing are well-established. Plaintiffs must allege 1) "concrete and actual or imminent" injury, 2) causation, and 3 redressability. See *Steel Co. v. Citizens for a Better Environment*, 118 S.Ct. 1003, 1016 (1998) Defendants contend that none of the plaintiffs can allege and prove all of these required elements.

Plaintiffs are concerned because in the past 18 months San Francisco, Oakland, and Berkeley, California, have all passed resolutions aiming to reduce PVC incineration and plastic use. These resolutions do not have any binding effect; they are statements of intent and future goals. These resolutions all cite scientific publications, including a reference to defendant National Institute of Environmental Health Sciences, supporting the carcinogenicity of dioxin. See Defs' Mot. at 5. Plaintiffs argue that because their businesses all entail the use or production of dioxin, resolutions like these threaten their livelihood.

a. Injury

Plaintiffs argue that listing dioxin as a "known" carcinogen in the RoC would provide a great deal of political and scientific pressure on municipalities to take further action against dioxin. Brevet's owner states in his affidavit that some of his major customers have already begun to abandon PVC products due to public, shareholder, and political pressures. See Affidavit of Charles Brewer, Pl. S.J. Mem. Exh. 1 at paragraph 8.⁴

Defendants counter that any conclusion as to whether, when or how much business Brevet may lose is wholly speculative, and therefore, Brevet falters on the first of the three standing requirements, an injury that is "certain and great;...actual not theoretical," *Wisconsin Gas Co. v. Federal Energy Regulatory Comm'n*, 758 F.2d 669, 674 (D.C. Cir. 1985).

⁴Plaintiffs are careful to note that the "Zero Dioxin Alliance" scheduled a rally in Oakland, California for Wednesday, February 23.

Plaintiffs state that defendants' argument boils down to this: 1) any anti-dioxin or loss of plaintiffs customers that has not already occurred is necessarily too "speculative" to support standing, but 2) any injury that has already occurred cannot support standing because such injury is proof that the proposed dioxin listing did not cause the harm. That is, plaintiffs argue that defendants are trying to eat their cake and have it too. See Pl.'s Opp. at 10. Plaintiffs also state that they make their injury showing under *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 120 S.Ct. 693, 698 (2000), in which the Court stated that the "injury in fact" necessary to support standing may be based on an affiant's "reasonable concerns about the effects of" the threatened harm.

Under the "injury in fact" standard articulated in *Friends of the Earth, Inc.*, and because of the affidavit from Charles Brewer, plaintiff Brevet has demonstrated sufficient injury.

Plaintiffs Tozzi, Empire State Restaurant & Tavern Association, and Greenbaum & Gilooley have not demonstrated sufficient injury to sustain standing. They are in the same position as any other restaurant, grocery store or food supplier that sells meat or dairy products and they have not demonstrated that any significant number of people would stop buying and consuming these products as a result of the publication of the 9th RoC. These plaintiffs do not have standing.

b. Causation

Defendants continue to argue that Brevet cannot prove causation, because any link between the upgrade of the dioxin listing in the RoC and losses to Brevet is far too attenuated. In support, defendants cite *Microwave Acquisition Corp. v Federal Communications Comm'n*, 145 F.3d 1410, 1412 (D.C. Cir. 1998), in which the court held that the plaintiff lacked standing because the alleged third party conduct was too attenuated.

Plaintiffs respond that activist groups are poised to seize upon the issuance of the RoC to bolster their anti-dioxin campaigns. The D.C. Circuit has recognized that harm may be inflicted through intermediate third parties, *see, e.g., National Wildlife Federation v. Hodel*, 839 F.2d 694, 705-6 (D.C. Cir. 1988), even when administrative conduct provokes a strong public reaction. *See, e.g., Block v. Meese*, 793 F.2d 1303, 1309 (D.C. Cir. 1986) (plaintiff had standing to challenge Department of Justice classification of films as political propaganda, although the alleged injury occurred only through irrational public perception of label). Here, plaintiff Brevet's losses are attenuated, however, based on Brevet's showing that the 9th RoC is likely to be used by the anti-dioxin movement, plaintiff Brevet has demonstrated sufficient causation.

C. Redressability

Finally, defendants scuttle plaintiff Brevet's redressability argument, stating that declaratory judgment or an

injunction against the RoC publication would not solve Brevet's problem, since many scientific and political groups have already taken positions supporting the containment and regulation of dioxin exposure. Defendants' argue that action by this Court may not prevent the harm plaintiffs fear, since there is already a growing body of scientific scholarship about the harmful effects of dioxin, and since public sentiment is already shifting against it. Plaintiff Brevet argues to the contrary. Plaintiff Brevet is correct that this Court's issuing an injunction might stave the effects of the attack on dioxin for a time. Thus, Brevet has demonstrated sufficient redressability, and has standing to proceed in this case.

II. Cross motions for Summary Judgment

Plaintiff Brevet has three causes of action. First, plaintiff claims that defendants have misapplied the criteria for listing dioxin in the RoC as a known human carcinogen, by relying on mechanistic and animal data. Second, plaintiff claims that, during the review process for the dioxin listing, defendants have presented evidence about dioxin's carcinogenicity in a misleading manner. Finally, plaintiff alleges that defendants have relied on otherwise improper and insufficient evidence upon which to list dioxin as a known human carcinogen.

The defendants argue that the plaintiff's claim that a listing in the "known to be a human carcinogen" category cannot be supported by mechanistic or animal data is without merit. The defendants, emphasize that they "have reasonably interpreted their own listing criteria." See Defs, Mot. at 11. Likewise, defendants maintain that plaintiff's other claims that the evidence in support of the dioxin listing was misleadingly presented, and was based on irrelevant and insufficient studies, are easily dismissed given the enormity of the scientific review at issue, and the deferential standard of review to be applied. Additionally, the defendants argue that the RoC, even once it is published, is merely an informational document that has no regulatory or other practical effect sufficient to render it subject to APA review.

Both parties move for summary Judgment. Summary judgment should be granted pursuant to Federal Rule of Civil Procedure 56 only if no genuine issue of material fact exists and the moving party is entitled to judgement as a matter of law. See *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, (1986) . In ruling upon a motion for summary judgment, the Court must view the evidence in the light most favorable to the nonmoving party. See *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 1986) ; *Bayer v. United States Dep't of Treasury*, 956 F.2d 330, 333 (D.C. Cir. 1992). In ruling on cross motions for summary judgment, the court shall grant summary judgment only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not genuinely disputed. See *Rhoads v. McFerran*, 517 F.2d 66, 67 (2d Cir. 1975). The cross motions for summary judgment pending before the Court present no genuinely disputed material facts that would preclude summary judgment.

This court must give deference to the agency in interpreting its own criteria. In *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994), the Supreme Court made it clear that a court must review an agency's interpretation of its own regulations with "substantial deference." The D.C. Circuit went a step further in *Wyoming Outdoor Council v. United States Forest Service*, 165 F.3d 43, 52 (D.C. Cir. 1999), in which the court held that an agency's interpretation of their own listing criteria "is controlling unless it is plainly erroneous or inconsistent with the regulation." Here, where the agency itself has drafted the rule or regulation at issue, the Court's review is "more deferential than that afforded under *Chevron*." *National Medical Center v. Shalala*, 43 F.3d 691, 697 (D.C. Cir. 1997). Most compellingly, in *Rollins v. U.S. Environmental Protection Agency*, 937 F.2d 649, 652 (D.C. Cir. 1991), the D.C. Circuit upheld an EPA interpretation of its own regulation that the court observed "would not exactly leap out at even the most astute reader," and that was "rather more strained" than the plaintiff's reading of the regulation.

Unlike the interpretation in *Rollins*, defendants' interpretation here is eminently reasonable. The final paragraph of the criteria state that "conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information." Defendants have chosen to consider mechanistic and animal data relevant. See Defs Mot. at 14. Additionally, the presentation of the proposed change in the Federal Register makes it clear that the proposed change is intended to apply to the criteria for both the "known" and the "reasonably anticipated" categories.

The plaintiff charges that defendants presented information concerning dioxin's toxicity in a misleading manner. Here plaintiffs attack the actual scientific support for the dioxin listing, instead of the procedure behind the listing. Here, too, defendants, as an agency charged with making scientific judgments, is due great deference. See *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). A court must review scientific judgments "not as the chemist, biologist or statistician that [it is] qualified neither by training nor experience to be, but as a reviewing court exercising [its] narrowly defined duty of holding agencies to certain minimal standards of rationality." *Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997). Defendants knock down each of plaintiff's substantive attacks, one by one. See Defs' Mot. 24-26. Again, defendants' reliance on the studies involved and interpretation of its own regulations survives plaintiff's allegations, partly because that reliance is imminently reasonable, and partly because defendant is due such deference on this point.

Conclusion

Defendants' motion to dismiss as to plaintiffs Tozzi, Empire State Restaurant & Tavern Association, and Greenbaum & Giloolley is **GRANTED**. Defendants' motion to dismiss as to plaintiff Brevet is **DENIED**. Based on the reasonableness of the defendants, interpretation of their own regulation and the deference owed by

the Court to agencies' scientific judgments, the defendants, motion for summary judgment is **GRANTED** and plaintiff Brevet's motion for summary judgment is **DENIED**.

9/30/00

Date

Notice to:

Charles J. Fromm

Multinational Legal Services, P.C.

11 Dupont Circle, Suite 700

Washington, D.C. 20036

(202) 797-7124

EMMET G. SULLIVAN

UNITED STATES DISTRICT JUDGE

David L. Smith

Assistant U.S. Attorney

Judiciary Ctr Rm. 10-452

555 4th Street, N.W.

Washington, D.C. 20001

(202) 353-9895