CASE SCHEDULED FOR ORAL ARGUMENT – SEPTEMBER 17, 2001

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 00-5364

JIM TOZZI, et al. **Appellants,**

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., **Appellees.**

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLEE

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CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

1. Parties and Amici

All parties and *amici* appearing in this Court are listed in the brief for Appellants.

2. Ruling Under Review

The ruling under review appears in the brief for Appellants.

3. Related Cases

References to related cases appear in the brief for Appellants.

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***** Authorities upon which we chiefly rely are marked with asterisks.

GLOSSARY

Abbreviations of filings in the district court and of the Supplemental Record filing in the Circuit Court (for non-final briefs to the Circuit Court only):

Dkt. Ref. __	Reference to numbered entry of district court clerk's docket
Am. Compl.	Amended Complaint (11/1/99)
Mot. Dismiss	Defendants' Motion to Dismiss (7/20/99)
Pl. Opp.	Plaintiffs' Opposition to Motion to Dismiss (8/13/99)
Def. Reply	Reply to Plaintiffs' Opposition to Motion to Dismiss (8/30/99)
P.I. App.	Plaintiffs' Application for Preliminary Injunction (9/8/99)
Def. P.I. Opp.	Defendants' Opposition to Prelim. Injunction (9/28/99)
P.I. Reply	Reply to Def. Opposition to Prelim. Injunction (10/8/99)
Pl. S.J. Mem.	Plaintiffs' Motion for Summary Judgment (12/17/99)
Def. S.J. Mem.	Defendants' Motion for Summary Judgment (12/17/99)
Pl. S.J. Reply	Reply to Def. Opp. to Motion for Summary Judgment (1/17/00)
Supp. S.J. Mem.	Plaintiffs' Supplemental Memorandum in Support of Motion for Summary Judgment (5/18/00)
Def. Opp. Supp.	Defendants' Opposition to Plaintiffs' Supp. Briefing (5/26/00)
R. __	"Administrative Record" (5/26/00)
Supp. R.	Supplement to Record on Appeal (Circuit Court filing, 4/23/01)
Appellants' Br.	Appellants' Brief (4/30/01)
Amici Br.	Brief *Amici Curiae* of Public Health Scientists

agency	Unless otherwise noted, all Defendants/Appellees collectively. Appellees are the United States Department of Health and Human Services ("DHHS"); Tommy G. Thompson, Secretary, DHHS; Kenneth Olden, Director of the National Institute of Environmental Health Sciences ("NIEHS") and Director of the National Toxicology Program ("NTP"); and Christopher Portier, Director of the NIEHS Environmental Toxicology Program.
APA	Administrative Procedure Act.
BRC	*Biennial Report on Carcinogens* ("*RoC*")
Brewer Aff.	Affidavit of Charles Brewer, President and owner of Plaintiff Brevet (filed 11/8/99)
DBD	Draft Background Document
DHHS	United States Department of Health and Human Services
dioxin	2,3,7,8-tetrachlorodibenzo-*p*-dioxin ("TCDD")

dioxin addendum	Addendum to 9th Report on Carcinogens containing the final listing for dioxin
epidemiologic data	Data on prevalence of a disease from studies in human populations known to have been exposed to a given substance
IARC	International Agency for Research on Cancer.
Leonard Aff.	Affidavit of Michael Leonard, owner of Plaintiff Greenbaum & Gilhooley's (filed 8/13/99).
NIEHS	National Institute of Environmental Health Sciences
NTP	National Toxicology Program
RG1	Review Group 1. The first review group to evaluate substances for listing in the *RoC*.
RG2	Review Group 2. The second review group in the *RoC* listing process.
RoC Subcommittee	Report on Carcinogens Subcommittee of the NTP Board of Scientific Counselors.
RoC	*Report on Carcinogens*. A biennial report published by the DHHS Secretary pursuant to 42 U.S.C. § 241(b)(4). The *RoC* lists substances to which a substantial number of persons residing in the U.S. are exposed and which are either (a) known to be carcinogenic to humans or (b) reasonably anticipated to be carcinogenic to humans.
TCDD	2,3,7,8-tetrachlorodibenzo-*p*-dioxin ("dioxin")
Wexler Aff.	Affidavit of Scott Wexler, Executive Director of Plaintiff Empire State Restaurant & Tavern Association (filed 8/13/99).

STATEMENT OF ISSUES PRESENTED

In the opinion of appellees, the following issues are presented:

1. Whether the District Court erred in holding that appellants Brevet Industries and Brevet, Inc. had standing to bring this action.

2. Whether the District Court correctly held that appellants Jim Tozzi, Empire State Restaurant & Tavern Association, and Greenbaum & Gilhooleys lacked standing to bring this action.

3. Whether the Report on Carcinogens constitutes agency action subject to judicial review.

4. Whether the District Court correctly held that the agency's interpretation of its own listing criteria is entitled to substantial deference and whether, under that standard, the agency's interpretation should be upheld as not arbitrary, capricious an abuse of discretion or otherwise not in accordance with law.

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APPEAL FROM THE U.S. DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLEE

JURISDICTIONAL STATEMENT

This case arises under the Administrative Procedure Act, 5 U.S.C. §§ 701-706 ("APA"). The District Court possessed federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331. This Court has jurisdiction pursuant to 28 U.S.C. § 1291.

COUNTER-STATEMENT OF THE CASE

Procedural History

Plaintiffs filed their lawsuit initially seeking to enjoin the defendants from including any

listing in the Biennial Report on Carcinogens ("RoC"), "that identifies the chemical tetrachlorodibenzo-*p*-dioxin ("dioxin" or "TCDD") as a 'known human carcinogen' or 'known to be carcinogenic to humans.'" At the time of the suit, dioxin was listed as "reasonably anticipated to be a human carcinogen." Plaintiff sought both declaratory and injunctive relief seeking to, inter alia, enjoin the agency from listing dioxin as "known to be carcinogenic to humans" in the RoC.

On July 20, 1999, defendant moved to dismiss, arguing that plaintiffs lacked standing and that, in light of the fact that the 9th Biennial Report ("9th RoC") had not yet been published, the matter was not ripe for review. Plaintiffs thereafter moved for a preliminary injunction on September 8, 1999, seeking to enjoin the Agency from listing dioxin as a known carcinogen in the 9th RoC. On November 1, 2000, plaintiff moved to amend the complaint, seeking to add Brevet Industries and Brevet Inc. as plaintiffs, and the District Court granted that motion on November 16, 1999. On November 29, 1999, plaintiff's Motion for Preliminary Injunction was denied by the Court.

On December 12, 1999, the parties filed cross-motions for summary judgment, which became ripe for adjudication on February 1, 2000, with oral argument scheduled for May 4, 2000. On May 4, 2000, prior to the oral argument, plaintiffs were presented with a copy of the final dioxin listing. Plaintiffs requested that the Court postpone the hearing in order to permit briefing with respect to the impact, if any, of this listing on the issues briefed by the parties. The supplemental briefing was completed on June 2, 2000, and oral argument held on June 14, 2000.

The District Court filed its Memorandum Opinion and Order on September 30, 2000, granting in part and denying in part defendants' Motion to Dismiss, granting defendants' Motion

for Summary Judgment, and denying plaintiff's Motion for Summary Judgment. Specifically, the Court determined that Tozzi, Empire State Restaurant & Tavern Association, and Greenbaum & Gilhooley's, had failed to demonstrate sufficient injury to permit standing. Mem. Op. At 6-7. The Court concluded that plaintiff Brevet had met the requirements of Article III standing. Id. at 8. With respect to the merits, the Court, after noting that an agency's interpretation of its own regulations must be given "substantial deference" by a reviewing court, id. at 10 (citing Thomas Jefferson University v. Shalala, 512 U.S. 504, 512 (1994)), determined that the agency's interpretation of its criteria was "eminently reasonable."

On October 4, 2000, plaintiff moved for an injunction pending appeal, which the District Court denied on November 15, 2000. On October 13, 2000 plaintiff filed its Notice of Appeal. On November 17, 2000, plaintiffs moved the Court of Appeals for an injunction pending appeal; defendant opposed this motion and moved for summary affirmance. The Court denied both plaintiff's motion for an injunction and defendant's motion for summary affirmance on December 15, 2000.

Factual Background

1. The Report on Carcinogens and the Revisions to the Listing Criteria

In 1978 Congress passed Public Law 95-622, 92 Stat. 3412, 3435-36, (42 U.S.C. § 241 (b)(4)), which authorized and required defendants to publish an annual Report on Carcinogens ("RoC"). The statute was amended in 1993 by section 2009 of Public Law 103-43, 107 Stat. 122, 213 to provide for a biennial, rather than annual, RoC. Congress has mandated that the RoC include, inter alia, a list of all substances which are either "known" to be carcinogens or "may reasonably be anticipated to be carcinogens" and to which a significant number of persons living

in the United States are exposed. 42 U.S.C. § 241(b)(4). Congress proposed the creation of the RoC in response to recommendations by scientists that a list of all known or suspected carcinogens be made available as part of a program to inform and educate both the public and health care professionals of the risk of environmental, dietary and occupational exposure to carcinogens. See H.R. Rep. No. 1192, 95th Cong., 2d Sess., at 18-22, 28. Mot. Dismiss Ex. 1. Significantly, the RoC has no direct regulatory effect.

The RoC's enabling statute does not provide criteria for listing a substance either as a known carcinogen or as reasonably anticipated to be a carcinogen. 42 U.S.C. § 241(b). Criteria for such listings were first promulgated and published by HHS in December 1982. R., Ex. 4, Third Report, 1982, at Introduction, pp. 8-9. The original 1982 criteria were:

Known to be Carcinogens:

> There is sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between the agent and human cancer.

Reasonably Anticipated to be a Human Carcinogen:

> A. There is limited evidence of carcinogenicity from studies in humans, which indicates that casual interpretation is credible, but that alternative explanations, such as chance, bias or confounding, could not adequately be excluded, or
>
> B. There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates that there is an increased incidence of malignant tumors: (a) in multiple species or strains, or (b) in multiple experiments (preferably with different routes of administration or using different dose levels), or (c) to an unusual degree with regard to incidence, site or type of tumor, or age at onset. Additional evidence may be provided by data concerning dose-response effects, as well as information on mutagenicity or chemical structure.

At a series of public meetings, beginning primarily in April 1995, it was proposed that the RoC listing criteria be expanded to include a broader array of information related to the

carcinogenic process. See R., Ex. 2, Eighth Report, 1998 Summary at 2. Revisions to the original listing criteria were first proposed at an April 24-25, 1995 meeting of the National Toxicology Program ("NTP") Board of Scientific Counselors Ad Hoc Working Group. See R. Ex. 5, at 2; see also R. Ex. 8 at 3. At the April 24-25 meeting, one of the primary topics of discussion was the "incorporation of mechanistic data as part of the criteria for listing substances in future Reports . . ." R., Ex. 5, at 2. Individual "break-out" groups were assembled and each group commented on the use of mechanistic data in the listing criteria. See generally R. Ex. 5. "Mechanistic data" includes genetic and related endpoints in humans, studies of biomarkers of exposure and effect, and studies of mechanisms of action using human tissues in vitro. R., Ex. 23 at 1.

Proposed listing criteria revisions were drafted and published in the Federal Register on June 8, 1995. See R., Ex. 6, 60 Fed. Reg. 30435. The proposed revisions were then reviewed and discussed at an NTP Board meeting. R., Ex. 7 at 3-9. Following discussion and public comment, it was "moved that mechanistic information should be included in the selection process for agents to be listed in the [RoC]." Id. at 7. The motion passed unanimously. Id. *Critically, at no point during the discussions of mechanistic data was it agreed or decided that such data should be used only for the reasonably anticipated and not for the known category.*

The references to mechanistic data were put in an explanatory paragraph that was placed at the end of the listing criteria. See Ex. 5, at 6; see also Final Criteria at R. Ex. 2, Eighth Report, Summary at 2; R. Ex. 1 Draft Background Document ("DBD") at LC-1. As printed, the draft of this explanatory paragraph had wider margins that either of the two specific listing categories. See R., Ex. 5, at 6. A later draft of the explanatory paragraph was placed above both specific

listing criteria. See R. Ex. 7, last page. Ultimately the explanatory paragraph was again placed at the bottom in the final draft. See R., Ex. 8 at 4.

The minutes of the January 26, 1996 NTP Executive Committee Meeting state that "Dr. Jameson then read a final paragraph which applies to all the criteria and discussed the role of scientific judgment, and other relevant information . . ." R., Ex. 11 at 8 (first page); see also R. Ex. 12 at 3-5. Further, during the June 29, 2995 NTP Board meeting, the participants discussed whether evidence of compelling mechanistic data could support the listing of a substance as a human carcinogen even if good epidemiological data was absent. Dr. Carl Barrett, NIEHS Scientific Director, stated that a chemical or agent could be listed as a known carcinogen, even lacking convincing epidemiological evidence, if a consensus of experts agreed that available mechanistic data strongly supported the chemical being a human carcinogen. R. Ex. 7 at 5.

The final version of the revised criteria was adopted by the Secretary on or about September 13, 1996, and was published in the Federal Register on September 26, 1996. See R., Ex. 13 at 2, 61 Fed. Reg. 50499. The revised criteria are as follows:

Known to be a Human Carcinogen:

> There is sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between exposure to the agent, substance or mixture and human cancer.

Reasonably Anticipated To Be A Human Carcinogen:

> There is limited evidence of carcinogenicity from studies in humans, which indicates that causal interpretation is credible, but that alternative explanations, such a chance, bias, or confounding factors, could not be adequately excluded, or
>
> There is sufficient evidence of carcinogenicity from studies in experimental animals which indicates that 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, however; the agent, substance or mixture belongs to a well-defined, structurally-related class of substances whose members are listed in a previous Annual or Biennial Report on Carcinogens as either a known to be human carcinogen, or reasonably anticipated to be human carcinogen or there is convincing relevant information that the agent acts through mechanisms indicating that it would likely cause cancer in humans.

Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes but is not limited to dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub populations [sic], genetic effects, or other data relating to mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans. R. Ex. 2, at 2.

When the final revised criteria were published in the Federal Register, the accompanying text states that at "each step of the review process there was concurrence with the following points . . . (2) mechanistic information should be used as part of the listing criteria." R., Ex. 13 at 1; 61 Fed. Reg. 50499. (emphasis added). The Federal Register text also notes just above a printing of the descriptive paragraph containing the reference to mechanistic data that "the following descriptive paragraph has been added to the criteria." Id. (emphasis added). Nowhere does the Federal Register text differentiate between the known category and the reasonably anticipated category with respect to the use of mechanistic data to support a listing. Shortly after the final adoption and publication of the revised criteria, Dr. George Lucier, Director of the Environmental Toxicology Program at the National Institute of Environmental Health Sciences ("NIEHS"), stated, at the October 30, 1997 NTP Board Meeting, that mechanistic data applied to both categories. See R. Ex. 16 at 7. Dr. Lucier made similar comments in December, 1998, and

noted that mechanistic data "impact both categories." See R. Ex. 25 at 10.

On April 2, 1999 and April 19, 1999, defendant published clarifications concerning the listing criteria in the Federal Register. Am. Compl. Ex. 27, 28. These clarifications, explained that "since these criteria were first published on September 26, 1998 [sic – 1996] (61 FR 50499), the [descriptive] paragraph has applied to both the 'known to be a human carcinogen' and the 'reasonably anticipated to be a human carcinogen' categories and will continue to apply."

2. Scientific Review and Publication of the RoC

Listing a substance in the RoC involves a six step review process. The process begins when nominations for listing or delisting an agent, substance, mixture or exposure circumstance are submitted to the NTP. The proposed substances are announced in the Federal Register, trade journals, and NTP publications to solicit public comment. R. Ex. 2, at 3.

The nominations and comments are first evaluated by an NIEHS/NTP Report on Carcinogens Review Committee (known as "RG1"). The RG1 is composed of scientists from NIEHS. Id. at 3 & Appendix B at 229 (listing participants) and Appendix C at 231. If the nomination warrants formal consideration, a search of pertinent databases will be performed, available citations will be reviewed, and a draft background document (DBD) containing all relevant information for application of the criteria for listing is prepared. Id. at 3, 231. The RG1 formally reviews the nomination and makes a recommendation concerning listing or delisting to the Director, NTP. Id. at 3, 231.

The second review phase is done by the NTP Executive Committee's Interagency Working Group for the RoC (known as "RG2"). Id. at 4, 231. The RG2 is composed of scientists (in addition to those from the defendants DHHS, NIH and NIEHS), from a number of

federal agencies. Id. at 4 & n.2, 229 (listing the agency representation). Upon completion of its review, RG2 provides comments and recommendations for changes or additions to the DBD and also makes its recommendation to the Director, NTP, for listing or delisting the substance.

The third review phase is performed in an open, public forum by a subcommittee (NTP Board RoC Subcommittee) of the NTP Board of Scientific Counselors, a chartered advisory committee. Id. at 4, 232. Prior to the public meeting, a notice is published in the Federal Register, trade journals, and NTP publications soliciting public comment on the nominations. Background documents are also made available to the public on request. The nominations and all related materials are then reviewed in a public meeting with an opportunity for the submission of both written and/or oral comments during the review meeting. Id. at 4, 232. Upon completion of its review, the NTP Board RoC Subcommittee provides comments and recommendations for any changes/additions to the draft documents, and a recommendation is made to the Director, NTP, for listing or delisting the substance.

Following review by the three scientific groups, a list of those agents that are recommended for listing or delisting is published in the Federal Register, trade journals and NTP publications, and final public comment is solicited. Id. The recommendations of the RG1, the RG2 and the NTP Board RoC Subcommittee and all public comments are then presented to the NTP Executive Committee, an interagency group, for the fourth, independent review phase, including comment and recommendations to the director, NTP. Id. at 232.

Fifth, the NTP Director takes the four independent recommendations from the RG1 and the RG2, the NTP Board RoC Subcommittee and the NTP Executive Committee, and reviews the proposed listings and makes decisions about what to list or delist. Id. The NTP director then

submits the final draft RoC to the Office of the Secretary. Id. The sixth and final review of the RoC is performed by the Office of the Secretary. Upon final review and approval of the Secretary, the RoC is submitted to Congress and a notice is published in the Federal Register identifying all newly listed or delisted substances and announcing the publication and public availability of the latest version of the RoC.

3. The Listing of Dioxin

2, 3, 7, 8-Tetrachlorodibenzo-*p*-dioxin (TCDD) or simply "dioxin," is a colorless, microscopic needle-shaped chemical compound. See R., Ex 1, DBD, at 1-1 to 2-2. It is chemically very stable, and it therefore remains in the atmosphere, soil, water and human tissue for long periods of time. Id. Dioxin is not produced commercially at this time except as a research chemical. R., Ex. 1 at 1-2. It has been detected in commercial samples of previously produced herbicides and defoliants, including Agent Orange. Id. It is also created as an unwanted by-product of paper and pulp bleaching, incineration of municipal, toxic and hospital wastes, and transformer fires and smelters. Id. at 2-2. Currently, dioxin is predominantly spread via "atmospheric fall-out" into soil and water, where it ultimately finds its way into most living creatures. Id. It is likely that every human being retains some level of dioxin in his or her body. See Def. Reply, Ex. D.

In February 1997, the International Agency for Research on Cancer ("IARC"), a subgroup of the World Health Organization, voted to upgrade its listing of dioxin to IARC's highest category, "Group 1." R., Ex. 1, DBD at 26, 343. An IARC Group 1 listing indicates that "the agent is carcinogenic to humans;" Id. at 26, 343 (emphasis added). Following the IARC decision to list dioxin as a known human carcinogen, NTP proposed upgrading the dioxin listing

in the RoC. A notice announcing the intent to review dioxin for possible listing in the 9th RoC as a "known human carcinogen" was published in the Federal Register on July 11, 1997. See 62 Fed. Reg. 37272-73. Prior to the proposed upgrade, dioxin had been listed in the RoC as "reasonably anticipated to be a human carcinogen." R., Ex. 2, Eighth RoC at 195.

An initial DBD was circulated to RG1, which after review recommended, on September 4, 1997, that dioxin be listed as a known human carcinogen. See R., Ex. 18, 27. The second review phase of the dioxin nomination was done by RG2, the NTP Executive Committee's Interagency Working Group for the Report on Carcinogens. On September 16, 1997, RG2 recommended the listing of dioxin as a known carcinogen in the RoC. Id.

A September 30, 1997 draft background document (DBD) for dioxin was prepared incorporating the changes and recommendations of RG1 and RG2. See generally R., Ex. 1. This draft listing for dioxin outlined and summarized the scientific findings supporting the proposed dioxin listing. These findings indicate that dioxin is known to be a human carcinogen based on (1) human studies that found "an association between dioxin exposure and cancer mortality with respect to all cancers combined, non-Hodgkin's lymphoma, and lung cancer"; (2) "studies in experimental animals that have shown that TCDD induces benign and malignant neoplasms at multiple tissue sites in multiple species"; and (3) a "compelling body of evidence [that] indicates a basic similarity in the mechanism of induction of animal and human biochemical and toxicological responses to TCDD and comparable doses and tissue levels." See R., Ex. 1, DBD at RC-1. The DBD reviewed the dioxin epidemiological studies and noted that the IARC monograph determined that the epidemiological evidence was "limited" for the carcinogenicity of dioxin in humans. See R. Ex. 1, DBD at ¶ 3.0, p. 3-1. The DBD also noted that IARC had

concluded that the epidemiological evidence overall showed that, "the strongest evidence of increased cancer mortality is for all cancers combined rather than for cancers of any particular sites." Id. at ¶ 3.0, p. 3-2.

The Federal Register published an October 2, 1997 notice soliciting comments on the substances nominated for listing or upgrading, including dioxin. See R., Ex. 15, 62 Fed. Reg. 51674-75. The third peer review committee, the NTP Board RoC Subcommittee, met in a public review session on October 30 and 31, 1997. See R., Ex. 16, at 267-340. At the close of the discussion, the members voted, 4 yes, 3 no, and 1 abstention to recommend listing dioxin under the "Known to Be a Human Carcinogen" category. Id. at 339-40, and R., Ex. 17, at 13-17; Ex. 18 at 1.

On March 19, 1998, a notice was published in the Federal Register soliciting final public comments on the nomination of dioxin. See R., Ex. 18 at 1. Stating that the October 30-31 public review of dioxin may not have been adequate, Dr. Kenneth Olden, the director of NTP and NIEHS, ordered a re-review of the dioxin listing by the Board RoC Subcommittee. See R., Ex. 19 at 1. The public comment period was extended until June 15, 1998, and written statements were again requested in addition to oral presentations for the meeting of the NTP Board RoC Subcommittee on December 2 and 3, 1998. See id. and R., Ex. 22 at 1-2. A supplement to the DBD for dioxin was also prepared. See R., Ex. 24. On re-review at the public meeting, the dioxin listing was again debated. R., Ex. 25 at 17-80 and Ex. 26 at 2-5. At the close of the meeting, the NTP Board RoC Subcommittee voted against the upgrade by a vote of 5 yes, 7 no, and 1 abstention. See R., Ex. 25 at 84-85, and Ex. 26 at 5, and Ex. 27 at 2.

NTP again solicited final public comments on the nomination of dioxin on December 14,

1998. See R., Ex. 27 at 1-2. The NTP Executive Committee subsequently voted on February 24, 1999 affirmatively to recommend listing dioxin as "Known To Be A Human Carcinogen." See R. Ex. 28 at 5, and Ex. 29 at 1. This listing proposal was then forwarded to Kenneth Olden, and in early spring 2000, he recommended that dioxin be upgraded to a known human carcinogen. Finally, on April 25, 2000, then-Secretary Shalala approved for publication the final draft of the Ninth Report on Carcinogens, and approved the listing of dioxin as a known human carcinogen. After this Court denied appellants' Motion for an injunction, appellees published, on January 19, 2001, an addendum to the 9th RoC containing the final dioxin listing ("Dioxin Addendum"). Dkt. Ref. 47.

SUMMARY OF ARGUMENT

It is unnecessary for the Court to delve into the merits of this case because it is plain that none of the appellants have standing to bring this action. Brevet Industries and Brevet Inc. ("Brevet") manufacture certain polyvinyl chloride ("PVC") products, which, when burned, produce dioxin. Brevet claims that the listing of dioxin as a known human carcinogen may result in local, state or other regulatory entities enacting measures that may have an impact on Brevet's sales, or, in the alternative, that purchasers of Brevet's products may reduce purchases of PVC products. But, Brevet's claim of injury is wholly speculative, depends in large part on the political process and/or decisions of third parties not before the Court, is plainly not caused by the RoC listing, and cannot be redressed by an action of the Court.

The other group of appellants, the "Restaurant Appellants," speculate that the dioxin listing will result in a widespread "food scare" that will allegedly cause people to stop dining in restaurants (or at least from ordering certain entrees), resulting in a loss of revenue. With respect

to their assertion of injury, it must be noted the dioxin addendum was released some six months ago, and no food scare has occurred. Appellants have marshaled no record evidence to support their notion that the listing of a substance as a known carcinogen in the RoC has ever resulted in a palpable "scare." Further, the number of authorities reporting the dangers of dioxin are legion, and it strains credulity to expect that this particular listing (or any scientific publication) will lead to widespread panic in 2001 that will impact on restaurant traffic.

This case may also be dismissed separate and apart from the merits because the 9th RoC is not agency action subject to review under the APA. Both Congress and the agency have characterized the RoC as an informational document, not a regulatory one. Nor is the RoC published in the Federal Register or the Code of Federal Regulations. Finally, the RoC itself has no direct binding effect on any person or entity.

Turning to the merits, the gravamen of plaintiff's claim is that the agency improperly applied its own listing criteria in relying, in part, on human mechanistic data in making the determination to list dioxin as a known carcinogen. Of course, an agency's interpretation of its own regulations is entitled to substantial deference by a reviewing court. Armed with that presumption, it is plain that appellees' interpretation of their listing criteria is, as the District Court found, eminently reasonable. Moreover, the record evidence supporting the agency's interpretation is considerable, if not overwhelming.

Appellants make a number of subsidiary arguments related to their central claim that the agency misinterpreted its own regulations, arguing that 1) the agency's interpretation contravenes congressional intent because the known and reasonably anticipated categories have allegedly been conflated; 2) that the agency has not adequately justified its decision to use mechanistic data

to support listings in the RoC; 3) and that the issuance of the final dioxin listing violated the formal RoC review procedures because the final listing differs from the DBD. Each of these claims are plainly belied by record evidence.

ARGUMENT

4. Plaintiffs Lack Standing to Challenge the Actions Taken by Defendants.

The standing and reviewability arguments present questions of law that this Court reviews de novo. See Eldred v. Reno, 239 F.3d 372, 374-75 (D.C. Cir. 2001). The APA argument is reviewed de novo under the familiar arbitrary and capricious standard.

Under Article III, section 2 of the Constitution, federal courts only have jurisdiction to hear and decide "cases" or "controversies." Allen v. Wright, 468 U.S. 737, 750 (1984). One aspect of this limitation is the “irreducible constitutional minimum” that a plaintiff must establish that he has standing to sue. See U.S. Airwaves, Inc. v. Federal Communications Commission, 232 F.3d 227, 232 (D.C. Cir. 2000) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). "The standing inquiry focuses on whether the plaintiff is the proper party to bring this suit, although that inquiry 'often turns on the nature and source of the claim asserted.'" Raines v. Byrd, 521 U.S. 811, 818 (1997) (quoting Warth v. Seldin, 422 U.S. 490, 500 (1975)) (internal citation omitted). The Supreme Court has always demanded strict compliance with the standing requirement. See Allen, 468 U.S. at 752.

Importantly, Article III standing “is not merely a troublesome hurdle to be overcome if possible so as to reach the 'merits' of a lawsuit which a party desires to have adjudicated." Valley Forge Christian College v. Americans United for Separation of Church and State, Inc., 454 U.S. 464, 476 (1982). To the contrary, it is an "essential and unchanging part of the

case-or-controversy requirement of Article III." Defenders of Wildlife, 504 U.S. at 560.

Article III standing requires satisfaction of three elements. First, a plaintiff must "have suffered an 'injury in fact'--an invasion of a judicially cognizable interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." Bennett v. Spear, 520 U.S. 154, 167 (1997) (citing Defenders of Wildlife, 504 U.S. at 560-61). The imminence requirement "ensure[s] that the alleged injury is not too speculative for Article III purposes--that the injury is 'certainly impending.' " See Defenders of Wildlife, 504 U.S. at 564 n. 2 (quoting Whitmore v. Arkansas, 495 U.S. 149, 155 (1990)). Second, there must be a causal connection between the injury alleged and the conduct complained of; the injury must be fairly traceable to the defendant's acts and not the result of conduct by a third party not before the court. Finally, it must be likely, as opposed to speculative, that the injury will be redressable through a court's favorable disposition of the matter. See Bennett, 520 U.S. at 167; Defenders of Wildlife, 504 U.S. at 560-61. Moreover, "[t]he party invoking federal jurisdiction bears the burden of establishing these elements." Id. at 561 (citing FW/PBS, Inc. v. Dallas, 493 U.S. 215, 231 (1990); Warth, 422 U.S. at 508). In this matter, no plaintiff satisfies the requisites for standing,[1] and, therefore, dismissal for lack of jurisdiction is proper.

Significantly, *none of the appellants in this case have asserted that they will directly face any additional regulatory or administrative constraint or hardship if dioxin is listed as a known*

[1]Appellants claim, albeit obliquely, that this Court need not revisit the issues of standing because defendants have not cross-appealed. Of course, it is settled that an appellee may defend a judgment won below on any ground supported by the record without filing a cross-appeal. See United States v. Chrysler Corporation, 158 F.3d 1350, 1355 (D.C. Cir. 1998) (citing United States v. American Ry. Express Co., 265 U.S. 425, 435 (1924). Nor may a party appeal a judgment in its favor.

carcinogen. They make no claim that the effect of publication of the 9th RoC will automatically set in motion any legal norm or obligation to which they must adhere.

1. The Manufacturer Plaintiffs Do Not Have Standing.

Brevet makes medical tubing connectors that use polyvinyl chloride ("PVC") plastic. PVC-based plastic, when burned, apparently produces dioxin as an unwanted by-product. See Comp. Ex. 6A at ¶ 17, 19-20; see also R., Ex. 1, DBD at 2-1. Brevet claims injury because the cities of San Francisco, Oakland and Berkeley, California have all, within last two years (but prior to the issuance of the dioxin addendum), passed resolutions setting as a generalized goal the elimination of PVC incineration and the reduction and/or elimination of PVC plastic use in the Bay Area. See Am. Compl. Ex. 5, 6, 6A. Attached to these resolutions are appendices listing scientific publications or pronouncements supporting the carcinogenicity of dioxin, and among some thirty-plus authorities cited is a reference to the NTP Board of Scientific Counselors of NIEHS, dated 1997. From this, Brevet contends listing dioxin as a known carcinogen will seriously impact sales. Brewer Aff. at ¶ 6.

The notion that Brevet will suffer an economic injury as a result of the upgrading of dioxin to the known category is precisely the type of entirely speculative claim of injury that this Court has routinely rejected. First, the resolutions are simply statements of intent and future goals by these cities; whether the cities will ever act in a manner with consequence, what forms those actions will take, and how, if at all, Brevet will be affected is a game of pure guesswork. See Simon v. Eastern Kentucky Welfare Rights Organization, 426 U.S. 26, 45 (1976) (where speculative inference is necessary to connect an injury to the conduct of defendant, there is no cognizable injury). Indeed, these city resolutions merely passed on their dioxin reduction goals

to a regional task force on dioxin, the political authority and power of which is unclear, to say nothing of whether the stated dioxin reduction goals will ever become binding law that will have a demonstrable impact on Brevet. See Amen. Comp. Ex 5 at 3, Ex. 6 at 3, Ex. 6A at 5. Reliance on a political outcome as a precondition to injury is the paradigm of speculation. Cf. Wisconsin Gas Co. v. Federal Energy Regulatory Comm'n, 785 F.2d 669, 674 (D.C. Cir. 1985). Even taking the unjustified leap that regulation is down the road, it still cannot be stated with reasonable certainty which of Brevet's customers will stop buying PVC plastic, when they will stop, or how Brevet will ultimately be impacted. In sum, there is no plausible claim that Brevet's purported injuries are either "actual" or "imminent." There are a number of contingent events that may never transpire, and the time between the issuance of the dioxin addendum and any economic impact on Brevet is, at best, years in the offing. See Whitmore, 495 U.S. at 158. This truly presents the situation where the Court is being called on to render an advisory opinion by "deciding a case in which no injury would have occurred at all." Defenders of Wildlife, 504 U.S. at 564 n.2.

Nor can Brevet satisfy the causation prong of the standing analysis. The RoC itself has no tangible or direct impact upon the behavior of others. It is purely an informational document, and prevents no one from buying or incinerating Brevet's products. Rather, Brevet's argument is based on the notion of indirect causation – that publication of the RoC will cause local or other governmental bodies to pass laws reducing or eliminating the use of PVC plastics, or that buyers will stop purchasing Brevet's products. See Brewer Aff. at ¶ 10. But, the law is clear that the defendant must be the cause of the injury. "Causation, or 'traceability,' examines whether it is substantially probable that the challenged acts of the defendant, not of some absent third party,

will cause the particularized injury of the plaintiff." Florida Audubon Soc'y v. Bentsen, 94 F.3d 658, 663 (D.C. Cir.1996) (en banc) (citations omitted). See also Allen, 468 U.S. at 753 n.19; Microwave Acquisition Corporation v. FCC, 145 F.3d 1410, 1412 (D.C. Cir. 1998).

Here, it is plain that there is no cause and effect between defendants' conduct – publication of the RoC – and Brevet's alleged injury. None of the resolutions referenced by Brevet were enacted as a result of the upgrade – they all predated the upgrade. Plainly, local governments had taken an interest in dioxin long before, and wholly independent of, the 9th RoC. None of the resolutions suggest that the upgrade would have any demonstrable impact upon future actions that the cities may (or may not) take. In fact, each of the resolutions already states that "dioxin is a known human carcinogen," which flatly obviates any claim that the upgraded listing in the RoC is of any moment. See Am. Compl. Ex 5, 6, 6A. Moreover the inclusion of the NTP Board of Scientific Counselors was merely one among some 34 references supporting the resolutions. There is no evidence in the record suggesting that the NTP reference is of singular importance such that the course set upon by these city governments would be altered by upgrading dioxin.

The same failure to demonstrate causation applies to Brevet's claim that they will be injured by the actions of buyers of PVC products. "When considering any chain of allegations for standing purposes, we may reject as overly speculative those links which are predictions of future actions (especially future actions to be taken the third parties) . . ." United Transportation Union v. Interstate Commerce Commission, 891 F.2d 908, 912 (D.C. Cir. 1989). Here, Brevet's claim of injury depends entirely upon the conduct of third parties not before the Court. See Florida Audubon, 94 F.3d at 663. Marketplace decisions to buy PVC plastic are governed by a

wide variety of factors beyond any RoC upgrade of dioxin. Attached to the Brewer Affidavit is an article indicating that Tenet Healthcare, a corporate operator of over 120 hospitals nationwide, will on its own accord seek to buy and use medical supplies that are not made from PVC plastic. See Brewer Aff. at ¶ 8. That corporate decision was made voluntarily and wholly independent of any action by defendants.[2] See id. In fact, the article does not even mention the RoC. Moreover, this decision was made well in advance of the finalization or issuance of the dioxin addendum. Consequently, the decision by Tenet Healthcare actually supports appellees' argument that marketplace events are not authorized, permitted, or caused by publication of the RoC. Tenet's action is plainly not "fairly traceable" to the RoC, and therefore, no causation for purposes of Article III standing exists. See Microwave Acquisition Corp., 145 F.3d at 1412.

Finally, Brevet's alleged future harm could not be redressed by a decision of this Court. See University Medical Center of Southern Nevada v. Shalala, 173 F.3d 438, 441 (D.C. Cir. 1999). Even were appellants to convince the Court that the decision to upgrade dioxin was arbitrary and capricious, remand and entry of an order calling for a downgrading would not solve Brevet's problems. The resolutions cited by appellants were enacted prior to the upgrade, and there is no evidence suggesting that they would be withdrawn or modified should appellants prevail. Similarly, Brevet has not pointed to a single purchaser of PVC products whose behavior is somehow tied to the listing decision.

2. The Restaurant Appellants Do Not Have Standing.

[2]Brevet has not, in any event, alleged that it sold PVC plastic products to Tenet or that it will lose business as a result of Tenet's decision.

The purported injury claimed by Empire State Restaurant & Tavern Association, Greenbaum & Gilhooley's (hereafter "restaurant appellants") and Jim Tozzi [3] is equally speculative, depends on contingent events which may or may never occur – in fact, ***have not occurred*** – and therefore cannot support Article III standing.

Appellants claim that the 9th RoC's statements on dioxin "vilify" the foods that the restaurant appellants serve most frequently, *i.e.* meat, dairy products, and fish. Appellants' Br. at 48. The Appellants claim that publication of the 9th RoC will result in the, "creation of a 'food scare' resulting in reduced public consumption of meats, including poultry, dairy products, and fish. [Appellants] would also face the practical necessity of expending effort and money to locate and provide such foods which are not so contaminated." Am. Compl. at ¶ 39.

"A plaintiff must allege that he has been or will in fact be harmed by the challenged

[3]Appellant Jim Tozzi's continued status as a party is puzzling. Dr. Tozzi was initially a plaintiff by virtue of his role as an investor in the BeDuCi restaurant, which was at one time a party. See Amended Complaint at ¶ 27. However, BeDuCi, by stipulation, dismissed itself from this case on July 7, 2000. Though the Stipulation stated that the dismissal of BeDuCi would not affect the status of other plaintiffs, it is well-settled that parties may not consent to standing. "[N]o action of the parties can confer subject-matter jurisdiction.'" National Resources Defense Counsel v. Pena, 147 F.3d 1012, 1021 n.3 (D.C. Cir. 1998). Mr. Tozzi's role as someone who provides advice and counsel "on regulatory matters before federal and state governmental agencies, including listing proposals for the RoC program," Am. Compl. at ¶ 24, is insufficient to confer standing.

agency action, not that he can imagine circumstances in which he could be affected by the agency's action." United States v. SCRAP, 412 U.S. 669, 688-89 (1973). See also id. (requiring something more than "an ingenious academic exercise in the conceivable" to support standing). The speculation of economic injury due to a "food scare" is entirely a flight of fancy by the restaurant plaintiffs. They hypothesize a "food scare" by referencing articles about a dioxin food contamination incident in Europe in spring 1999, in which animal feed was found to be laced with dioxin. See Pl. Opp., Ex. 5-19, 23. The restaurant plaintiffs seek to compare apples and oranges in the hopes of establishing cognizable injury. The "food scare" reported in the articles resulted from *actual contamination of the food supply, not from the issuance of a scientific report*. See id. Indeed, the affidavit of Michael G. Leonard, owner of Greenbaum and Gilhooley's, nicely illustrates this illogical bootstrapping:

> Following news of the dioxin food contamination incident in Europe this spring [1999], I read with interest and great concern in the *New York Times* and elsewhere reports on the effect of the dioxin scare on restauranteurs and other food purveyors. Those reports explain that as a result if the news that dioxin had entered the food supply, food supplies were disrupted, and many restaurants were forced to eliminate meat and dairy products from their menus. *I know of no reason why news of dioxin contamination of the food supply would have a different effect in this country*.

Leonard Aff. at ¶ 3 (emphasis added). But, what is at issue in this case is not a report about contamination, but rather a report concluding that dioxin is a "known," as opposed to a "reasonably suspected" carcinogen. Stripped of its inapposite premise, this claim of injury cannot sustain scrutiny.

Nor can the restaurant plaintiffs establish causation, as they cannot legitimately argue that the mere publication of a scientific report stating that dioxin is a known human carcinogen will

cause widespread panic. That dioxin is carcinogenic and a hazardous substance is hardly the stuff of banner headlines in the year 2001. The Working Group of the International Agency for Research on Cancer (IARC) concluded in a 1997 report that dioxin was carcinogenic to humans. See Comp. at ¶ 51. The Environmental Protection Agency already regulated dioxin as a hazardous waste and toxic pollutant under the Clean Water Act (CWA), 40 C.F.R. § 132.6; the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 40 C.F.R. § 173.2; the Resource Conservation and Recovery Act (RCRA), 40 C.F.R. §§ 261, 266, 268; the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 40 C.F.R. § 3024 and the Toxic Substances Control Act (TSCA), 40 C.F.R. § 707, 766. The FDA regulates dioxin in beverages, specifically bottled water. See 21 C.F.R. § 165.110. NIOSH has recommended the exposure limit to dioxin be the lowest feasible concentration. OSHA regulates dioxin under the Hazard Communication Standard and as a hazardous chemical in laboratories. See 29 C.F.R. § 1910.1450. Moreover, it cannot be overlooked that dioxin has been listed in the RoC as a suspected carcinogen for twenty years. Plainly, with all of the foregoing pronouncements concerning dioxin, it simply cannot be argued that any purported injury to these restaurants is "fairly traceable" to the upgrade in the 9th RoC.

It is noteworthy that the final listing of dioxin was issued in January 2001 and, some six months later, there has not been any "food scare." The dire prediction of "banner headlines," Tr. at 14, has not come to pass. See also Am. Compl. at ¶ 44. Plainly, the speculative injury that plaintiffs claimed would result from publication of the RoC has not come to pass, and there is no

reason to suspect that it suddenly will.[4]

[4]In light of the fact that the Ninth RoC has been issued, and the addendum identifying dioxin as a known human carcinogen released, this entire matter has arguably been rendered moot. "[I]f an event occurs while a case is pending on appeal that makes it impossible for a court to grant 'any effectual relief whatsoever' to a prevailing party, the appeal must be dismissed [as moot]." Church of Scientology of California v. United States, 506 U.S. 9, 12 (1992). Here, plaintiff's injury was entirely predicated on the fact that the listing decision would be published, disseminated and widely distributed. They claim, in their Amended Complaint that "[a]s a practical matter, it would not be possible to retrieve and rescind such information." Am. Compl. at ¶ 47. As appellants purported injury stems exclusively from the dissemination of information, and that information has been disseminated and out for six months, it is questionable whether the court can fashion an effective remedy.

Finally, as the District Court noted, the Restaurant Plaintiffs failed to present sufficient evidence as to how a purported "food scare" would uniquely affect them. See Dkt. Ref. 62, at 6-7. They claim that a dioxin scare might impact sales of beef, veal, poultry, fish and dairy, but have not adequately shown how they would suffer an injury distinct from any other restaurant, grocery store or other food supplier who sells this variety of products.[5] Plainly, these parties are not being affected in a "personal and individual way" such that Article III standing is proper. Animal Legal Defense Fund, Inc. v. Glickman, 154 F.3d 426, 433 (D.C. Cir. 1998).

In sum, none of the plaintiffs have demonstrated an sufficient injury in fact, causation or redressibility so that a case or controversy exists. Therefore, this matter should be dismissed.

2. The Agency's Publication of the Ninth Roc Is Not a Reviewable Agency Action Subject to Judicial Review.

"The APA authorizes review of 'agency action made reviewable by statute and final agency action' for which there is no other adequate remedy in a court." Industrial Safety Equipment Ass'n, Inc. v. EPA, 837 F.2d 1115, 1117 (D.C. Cir. 1988) (quoting 5 U.S.C. § 704). Reviewable agency "rules" under the APA are defined as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy." 5 U.S.C. § 551(4). This Court has held that "Congress did not intend that [this definition] be construed so broadly that every agency action would be subject to

[5]In fact, it could be just as convincingly argued that increased sensitization to dioxin by the public would *benefit* these restaurants. As made clear in the Affidavit of Michael J. Leonard, Greenbaum & Gulhooley's prepares "fine meals" and that their patrons "expect high quality, value and purity." Leonrad Aff. at ¶ 2. Surely it is possible that, in the wake of increased sensitivity about dioxin by the public, restaurant patrons would engage in a "flight to quality," seeking out higher end restaurants such as Greenbaum and Gulhooley's. The point is that the ultimate effect on the restaurant plaintiffs is a plain exercise in speculation.

review." Industrial Safety, 837 F.2d at 1119. Here, the RoC is merely an informational document that has no direct future effect, and, consequently, is not subject to review under the APA.

In determining whether final agency action is subject to judicial review under the law of this circuit, a Court is to review several factors, including, (1) the agency's own characterization of the action, (2), whether or not it is published in the Federal Register or Code of Federal Regulations, and (3) whether it has a binding effect on parties' rights and on the agency's ability to exercise discretion in the future. American Portland Cement Alliance v. EPA, 101 F.3d 772, 776 (D.C. Cir. 1996); see also American Petroleum Inst. v. EPA, 216 F.3d 50, 68 (D.C. Cir. 2000). Looking at each of these factors, it is clear that the RoC is not agency action subject to APA challenge.

Here, both Congress and the agency have characterized the RoC as an informational document, not a regulatory one. The legislative history behind the RoC establishes that Congress did not intend that the RoC implement policy, alter behavior, or have the force of law. Instead, the RoC was intended to be a "comprehensive document containing an updated list of all known or suspected carcinogenic agents, the nature of exposure and the approximate number of persons exposed . . ." H.R. Rep. No. 1192, 95th Cong., 2d Sess., at 28. Although the RoC was also intended to provide scientists an opportunity to evaluate the "efficacy of appropriate existing regulatory standards," of carcinogenic materials, id., Congress did not mandate that any federal regulations be updated or altered in any way as a result of anything published in the RoC. Equally telling is the RoC preamble which states, "[t]he Report on Carcinogens is mandated by Section 301(b)(4) of the Public Health Services Act, as amended, *and is for informational*

purposes only" R. Ex. 2 (preamble) (emphasis added). See also id. at 1 (stating that the RoCs are "informational scientific and public health documents" and that formal risk assessments are the purview of appropriate federal, state, and local agencies). See Telecommunications Research & Action Center v. FCC, 800 F.2d 1181, 1186 (D.C. Cir. 1986)(an agency's characterization, though not dispositive, gives guidance as to reviewability).

The second factor is whether the RoC is published in the Federal Register or Code of Federal Regulations. "The real dividing point between regulations and general statements of policy is publication in the Code of Federal Regulations . . ." Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533, 539 (D.C. Cir. 1986); see also Industrial Safety, 837 F.2d at 1121. The RoC is not published in the Federal Register. Rather, a notice is published in the Federal Register announcing the availability of the RoC and providing a summary of the newly listed substances. Moreover, no part of the RoC is published in the Code of Federal Regulations.

Finally, the RoC has no direct binding effect on any person or business entity. It is exclusively an informational document listing suspected or known carcinogenic substances. Certainly the RoC has far less coercive effect than the EPA report in American Portland Cement, which this court held was not reviewable. That report affirmatively stated that a particular hazardous substance, cement kiln dust, did not warrant identification and regulation under the existing comprehensive RCRA regulatory scheme because to do so would be "prohibitively burdensome" to the cement industry. Id. at 774, 776-77. Despite the apparently definitive pronouncement that cement kiln dust was not subject to a particular regulatory scheme, the Court held that the report was intended more as an announcement of EPA's intent to regulate cement kiln dust uniquely in the future. Id.

Also substantially similar is Industrial Safety Equipment, 837 F.2d at 1121, in which this circuit held unreviewable, on virtually the same ground as that urged here, a published guide by the National Institute for Occupational Safety and Health ("NIOSH") that ranked 13 different respirators that were designed to protect against asbestos intake. The guide actually stated that NIOSH and the EPA did "not recommend" using 11 of the 13 respirators listed. Id. at 1117. Thus, unlike the RoC, gives no quantitative assessment of the risk associated with the listed carcinogenic substances, the guide reviewed in Industrial Safety was explicitly intended to dissuade people from using specific products. Nevertheless, the Industrial Safety Court held that the Guide was unreviewable under the APA. No administrative or legal consequences flowed from the Guide other than consumers' informed choices, which was held to be insufficient to make the Guide a reviewable "rule" under the APA. The Court noted that the mere fact that an agency action has a "substantial impact" does not thereby transform that action into a reviewable rule. Id. at 1121 (citing American Postal Workers Union v. United States, 707 F.2d 548, 560 (D.C. Cir. 1983)).

Nothing in the 9th RoC approaches the apparent regulatory impact of the reports in either Portland Cement or Industrial Safety. That, in combination with the underlying congressional intent and the informational nature of the RoC, leads inexorably to the conclusion that the Court should hold that the RoC is unreviewable, and, therefore, the case should be dismissed for lack of subject matter jurisdiction.[6]

[6]In briefing before the District Court, plaintiffs noted Synthetic Organic Chemical Manufactures Ass'n. v Secretary, DHHS, 720 F. Supp. 1244, 1249 (W.D. La. 1989) ("SOCMA"), which held that listing decisions in the RoC were reviewable. Appellees respectfully submit that this Court is not bound by a decision of a district court in Louisiana, and

3. The Agency's Decision To List Dioxin Was Not Arbitrary And Capricious.

Even if reviewable, the decision to list dioxin comfortably passes muster under the APA. Under the APA, agency action will be upheld unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). A court should not "substitute its own judgment for that of the agency." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971); see also Troy Corp. v. Browner, 120 F.3d 277, 283 (D.C. Cir. 1997). Appellants raise essentially two core issues on appeal (albeit with numerous sub-arguments): first, that the agency improperly interpreted its listing criteria in listing dioxin as a known human carcinogen; and, second, that issuance of the final dioxin listing violated the formal RoC process because the final listing differs from the summary language in the draft background document. See App. Br. at 2-3. Amici raise an additional issue, that the scientific data supporting the listing are insufficient.

1. Defendants Were Not Arbitrary And Capricious In Interpreting And Applying Their Listing Criteria.

The Supreme Court has made it clear that a court reviews with "substantial deference" an agency's interpretation of its own regulations. See Auer v. Robbins, 519 U.S. 452, 461 (1997); Thomas Jefferson University v. Shalala, 512 U.S. 504, 512 (1994). Indeed, appellees' interpretation of its own regulations "is controlling unless it is plainly erroneous or inconsistent with the [criteria]." Wyoming Outdoor Council v. United States Forest Service, 165 F.3d 43, 52 (D.C. Cir. 1999) (internal quotations and emphasis added); see also National Trust for Historic

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that the Industrial Safety Equipment and Portland Cement decisions of this Court dictate a result contrary to SOCMA.

Preservation v. Dole, 828 F.2d 776, 782 (D.C. Cir. 1987). Critically, in circumstances such as here, where the agency itself has drafted the rule or regulation at issue, not only is the Court's review deferential, it is "more deferential . . . than that afforded under Chevron." National Medical Enterprises, Inc. v. Shalala, 43 F.3d 691, 697 (D.C. Cir. 1995) (citing Stinson v. United States, 508 U.S. 36, 45 (1993)). Indeed, the Supreme Court has made it clear that "broad deference is all the more warranted when . . . the regulation concerns 'a complex and highly technical regulatory program." Thomas Jefferson, 512 U.S. at 512; Wyoming Outdoor, 165 F.3d at 52.

A court "need not find that the agency's construction is the only possible one, or even the one that the court would have adopted in the first instance." Wyoming Outdoor, 165 F.3d at 52. For example, in Rollins Environmental Servs. v. EPA, 937 F.2d 649, 651-52 (D.C. Cir. 1991), the Court sustained an EPA interpretation of its own regulation that the Court believed "would not exactly leap out at even the most astute reader," and was "rather more strained" than the plaintiff's reading of the regulation. Nevertheless, this Court upheld the interpretation because it was consistent with the regulation and "in a competition between possible meanings of a regulation, the agency's choice receives substantial deference." Id.

The final listing for dioxin states, in part:

> 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (2,3,7,8 - TCDD or TCDD) is *known to be a human carcinogen* based on sufficient evidence of carcinogenicity from studies in humans, involving a combination of epidemiological and mechanistic information which indicate a causal relationship between exposure to TCDD and human cancer.

Dkt. Ref. 47. Appellants claim that the agency violated its listing criteria because its

determination was not made exclusively based upon epidemiological studies.[7] Appellants' Br. at 21. Plaintiff's interpretation of the 1996 listing criteria is simply erroneous.

First, looking to the plain text of the listing criteria, it is clear that it permits evaluation and consideration of human mechanistic data in considering the carcinogenic status of any given substance. The known listing language has the phrase "from studies in humans," which may reasonably be interpreted to mean "from human studies." Human studies may reasonably be interpreted to include human mechanistic studies – studies that show the mechanism by which dioxin works on and in human cells, and the connection this mechanism has to cancer. Such an interpretation of the criteria is patently reasonable. See, e.g., Wyoming Outdoor Council, 165 F.3d at 52 (agency's reasonable interpretation of its regulations is controlling); see also Rollins, 937 F.2d at 652.

Furthermore, the final paragraph of the revised criteria states that "[c]onclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information." R., Ex. 2 at 2 (emphasis added). All relevant information includes mechanistic information, as the text of the final paragraph makes clear. This point appellants essentially concede. What they are forced to argue is that the final descriptive paragraph applies only to the reasonably anticipated category, and not the known

[7]Appellants suggest that the agency is misapplying its listing criteria because of the "charged political environment" concerning dioxin. Appellants' Br. at 14; see also Amici Br. at 4. But dioxin is not the only substance listed in the 9th RoC listed as a known carcinogen based on a combination of epidemiological and mechanistic information. Both 1,3 Butadiene and Ethylene Oxide are listed as known human carcinogens based on a combination of epidemiological and mechanistic investigations. See Addendum. Consequently, the notion that the Agency developed this position simply because of the specter of this litigation, see Appellees' Br. at 13, 28, is unsupportable.

category. There is, however, ample evidence in the record demonstrating that it was well known and understood that mechanistic data were to be considered in making listing determinations for either category. This evidence comes from the administrative history leading up to the promulgation of the revised criteria in 1996, the text of the RoC, and agency statements regarding the revised criteria following their publication.

Revisions to the 1982 listing criteria were first proposed at an April 24-25, 1995 meeting of the NTP Board of Scientific Counselors Ad Hoc Working Group. See R. Ex. 5, at 2; see also R., Ex. 8, at 3. At that first meeting, one of the primary topics of discussion was the possible "incorporation of mechanistic data as part of the criteria for listing substances in future reports . . ." R., Ex. 5, at 2 (emphasis added). Individual "break-out" groups were assembled and each group commented on the topic. See generally R. Ex. 5; see also R. Ex. 9 (noting that it was the clear opinion of the ad hoc working group that more mechanistic information should be considered in listing substances in the Report).

The proposed revisions were then published in the Federal Register on June 8, 1995, where, it was stated that, "[t]he recommended revisions [to the criteria] are to permit consideration of more mechanistic information in listing substances in the [RoC]." R., Ex. 6 at 2. There is no suggestion of any intent to limit this to just the reasonably anticipated category. The comments were then presented and discussed at a June 29, 1995 NTP Board meeting. The minutes show that the explicit point raised by appellants here – whether mechanistic information could support listing a substance as a known carcinogen – was raised and addressed:

> Dr. Lucier stated that a point of discussion might be whether there could be compelling mechanistic data that would allow a chemical to be classified a human carcinogen even though it may lack good epidemiological data. Dr. Carl Barrett,

> NIEHS Scientific Director, contended that a chemical or agent could be placed in category 1 [known], lacking convincing epidemiological evidence, if there was a consensus of experts that available mechanistic data strongly supported the chemical being a human carcinogen.

R., Ex. 7 at 5. *This exchange clearly shows that drafters of the revised criteria intended that mechanistic data could be used to support a finding in the known category even where the traditional epidemiological evidence was less than "sufficient."* Thus, it was clear from the outset both that (a) human mechanistic data could be used to consider a listing under the known category, and (b) that such data may, if the evidence supports it, be combined with limited human epidemiological data to jointly support finding "sufficient evidence" of a "causal relationship" between the agent and cancer in humans. See, R., Ex. 7 at 3-9.

Following discussion and public comment, it was "moved that mechanistic information should be included in the selection process for agents to be listed in the [RoC]." Id. at 7 (emphasis added). The motion passed unanimously. Id. Nowhere during the discussions of mechanistic data was it agreed or decided that such data should be used only for the reasonably anticipated and not for the known category.

The references to mechanistic data in the proposed Revised Criteria were then placed in an explanatory paragraph ("descriptive paragraph") that applied to *both* listing categories. This is made clear by the fact that the explanatory/descriptive paragraph was, in some interim drafts, placed *above* the specific language for the two listing categories. See R., Ex. 7, last page; see also R., Ex. 8, at 4; R. Ex. 9, at 2 (stating that the explanatory paragraph should be placed at the beginning of the text).[8] Ultimately the final paragraph was placed below the two listing

[8]Also in these minutes is the recognition that the NTP Board had unanimously approved

categories. See R., Ex. 5, at 6. There is nothing in the record that suggests that the change in placement was intended to narrow its application. Plainly, if the explanatory paragraph had only been intended to refer to the reasonably anticipated category, it never would have been suggested to place it above both listing categories. That simply would have made no sense.

After the explanatory paragraph had been moved back to the bottom, the minutes of the January 26, 1996 NTP Executive Committee Meeting leave no doubt that the explanatory paragraph was to apply to both criteria. The minutes state that "Dr. Jameson then read a final paragraph which applies to all the criteria and discusses the role of scientific judgment, and other relevant information . . ." R., Ex. 11 at 8 (first page); see also R., Ex. 12 at 4-5 (same). Moreover, the original proposed criteria and the version appearing in the published version of the RoC show the explanatory paragraph with wider margins than either of the two specific listing categories, indicating by that format that they apply to both. See R., Ex. 5, at 6; R., Ex. 2, at 2.

The fact that mechanistic data should be used to support listings in the known category should not be surprising; it would be nonsensical for appellees, after considerable debate and discussion, then to preclude the use of mechanistic data, a powerful and emerging tool in toxicologic analysis, for consideration in the known category, which is the highest listing category possible. In addition, appellees' own post-publication statements about the revised criteria, with one exception, show that appellees understood that mechanistic data was to be

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the resolution that "mechanistic information should be used as part of the selection criteria." R., Ex. 8, at 1-2. Again, there was no distinction drawn that mechanistic information could only support listings in the reasonably anticipated category.

considered for listing substances in the known category.

When the final, revised criteria were published in the Federal Register on September 26, 1996, the accompanying text provided a brief summary of the review process. It states that at "each step of the review process there was concurrence with the following points . . . (2) mechanistic information should be used as part of the listing criteria." R. Ex. 13. Critically, the text did not state that mechanistic information should only be used for one of the two "categories," but rather "as part of the listing criteria." The Federal Register text also notes – just above a printing of the descriptive paragraph containing the reference to mechanistic data – that "the following descriptive paragraph has been added to the criteria." Id. Again, had the scope of the application of mechanistic information been limited as appellants suggest, the Federal Register would have stated that descriptive paragraph applied only to the reasonably anticipated category. This Federal Register notice is clear, contemporaneous evidence that mechanistic information could support listings in either category.

Following adoption of the revised criteria, appellees have consistently adhered to the position that mechanistic data can support listings in either category. Shortly after the revised criteria were published, at the October 30, 1997 NTP Board meeting, Dr. Lucier clearly stated that mechanistic data applied to both categories. See R., Ex. 16 at 7.[9] He made similar comments in December 1998, one year later, and noted specifically that mechanistic data "impacts both categories." See R., Ex. 25, at 10. Further, despite appellants' protestations to the contrary, Dr. Lucier is not a "subordinate agency official" – he was the associate director of the

[9]This record evidence also obviates appellants' oft-repeated claim that the agency's position was established only in the face of this litigation. See, e.g., Appellees' Br. at 30.

NTP and the person directly charged with responsibility for the RoC. Consequently, the invocation of Paralyzed Veterans of America v. D.C. Arena L.P., 117 F.3d 579, 587 (D.C. Cir. 1997) inapposite.

On April 2, 1999, HHS published a "Clarification of the Criteria" which stated that listing a substance in the known category required evidence from studies of humans, which included both traditional epidemiologic studies and "data derived from the study of tissues from humans exposed to the substance in question." Am. Compl. Ex. 27. Thereafter, on April 19, 1999, the agency stated that "[s]ince these criteria were first published on September 26, 1998 [sic – 1996], the paragraph [the descriptive paragraph] has applied to both the 'known to be a human carcinogen' and the 'reasonably anticipated to be human carcinogen' categories and will continue to apply." Am. Compl. Ex. 28.

Based on the vast record evidence set forth above, it is virtually beyond dispute that the agency's position -- that human mechanistic information can support a listing in the known category -- is reasonable. Since the agency's interpretation of this regulatory language is reasonable, that interpretation should be given effect. See Martin v. Occupational Safety & Health Review Comm'n, 499 U.S. 144, 150 (1991).

2. The Press Release And Newsletter Do Not Alter The Foregoing.

Appellants pin their hopes that the agency's interpretation of its own rule arbitrary and capricious based solely upon a staff-authored HHS press release entitled "Updated Criteria for Anticipated Human Carcinogens," Am. Comp. Ex. 2, and an Environment Health Perspectives article ("NIEHS newsletter article"), Am. Comp. Ex. 3, that stated that the revised criteria for the known category remained either unchanged, or substantively unchanged. See Appellants' Br. at

23-27. Appellants claim that these statements, not withstanding all of the foregoing indicia of the agency's intent, indicate that mechanistic data was not to be considered for listings in the known category. Appellants are simply wrong.

This press release did state the listing criteria had been updated and that mechanistic data was included for use in the reasonably anticipated category. Am. Compl. Ex. 2. It also stated that "the original criteria for listing a substance as a known human carcinogen remained unchanged . . ." Id. at 2. This second statement, which was not a quote from, or attributed to, anyone in the program, is both incorrect on its face and misleading. It is incorrect on its face because the text of the known category did, in fact, change. See R., Ex. 13 at 2. It is also misleading to the extent that it implies that the final descriptive paragraph does not apply to the known category, a fact that is clear from the record as set forth above.

Although the statement is somewhat misleading, the confusing nature of the press release may be explained. Even administrative references prior to the adoption of the revised criteria indicate that there were few or modest textual changes to the text of the known category. See R., Ex. 12 at 4. The textual revisions to the reasonably anticipated category were far more extensive. Moreover, the release's focus on the reasonably anticipated category makes sense in light of the opinion at the time that mechanistic data would have the biggest impact in connection with the reasonably anticipated category. Indeed, the NIEHS newsletter states that "most substances listed in the BRC are contained in the 'reasonably anticipated to be a human carcinogen' [category] . . ." Id. Consequently, it is not surprising that the attention was centered around the reasonably anticipated category.

With respect to the newsletter (which, contrary to appellants' assertion it did not receive

Department clearance), it does state that HHS had approved a revision for listing substances as reasonably anticipated, which is accurate. However, the article goes on to say that "the last factor (mechanistic information) is especially important for the 'reasonably anticipated to be a human carcinogen' category . . ." Am. Compl. Ex. 3. *Plainly, if mechanistic data is "especially important" for one category, it necessarily applies to the other category*, albeit to a lesser extent. Therefore, the newsletter actually supports the view the agency has advanced from day one – that human mechanistic information can support listings in the known category.

Moreover, Dr. Lucier, NIEHS Environmental Toxicology Program Director and Associate Director, NTP, during the relevant time period, has stated by affidavit that statements "indicating that there was little or no change in the 'known human carcinogen' category after publication of the criteria in September 1996 related to the precise wording of the category only" and not to the impact of the descriptive paragraph. R., Ex. 30, at ¶ 5. Though appellants try to make much of the fact that the District Court did not address the press release or the newsletter, App. Br. at 23, this fact is beside the point. In its opinion, the Court made clear that appellees' interpretation of the revised criteria was entitled to substantial deference, thus clearly rejecting appellants' claim that the press release and newsletter eviscerated the substantial deference ordinarily accorded an agency interpretation of its regulations.

3. Application Of The Final Descriptive Paragraph To Both Categories Does Not Blur The Distinction Between The Two.

Appellants claim that permitting the use of mechanistic data as a basis, in part, to list a substance in the known category renders the two categories indistinguishable, thereby contravening "congressional directive." See Appellants' Br. at 34; Amici Br. at 4-5. This

argument is belied by the plain text of the two criteria and may be addressed in short fashion.

For the known category the standard is "*sufficient evidence* of carcinogenicity from studies in humans." (emphasis added). For the reasonably anticipated category, there are three different standards; appellants' allegations of "blurring" are directed at the third. For that standard, the requirement is "less than sufficient evidence of carcinogenicity in humans or laboratory animals . . ." Clearly, there is a critical difference in the *quantum* of evidence that must be marshaled to list a substance in one category, even if the *types* of evidence that may be considered to meet the burden are similar. Moreover, listing a substance in the known category requires a showing of a "causal relationship between exposure to the agent substance or mixture and human cancer"; this requirement of a casual relationship is not required under the reasonably anticipated category. Id. In short, it is simply not the case that the 1996 revisions, which did broaden the types of information that could be considered, effectively eliminated the distinction between the two categories.

D. Appellants Have Set Forth A Reasoned Justification For Including Mechanistic Data As Part Of The Listing Criteria.

Finally, appellants contend that, even if the Court agrees with the agency's interpretation of its own regulations that mechanistic data can support listings for both categories, the agency has still acted in an arbitrary and capricious manner because it has not provided a reasoned justification for a "change in policy." See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 41-42 (1983).

Of course, as a threshold matter, there was no need to announce a change specifically addressing only the known category because, as explained above, the agency did not revise only

one of the two categories – *it revised the listing criteria generally*. See supra. Therefore, appellants' articulation of its claim that the agency did not announce a rationale is founded on a faulty premise. With respect to revising the listing criteria generally, the agency has provided an unambiguous rationale, plainly set forth in the RoC, which states:

> In recognition of *advances in understanding the biological events involved in carcinogenesis*, the criteria for listing were expanded to include a broader array of information related to the carcinogenic process. In addition to epidemiology studies and studies to detect carcinogenic effects in experimental animals, other information contributing to scientific judgments about carcinogenicity was formally introduced into the process of deciding when to list a chemical.

R. Ex. 2 at 2 (emphasis added). The agency's announced rationale could not be clearer: mechanistic information is now included because the science in this area has advanced to the point where this powerful evidence can be harnessed and utilzed in making listing determinations. Since the agency's rationale for considering mechanistic information is "perfectly reasonable," Cassell v. FCC, 154 F.3d 478, 484 (D.C. Cir. 1998), the revised listing criteria cannot be held as arbitrary and capricious.

3. The Revision Of The Listing From The Draft Background Document To The Final Listing Was Entirely Proper.

1. The National Toxicology Program Director Makes The Final RoC Listing Decision For Review And Approval By The Secretary.

Appellants contend that issuance of the final dioxin listing violates the formal RoC review procedures because the summary description of the final listing differs from the summary language used in the DBD. The claim of a "whipsaw" in the normal review process, see Appellants' Br. at 39, is totally without foundation.

It is true that a Court's review of alleged procedural violations is made with greater

scrutiny than when the Court reviews an agency's substantive decision. See Natural Resources Defense Council, Inc. v. Securities and Exchange Comm'n, 606 F.2d 1031, 1048-49 (D.C. Cir. 1979). Here, however, appellants' allegation of procedural impropriety fails completely because appellants have not and cannot point to any procedural regulation, rule or policy that was violated. In fact, the RoC multi-level review procedures envision *exactly* the type of changes that occurred here.

The procedures for review in the RoC are described in Appendix C of the Ninth RoC Summary, and have been summarized in the Statement of Facts. The important point to note is that each level of review is independent of the preceding review, and that the final draft for listing a substance is made by the NTP Director, who submits that draft to the Secretary for approval.

> The independent recommendations of RG1, RG2 and NTP Board RoC Subcommittee and all public comment will be presented to the NTP Executive Committee for review and comment . . . [Then the] Director, NTP receives the four independent recommendations from RG1, RG2, NTP Board RoC Subcommittee, and the NTP Executive Committee and makes the final decision regarding the proposed listing and/or delisting and submits the RoC to the Office of Secretary DHHS.

R. Ex. 2 at p. 232 (emphasis added). Quite plainly the "final decision regarding the proposed listing" is made at the NTP Director level, and that decision is then subject to "review and approval" by the Office of the Secretary. The NTP Director's authority to make the final listing decision (subject to Secretary approval) clearly brings with it inherent authority to draft the final listing, which is then submitted to the Secretary for approval. Compare Pl. Opp. at 15. Plaintiff's argument that the NTP Director's office cannot make changes in the very report that it is charged with drafting for submission to the Secretary is simply incredible.

Reduced to its essence, appellants argue that the word "draft" in the term "draft background document" has no meaning. Under their rules, no changes could be made to the DBD, and it would have to be submitted directly to the Secretary in its RG2 iteration. This is a facially implausible claim. The draft background document is a draft. It is used by the various review groups to initiate discussion of a proposed listing prior to the final decision on that listing.

Appellants cite the NTP statement describing the DBD as "the document of record" which "will not be changed in response to any subsequent stakeholder input except to correct errors." Supp. S.J. Mot. Ex. 1. This statement, which concerns only the DBD, does not divest the NTP Director of the authority to make the final listing decision and to draft the final listing document for review by the Secretary. Rather, it simply makes clear that, despite whatever public comment it may engender as the focal point of the review process, the DBD will remain unchanged following RG2 review, and then will become part of the record for any giving listing. Public "stakeholder" comments are generated prior to the final listing decision. Thus, the unchanged DBD, along with all public comments concerning it will be passed to the NTP Director for his final decision and the creation of the final listing, which will then be reviewed by the Secretary.

Appellants cite no authority to support their claim that the DBD is cast in stone once it reaches the NTP Director or the Secretary. Contrary to appellants' assertion, the agency did not "abrogate its voluntary procedures" in making revisions to the DBD before final publication – it followed them. Neither the law nor past agency practice precluded the agency from revising the listing prior to publication. Indeed, the procedure anticipates such changes; otherwise, the NTP Director could not make a change in response to public comments (which are elicited after RG2

review), thereby defeating the purpose of comments. Of course, to the extent that Court deems that there is an ambiguity on this point, the agency's position is entitled to substantial deference. See Auer, 519 U.S. at 461.

2. The Listing Rationale In The RoC Has Not Substantively Changed From That In The DBD.

Notwithstanding appellants' claim of an attempt by defendants to "sanitize" or "scrub" the listing criteria, the fact is that the final listing and the DBD are not substantively different. As explained above, so long as the scientific evidence meets the criteria, there is no prohibition against the Secretary's approval of a listing based on a listing rationale that is different from the one put forth in a DBD or discussed by the various review committees. Having said that, however, it would be suspect if none of the review committees had ever discussed the rationale under which a substance was ultimately listed.

Here, the listing criteria never fundamentally changed: it has always been articulated as a combination of human epidemiological and mechanistic data together. A comparison of the language from the DBD and the final listing shows that appellants' argument of a "sea change" cannot withstand scrutiny. The summary language in the DBD states that:

> [Dioxin] is *known to be a human carcinogen* based on several types of evidence: Human studies have found an association between dioxin exposure and cancer mortality with respect to all cancers combined, non-Hodgkin's lymphoma, and lung cancer; Studies in experimental animals have shown that TCDD induces benign and malignant neoplasms at multiple sites in multiple species; A compelling body of evidence indicates a basic similarity in the mechanism of induction of animal and human tissue biochemical and toxicological responses to TCDD at comparable doses and tissue levels. R. Ex. 1 at RC-1.

The summary explanation in the 9th RoC states:

> [Dioxin] is *known to be a human carcinogen* based on sufficient evidence of

> carcinogenicity from studies in humans, involving a combination of epidemiological and mechanistic information which indicate a causal relationship between exposure to TCDD and human cancer. Supp. R. at III-58A.

After discussing the epidemiological studies in general terms, the final listing goes on to clearly state that:

> The evidence that TCDD is a human carcinogen is also supported by experimental animal studies that have shown that TCDD induces benign and malignant neoplasms at multiple tissue sites in multiple species. In addition, a compelling body of evidence has been developed that indicates a basic similarity in the mechanism of induction of animal and human tissue biochemical and toxicological responses to TCDD. Since 1977, many independent animal studies of TCDD have all found TCDD to be carcinogenic. Supp. R. at III-58A.

The final listing also addresses "statistically significant increases in relative risks for all cancers combined, lung cancer and non-Hodgkins lymphoma . . ." Id. Further, the listing describes generally the findings of animal studies, stating that "the evidence that TCDD is a human carcinogen is also supported by experimental animal studies." Clearly, the 9th RoC expressly references all of the matters that were set forth in the DBD. Plaintiff's notion that the agency was somehow trying to "scrub[][the listing's] blatant reliance on animal data" or "sweeping the rug out from under [the] established procedure" is wrong on both the law and the facts, and provides no basis to have the listing declared arbitrary or capricious.

4. The Scientific Findings Set Forth In The Listing Are Entitled To Substantial Deference.

Though appellants assured the Court that it was "*not* being called upon to second guess any agency determination regarding complicated scientific or technical issues relating to dioxin's alleged carcinogenicity," Appellants' Br. at 18, Amici seek to delve into the science. While most

of their brief merely restates arguments made by appellants,[10] they do raise questions as to whether the epidemiological data are sufficient to classify dioxin as a known human carcinogen, see Amici Br. at 12-14, and, with respect to the mechanistic data, whether Ah receptors operate identically in animals and humans. See at 14-16.

Although courts do stand as a bulwark against arbitrary and capricious agency action, it is well-settled that they have neither the expertise nor the resources to evaluate complex scientific claims. "We review scientific judgments of the agency 'not as the chemist, biologist, or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.'" Troy Corp., 120 F.3d at 283 (quoting Ethyl Corp. v. EPA, 541 F.2d 1, 36 (D.C. Cir 1976)); see also New York v. Reilly, 969 F.2d 1147, 1152 (D.C. Cir. 1992). Even appellants admit that scientific and technical issues are entitled to "substantial deference." Appellants' Br. at 18. Furthermore the record on appeal is devoid of the necessary scientific evidence that would permit the court to call into question the agency's determination. Therefore, this issue raised by Amici provides no basis to reverse the judgment of the District Court.

CONCLUSION

For the foregoing reasons, appellees respectfully submit that the judgment of the District Court be affirmed.

[10]See Amici Br. at 6-12 (arguing that NTP's criteria require that a listing in the known category must be based exclusively upon epidemiological studies).

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CERTIFICATE OF COMPLIANCE

I HEREBY CERTIFY that according to the word processing software utilized by counsel for appellees, the attached brief is 13843 words in length and therefore complies with the type-volume limitation of Fed. R. App. P. 32(a)(7).

_____P
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that, on June 19, 2001, I served two copies of the foregoing Brief for Appellees by first class mail, postage pre-paid, on the following:

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ADDENDUM