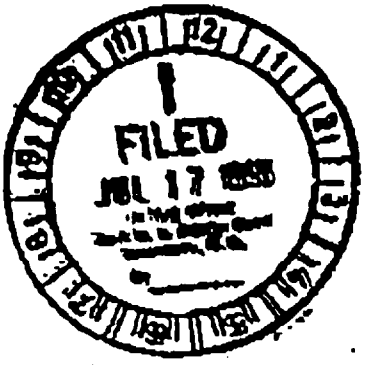
IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
WINSTON-SALEM DIVISION



FLUE-CURED TOBACCO COOPERATIVE STABILIZATION CORPORATION, THE COUNCIL FOR BURLEY TOBACCO, INC., UNIVERSAL LEAF TOBACCO COMPANY, INCORPORATED, PHILIP MORRIS INCORPORATED, R.J. REYNOLDS TOBACCO COMPANY, and GALLINS VENDING COMPANY,

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and CAROL BROWNER, Administrator, Environmental Protection Agency,

Defendants.

6:93CV00370

ORDER AND JUDGMENT

OSTEEN, District Judge

For the reasons set forth in the memorandum opinion entered contemporaneously herewith,

IT IS ORDERED AND ADJUDGED that Plaintiffs' Motion for Partial Summary Judgment is granted [117].

IT IS FURTHER ORDERED AND ADJUDGED that Defendants' Cross Motion for Summary Judgment is denied [126]. The court vacates Chapters 1-6 of and the Appendices to EPA's Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders. EPA/600/6-90/006F (December 1992). To ripen its judgment for purposes of appellate review, pursuant to Federal Rule of Civil Procedure 54(b), the court finds there is no just reason for delaying entry of judgment.

IT IS FURTHER ORDERED AND ADJUDGED that Plaintiffs' Motion for Leave to File Supplement Pleading under Rule 15(d) is granted [120].

This the 17th day July 1998.

United States District Judge

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WINSTON-SALEM DIVISION

FLUE-CURED TOBACCO COOPERATIVE STABILIZATION CORPORATION, THE COUNCIL FOR BURLEY TOBACCO, INC., UNIVERSAL LEAF TOBACCO COMPANY, INCORPORATED, PHILIP MORRIS INCORPORATED, R.J. REYNOLDS TOBACCO COMPANY, and GALLINS VENDING COMPANY,

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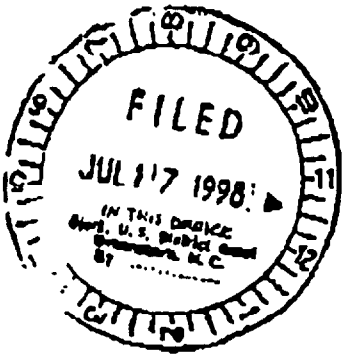

6:93CV00370

MEMORANDUM OPINION

OSTEEN, District Judge

This case is before the court on the parties' cross motions for partial summary judgment on Counts I-III of the Complaint. These counts raise Administrative Procedure Act (APA) challenges to EPA's report, Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders, EPA/600/6-90/006F, December 1992

(ETS Risk Assessment). EPA claims its authority to conduct the ETS Risk Assessment derives from the Radon Gas and Indoor Air Quality Research Act of 1986, Pub. L. No. 99-499, 100 Stat. 1758-60 (1986) (Radon Research Act) (codified at 42 U.S.C. § 7401 note (1994)). In the ETS Risk Assessment, EPA evaluated the respiratory health effects of breathing secondhand smoke (environmental tobacco smoke or ETS) and classified ETS as a Group A carcinogen, a designation meaning there is sufficient evidence to conclude ETS causes cancer in humans. Disputing the Assessment, Plaintiffs argue: EPA exceeded its authority under and violated the restrictions within the Radon Research Act; EPA did not comply with the Radon Research Act's procedural requirements; EPA violated administrative law procedure by making a conclusion regarding ETS before it concluded its risk assessment, and EPA's ETS Risk Assessment was not the result of reasoned decision making.[1] EPA denies the same and argues the administrative record (record) demonstrates reasoned decision making. Plaintiffs have also filed a motion to supplement the

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[1] Plaintiffs also allege that EPA's issuance of the ETS Risk Assessment violated Plaintiffs' due process rights. The court has stayed consideration of the due process claims pending resolution of the APA claims. See Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA, 857 F. Supp. 1137 (M.D.N.C. 1994).

pleadings. For the reasons stated herein, the court will enter an order granting Plaintiffs' motions.

I. THE RADON RESEARCH ACT

The Radon Research Act was enacted by Congress as Title IV of the Superfund Amendments and Reauthorization Act of 1986 (SARA) and codified with the Clean Air Act at 42 U.S.C. § 7401 note. The Act was based on Congress' finding: "exposure to naturally occurring radon and indoor air pollutants poses public health risk[s]," id. § 402(2); "Federal radon and indoor air pollutant research programs are fragmented and underfunded," id. § 402(3); and an "information base concerning exposure to radon and indoor air pollutants should be developed . . . ." Id. § 402(4). The act provides

> (a) Design of Program. - [The EPA] shall establish a research program with respect to radon gas and indoor air quality. Such program shall be designed to -
>
> > (1) gather data and information on all aspects of indoor air quality in order to contribute to the understanding of health problems associated with the existence of air pollutants in the indoor environment;
> >
> > (2) coordinate Federal, State, local, and private research and development

> efforts relating to the improvement of indoor air quality; and
>
> (3) assess appropriate Federal Government actions to mitigate the environmental and health risks associated with indoor air quality problems.

(b) Program requirements. - The research program required under this section shall include -

> (1) research and development concerning the identification, characterization, and monitoring of the sources and levels of indoor air pollution . . . .
>
> . . . .
>
> (2) research relating to the effects of indoor air pollution and radon on human health;
>
> . . . .
>
> (6) the dissemination of information to assure the public availability of the findings of the activities under this section.

Id. § 403(a) & (b). Congress also required a narrow construction of the authority delegated under the Radon Research Act. Nothing in the act "shall be construed to authorize the [EPA] to carry out any regulatory program or any activity other than research, development, and related reporting, information dissemination, and coordination activities specified in [the Radon Research Act]." Id. § 404.

The Act requires EPA to establish two advisory groups to assist EPA in carrying out its statutory obligations under the Radon Research Act. One of the advisory groups is to be a committee comprised of representatives of federal agencies concerned with various aspects of indoor air quality, and the other group is to be "an advisory group comprised of individuals representing the States, the scientific community, industry, and public interest organizations . . . ." Id. § 403(c). The Act requires EPA to submit its research plan to the EPA Science Advisory Board which, in turn, would submit comments to Congress. Id. § 403(d).

II. STANDARD OF REVIEW[2]

Administrative agencies have no power to act beyond authority conferred by Congress. See, e.g., Louisiana Public Serv. Comm'n v. FCC, 476 U.S. 355, 374, 106 S. Ct. 1890, 1901, 90 L. Ed. 2d 369 (1986). Title 5 U.S.C. § 706(2)(C) requires the

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[2] As this case involves review of administrative agency action, the court will not conduct de novo review but must review the record before EPA at the time EPA made its decision. For a discussion on the scope of review, see Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA, No. 6:93CV00370 at 16-20 (M.D.N.C. May 23, 1995) (Memorandum Opinion discussing summary judgment on scope of review).

court to "hold unlawful and set aside agency action . . . found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." The initial inquiry for judicial review of agency action is "whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43, 104 S. Ct. 2778, 2781, 81 L. Ed. 2d 694 (1984). "The task of resolving the dispute over the meaning of [the statute] begins where all such inquiries must begin: with the language of the statute itself." United States v. Ron Pair Enter., Inc., 489 U.S. 235, 241, 109 S. Ct. 1026, 1030, 103 L. Ed. 2d 290 (1989) (citations omitted). "The judiciary . . . is the final authority on issues of statutory construction and will reject administrative interpretations which are contrary to the clear congressional intent." Adams v. Dole, 927 F.2d 771, 774 (4th Cir. 1991).

"[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the

statute." Chevron, 467 U.S. at 843, 104 S. Ct. at 2782. Courts do not always abide by this Chevron deference. Although the circuits appear divided, the majority of post-Chevron cases hold no deference is accorded to an agency's view of a statute where the statute does not confer rule making authority on the agency. Compare Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (Chevron does not apply to interpretive rules); Atchison, Topeka & Santa Fe Ry. v. Pena, 44 F.3d 437, 441-42 (7th Cir. 1994) (en banc) (same), aff'd on other grounds sub nom. Brotherhood of Locomotive Eng'rs v. Atchison, Topeka & Santa Fe Ry., 116 S. Ct. 595 (1996) with Trans Union Corp. v. FTC, 81 F.3d 228, 230-31 (D.C. Cir. 1996) (applying Chevron to interpretive rule); Elizabeth Blackwell Health Ctr. for Women v. Knoll, 61 F.3d 170, 182 (3d Cir. 1995) (same), cert. denied, 116 S. Ct. 816 (1996). See Ronald M. Levin, Scope of Review Legislation: The Lessons of 1995, 31 Wake Forest L. Rev. 647, 662-64 (1996). Another factor in determining an agency's discretion in statutory interpretation is the specificity of interpretation. Courts determine the general meaning of legislation, whereas agencies are often better equipped to determine interstitial meanings. John H. Reese, Administrative Law Principles and Practice 709-713 (1995).

III. EPA's AUTHORITY UNDER THE RADON RESEARCH ACT

The parties assert the plain language of the statute determines whether EPA had authority to assess the risks of and classify ETS. The court agrees. However, the parties, reading the plain language, come to opposite conclusions. Plaintiffs argue EPA exceeded its statutory grant of authority under the Radon Research Act by conducting a risk assessment, making a carcinogen classification, and by engaging in de facto regulation. Plaintiffs also argue the Toxic Substance Control Act prohibited EPA's risk assessment of ETS.

A. The Radon Research Act Authorizes EPA's Risk Assessment and Classification of Environmental Tobacco Smoke.

Plaintiffs concede EPA was authorized to conduct research on ETS and indoor air quality but argue EPA's ETS carcinogen risk assessment and carcinogen classification are regulatory activities, not research activities. EPA's Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,993 (1986) (Risk Assessment Guidelines) state: "[r]egulatory decision making involves two components: risk assessment and risk management." See also, 60 Fed. Reg. 52,032, 52,034 (1995) (Risk assessment is a component of the regulatory process.).

Plaintiffs also rely on the National Resource Council's (NRC) Redbook which recognizes risk assessment as a distinct element of the regulatory process. See NRC, Risk Assessment in the Federal Government: Managing the Process 3 (1983) (NRC Redbook). Plaintiffs argue that since risk assessment is a component of regulatory activity, risk assessment is not authorized research but rather proscribed regulatory activity.

EPA's Risk Assessment Guidelines state risk assessment incorporates judgmental positions and the Agency's regulatory mission. Risk Assessment Guidelines at 33,994. Plaintiffs also offer evidence that EPA has promulgated regulations for every other substance for which it has conducted a risk assessment and classified the substance as a Group A carcinogen.[3] Thus, Plaintiffs conclude that EPA's guidelines and actions demonstrate risk assessment is a regulatory, not research, tool.

In arguing EPA recognizes this distinction between risk assessment and research, Plaintiffs offer evidence that EPA is assessing the risks of several other indoor air pollutants, none of which are being conducted under the authority of the Radon

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[3] See Assessing the Effects of Environmental Tobacco Smoke: Hearing on S. 262 and S. 1688 Before the Subcomm. on Clean Air and Nuclear Reg. of the Sen. Comm. on Env't and Public Works, 103d Cong. 177, 204-05 (1994) (Browner Hearing Responses).

Research Act. Included is evidence that EPA did not conduct its risk assessment of radon under the authority of the Radon Research Act.[4] Instead, EPA relied on the Toxic Substance Control Act (TSCA), 15 U.S.C. §§ 2601 et seq., which authorizes EPA to describe "action levels indicating the health risk associated with different levels of radon exposure." TSCA § 2663(b)(1).[5] Plaintiffs argue EPA's reliance on TSCA indicates EPA realizes the Radon Research Act does not authorize risk assessments or carcinogenic classifications.

EPA replies that the Radon Research Act provides a broad mandate to conduct activities short of actual regulation. Upon a sparse legislative record and subsequent congressional funding, EPA urges that Congress intended the act to include ETS.

The court is not persuaded by Plaintiffs' arguments or EPA's reliance on what certain members of Congress intended. The plain language of the statute is sufficient to resolve this dispute. In the Radon Research Act, Congress directed EPA to gather information on all aspects of indoor air quality, research indoor

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[4] See Browner Hearing Responses at 190-92.

[5] Plaintiffs also provide evidence that EPA did not include the ETS project when providing Congress with a listing of Agency research activity.

pollutants' effects on health, characterize sources of pollution, and disseminate the findings. Determining whether Congress authorized risk assessments requires defining risk assessment. "Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations." NRC Redbook, at 3. "[NRC] use[s] risk assessment to mean the characterization of the potential adverse health effects of human exposures to environmental hazards." Id. at 18. "The qualitative assessment or hazard identification part of risk assessment contains a review of the relevant biological and chemical information bearing on whether or not an agent may pose a carcinogenic hazard." Risk Assessment Guidelines at 33,994.

> Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgments as to the number and characteristics of persons exposed at various intensities and durations; and summary judgments on the existence and overall magnitude of the public-health problem. Risk assessment also includes characterization of the uncertainties inherent in the process of inferring risk.

NRC Redbook, at 18.

In researching effects on health, EPA must assess whether pollutants are hazardous to health. Researching whether pollutants are hazardous to health necessarily entails assessing the risk such pollutants pose to health. Thus, researching health effects is indistinguishable from assessing risk to health. Congress' directives to research the effects of indoor air pollution on human health and disseminate the findings encompass risk assessment as defined by NRC and explained by EPA's Risk Assessment Guidelines.

The NRC explains "description of the potential adverse health effects" is a component of risk assessment. Id. The Radon Research Act requires researching pollutants' effects on health and disseminating the findings. The mandate of the Act requires more of EPA than merely describing effects. Congress intended EPA to disseminate findings, or conclusions, based upon the information researched and gathered. Utilizing descriptions of health effects to make findings is risk assessment.

The Radon Research Act contains two independent directives which authorize EPA to classify indoor pollutants as carcinogenic. First, Congress required EPA to characterize sources of indoor air pollution. Radon Research Act § 403(b)(1). Since they emit gasses and particulates, burning cigarettes are a

source of indoor air pollutants. By determining whether these emissions cause cancer in people exposed to burning cigarettes, EPA is characterizing a source of indoor air pollution. Second, Congress required EPA to determine indoor pollutants' effects on health. Id. § 403(b)(2). In determining whether health is affected by a pollutant, the researcher must identify whether a causal relationship exists between the pollutant and deteriorating health. Put simply, the researcher must determine how, if at all, a pollutant affects health. Once a researcher has identified how a pollutant harms human health, the risk is most often identified.[6] This is especially true regarding carcinogens. The Radon Research Act's general language authorizing EPA to characterize sources of pollutants, research effects on health, and disseminate the findings encompasses classifying pollutants based on their effects.

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[6] For example, if research determines a pollutant harms human health by causing malignant tumors, it is ipso facto a carcinogen. See Ted A. Loomis & A. Wallace Hayes, Essentials of Toxicology 232-36 (4th ed. 1996) (tests for carcinogenicity). If research determines the pollutant causes blockage of neurotransmissions, it is ipso facto a neurotoxin. See David R. Franz, et al., Clinical Recognition and Management of Patients Exposed to Biological Warfare Agents, 278 JAMA 399 (1997) (discussing botulinum toxins).

The court is not persuaded by Plaintiffs' evidence showing risk assessment incorporates judgmental positions and an agency's regulatory mission. Researching how a pollutant affects health entails conducting risk assessment. Judgment and inference do not automatically remove risk assessment from what constitutes researching health effects. To the contrary, judgment and inference inhere in the "use of [a] factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations." NRC Redbook, at 3, 18, 28. "Risk assessment . . . includes characterization of the uncertainties inherent in the process of inferring risk." Id. at 18.

> The uncertainties inherent in risk assessment can be grouped in two general categories: missing or ambiguous information on a particular substance and gaps in current scientific theory. When scientific uncertainty is encountered in the risk assessment process, inferential bridges are needed to allow the process to continue. . . . The judgments made by the scientist/risk assessor for each component of risk assessment often entail a choice among several scientifically plausible options; the Committee has designated these inference options.

Id. at 28. In conducting a scientific inquiry into whether a pollutant affects human health, a researcher will have to choose inference options. In fulfilling its obligation under the Radon

Research Act, EPA must adopt inference options in conducting research, characterizing, and making findings. Inference options that are scientifically plausible and fundamentally fair are part of risk assessment. EPA may conduct risk assessments under the Radon Research Act so long as the assessments do not impede the Act's general requirements of gathering all relevant information, researching, and disseminating the findings.

The court disagrees with Plaintiffs' argument that risk assessment constitutes a regulatory activity and is thus prohibited under the Radon Research Act. Both the NRC's Redbook and EPA's Risk Assessment Guidelines identify regulatory activity as being comprised of two elements: risk assessment and risk management. Prohibition of certain conduct does not include prohibition of lesser included activities.[1] Prohibiting conduct entails a prohibition against conducting the lesser included activities in concert to arrive at the proscribed result. Risk assessment is a component of regulation. Congress' prohibition of regulation is not a prohibition against the components comprising regulation. In the Radon Research Act, Congress intended EPA to research, collect, and disseminate information

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[1] Standing upright is a component of running. A prohibition on running is not also a prohibition on standing.

and findings on indoor air pollutants' effect on health without engaging in regulating. Risk assessments are incidental to researching effects on health, characterizing sources of pollutants, and making findings. So long as collecting and researching information and disseminating the resulting information are EPA's lodestar, Congress' prohibiting regulation under the Radon Research Act does not preclude risk assessment. The court will review the ETS Risk Assessment to determine whether EPA conducted its research activities in accordance with the Act.

Finally, Plaintiffs' evidence of EPA's reliance on other statutes for assessing risks of other indoor air pollutants is not persuasive. In these statutes, Congress granted EPA regulatory power over certain pollutants. EPA has since promulgated regulations pursuant to these statutes. It is unremarkable that when asked its authority to conduct elements of its regulatory process from which regulation occurred, EPA cited the statutes granting full regulatory power.[1]

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[1] Even if it were persuasive evidence that EPA interpreted the Radon Research Act to exclude risk assessment, the court makes its determination based upon the language Congress used, not agency interpretation.

B. EPA's Environmental Tobacco Smoke Activities Do Not Constitute a Prohibited Regulatory Program Under the Radon Research Act.

Plaintiffs have shown that EPA aggressively disseminated information, coordinated activities with government agencies and non-governmental organizations, and promoted ETS regulation and prohibition.[1] Plaintiffs argue EPA's conduct constitutes de facto regulatory activity in violation of the Radon Research Act.

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[1] See, e.g., Summary of EPA Draft Conclusions and SAB Review, Steven Bayard, EPA ETS Project Manager, CRD Q.9 at 1 (April 4, 1991) (Joint Appendix (JA) 6,700) ("EPA has no regulatory authority on ETS, but is coordinating with OSHA which does have regulatory authority in the workplace."); EPA Memorandum from William G. Rosenberg, Assistant Administrator for Air and Radiation, to Erich W. Bretthauer, Assistant Administrator for Research and Development at 1 (Oct. 7, 1991) (JA 6,696-97) (urging expedition of ETS study; local, state and federal agency projects awaiting its issuance); EPA Memorandum from William G. Rosenberg, Assistant Administrator for Air and Radiation, to Donald G. Barnes, Director, Science Advisory Board (June 28, 1991), and attached ETS Technical Compendium, Draft (May 1991) at 2 (JA 6,755-56, 6,758) (intended to help state legislators ban smoking in workplaces, restaurants, and public places).

EPA's activities did not amount to formal regulation,[1] for it issued no regulations and made no attempt to directly manage ETS risks. EPA's activities constituted de facto regulatory activity but were achieved through means authorized by Congress. Congress prohibited any regulatory program or activity "other than research, development, and related reporting, information dissemination, and coordination activities . . . ." Radon Research Act § 404 (emphasis added). EPA may be using its authority under the Act more aggressively and effectively than Congress had foreseen, however, such activities are within the law as written. Removal of EPA's authority to engage in de facto regulatory activity under the Radon Research Act requires an act of Congress, not the court's judgment.

C. The Toxic Substance Control Act's Prohibition With Respect to Tobacco Does Not Apply to the Radon Research Act.

In the Toxic Substance Control Act (TSCA), Congress authorized EPA to regulate chemical substances presenting an

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[1] Plaintiffs also seek leave to supplement the pleadings, claiming EPA is promulgating indoor air regulations by funding and controlling a private entity that drafts indoor air ventilation standards that are adopted in state and local building codes. The court does not consider these allegations in ruling on the parties' summary judgment motions.

unreasonable risk of injury to health or the environment. 15 U.S.C. § 2605. TSCA does not authorize EPA to regulate tobacco products. Id. § 2602(2)(B)(iii). Some in Congress have attempted to repeal the tobacco exemption for the purpose of providing EPA with authority to regulate tobacco smoke under TSCA. See 136 Cong. Rec. E2223, E2224 (daily ed. June 28, 1990) (statement of Rep. Luken). More recently, a bill was introduced to amend TSCA "to protect the public from health hazards caused by exposure to [ETS]." S. 1680, 103d Cong., 1st Sess., 139 Cong. Rec. S16222 (daily ed. Nov. 18, 1993). Both bills were introduced after the enactment of the Radon Research Act, and neither passed. Plaintiffs argue the specific language in TSCA, regarding tobacco, takes precedence over the general conflicting language of the Radon Research Act.

The court does not find the conflict Plaintiffs' argument presumes. In the TSCA, Congress directed EPA to prohibit, limit, and regulate the manufacture, processing, or distribution of hazardous chemical substances. Congress exempted tobacco from TSCA's regulatory reach. The Radon Research Act contains no regulatory authority. Compare TSCA § 2605 (EPA's requirements in regulating manufacturing, processing, and distribution of hazardous chemical substances), with Radon Research Act § 404 (no

regulatory authority except research, development, dissemination, and coordination regarding indoor air pollutants).

To the extent the Radon Research Act authorizes de facto regulatory activity, Congress simply excluded tobacco from the definition of chemical substance as used in the TSCA chapter. See TSCA § 2602 (definitions "As used in this chapter"). Congress' defining "chemical substance" under the TSCA to exclude tobacco does not mean Congress conclusively removed tobacco from EPA's jurisdiction. It means Congress removed tobacco from the authority granted to EPA under TSCA. Congress did not so limit the definition of "indoor air pollutant" under the Radon Research Act. See generally Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1379-80 (M.D.N.C. 1997) (declining to infer preemption of FDA authority to regulate tobacco products from other tobacco-specific legislation or Congress' failure to act). There being no conflict between the statutes and finding Congress' TSCA restriction by definition inapplicable to the Radon Research Act, Plaintiffs' argument fails.

IV. EPA'S PROCEDURAL REQUIREMENTS UNDER THE RADON RESEARCH ACT

Plaintiffs argue EPA failed to establish and consult the advisory group mandated by the Radon Research Act, therefore,

EPA's conduct under the Act was unlawful and must be vacated. EPA responds by arguing it satisfied its procedural requirements by consulting the EPA Science Advisory Board (SAB). EPA states it formed an advisory group within SAB which included representatives of all the statutorily identified constituencies. EPA further argues that even if it did not satisfy the Radon Research Act's procedural requirements: (1) the Act speaks in general terms and committee formation was not a prerequisite to research activity under the Act, and (2) Plaintiffs were not prejudiced because EPA utilized public participation and peer review procedures in developing the ETS Risk Assessment. In reply, Plaintiffs analyze SAB and the members of the board which reviewed the ETS Risk Assessment.

A. Background

"[T]he SAB is an independent group of non-Federal government scientists and engineers who are mandated through the Environmental Research, Development and Demonstration Act of 1978 to provide advice to the EPA Administrator on technical aspects of issues confronting the Agency." EPA Memorandum from William K. Reilly, Administrator, to Congressman Thomas J. Bliley, Jr., U.S. House of Representatives 1 (Oct. 11, 1990) (Reilly Mem.) (JA

9,310). See also, 42 U.S.C. § 4365 (statute authorizing SAB). "The objective of the Board is to provide independent advice . . . . The Board will review scientific issues, provide independent scientific and technical advice on EPA's major programs and perform special assignments . . . ." SAB Charter ¶ 3, reprinted in, EPA, U.S. Environmental Protection Agency Advisory Committees 137 (July 1994) (JA 3,445). "[T]he Board augments its standing committee membership with the inclusion of subject-matter experts ('consultants') to provide special insights on particular issues. In identifying appropriate consultants, the [SAB] . . . solicits names of candidates from a variety of public and private sources, which generally include the Agency and the affected parties." Reilly Mem. at 2 (JA 9,311). SAB then attempts to select experts from "either side of the middle of the spectrum of views in the technical community, with few, if any, coming from either end of the spectrum." Id. at 1 (JA 9,310).

In 1986, Congress passed the Radon Research Act which required that EPA "establish . . . an advisory group comprised of individuals representing the States, the scientific community, industry, and public interest organizations to assist [EPA] in carrying out the research program for . . . indoor air quality" Radon Research Act § 403(c). The Act also required EPA to submit

its research plan to SAB. Id. § 403(d). In response, "the SAB established the Indoor Air Quality/Total Human Exposure Committee (IAQC) as the forum in which the SAB would consider indoor air issues." Reilly Mem. at 1 (JA 9,310).

An EPA Ethics Advisory sent to IAQC draws the distinction between "representatives" on advisory committees and "Special Government Employees." EPA Memorandum from Robert Flaak, Assistant Staff Director, SAB, to IAQC at Enclosure G[11] (June 17, 1992) (JA 10,938-40) (Flaak Mem.). Representatives are those who "appear in a representative capacity to speak for firms or an industry . . . or for any other recognizable group . . . ," whereas "Special Government Employees" do not. Id. (JA 10,940). Another attachment, captioned "Procedures for Public Disclosures at SAB Meetings," states the IAQC panel members were serving as Special Government Employees, not as representatives: "SAB members and consultants (M/Cs) carry out [sic] their duties as Special Government Employees (SGE's) and are subject to the COI [conflict of interest] regulations." Id. at Enclosure F (JA

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[11] Enclosure G: EPA Memorandum from Gerald Yamada, Principal Deputy General Counsel, Designated Agency Ethics Official, to Deputy Ethics Officials (April 24, 1992).

10,936). See 18 U.S.C. §§ 202-09 (restrictions on special government employees).

B. Neither the Science Advisory Board Or Its Subcommittee Is the Representative Advisory Group Congress Mandated In the Radon Research Act.

The language used in the Radon Research Act, the nature of SAB, and the composition of the IAQC which reviewed the ETS Risk Assessment, demonstrate that EPA failed to comply with the procedural requirements set forth by Congress. In § 403(c) of the Radon Research Act, Congress clearly requires EPA to establish a representative advisory group to assist EPA in carrying out research programs conducted under the Act. The group is to be comprised of representatives from the states, scientific community, industry, and public interest organizations. In the following paragraph, § 403(d), Congress requires that EPA submit its research plan "to the EPA Science Advisory Board . . ." which would then submit its comments to Congress. "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." Brown v.

Gardner, 513 U.S. 115, 130, 115 S. Ct. 552, 556, 130 L. Ed. 2d 462 (1994)(citation omitted). The presumption is strengthened where, as here, the disparate language is used within the same section. Had Congress meant SAB when requiring a representative advisory group, Congress would have specified SAB as it did in the subsequent paragraph. Further, § 403(c) calls upon EPA to establish the advisory group. In 1977, Congress mandated creation of SAB, and EPA complied. Congress' use of "establish" suggests that EPA should create a group. Congress would not likely direct EPA to establish what already exists. A closer examination of SAB verifies the court's statutory construction.

Congress directed EPA to establish and consult a representative group to assist EPA in conducting research under the Radon Research Act. To "represent" or be a "representative," one must possess the ability to "speak or act with authority on behalf of," or "act as [a] substitute or agent" for the person or interest represented.[12] Black's Law Dictionary 1301 (6th ed. 1990). In contrast, EPA designed SAB to provide independent

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[12] The legislative history supports this common sense interpretation of "represent." Senator Lautenberg, one of the sponsors of the bill that became the Rador Research Act, said the Advisory Committee was to be "a blue ribbon advisory committee, composed of members" of the specified constituencies. 131 Cong. Rec. S11684 (daily ed. Sept. 18, 1985) (JA 657).

advice. EPA designated SAB employees as special government employees (SGE's), meaning the employees are temporarily appointed, "as contrasted with members who are designated as 'representatives' . . . ." Flaak Mem. at Enclosure G (JA 10,938). SGE's may not participate in matters that affect their employers' financial interests.[12] Id. (JA 10,939). Congress' requiring a collegium of representatives is incompatible with SAB's independent and aspiringly neutral composition. Both the role Congress assigned to each group and the composition of the group that provided advice on the ETS Risk Assessment provides further evidence of this incompatibility.

Congress set forth in § 403(d) a role for the SAB that tracks the SAB's traditional mission: providing independent scientific review and comment on EPA's plan for implementing the research program. In contrast, § 403(c) charged the advisory group with representing specified constituencies and providing assistance to EPA in carrying out the research program. Those are two different roles for two different groups.

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[12] EPA may waive conflicts where the interest affected is insubstantial or the need for the SGE's service outweighs the conflict.

The IAQC group that provided advice to EPA on the ETS Risk Assessment was not the representative body required by § 403(c). See ETS Risk Assessment at xviii-xx. In the ETS Risk Assessment, EPA lists nine members of IAQC who participated in the reviews of two review drafts. Seven of the members are listed as university professors or members of schools, one was listed as a scientist in a national laboratory, and one was a state employee. Of the nine consultants involved, seven were employed by universities, and two by special interest groups. EPA claims that one of the listed members, Dr. Woods, represented industry. However, this is not possible since Dr. Woods left industry for employment with a university almost a year before the first draft of the ETS Risk Assessment was made available for review by IAQC. See JA 7,063-73 (Dr. Wood's curriculum vita). EPA further asserts that two other individuals represented industry. The ETS Risk Assessment IAQC listing does not contain the names of these individuals. The individuals are not listed in the IAQC ETS reviews' transcripts,[14] nor does EPA assert or direct the court's

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[14] See U.S. EPA SAB IAQC ETS Review, I.SAB.16.1 & .2 (December 4 & 5, 1990) (transcript volumes I & II) (1990 IAQC Transcript) (JA 8,793 9,213); U.S. EPA SAB IAQC ETS Review Panel, II.SAB.6.1 & .2 (July 21 & 22, 1992) (transcript volumes I & II) (1992 IAQC Transcript) (JA 11,641-12,105).

attention to evidence that these individuals provided any participation in the ETS Risk Assessment.

EPA points out that some panelists were associated with organizations that had received some industry funding pursuant to contract. That does not convert those individuals into industry representatives under § 403(c). EPA also urges that one of the panelists was selected as a consultant on the recommendation of the tobacco industry. Appropriately, EPA does not attempt to argue that one becomes a member or representative of industry upon a recommendation by industry.

EPA confirmed IAQC's independence from outside interests. When he was preparing the panel for the second public meeting on the draft ETS Risk Assessment, the SAB assistant director included in his transmittal letter a reminder to panel members of their conflict of interest and disclosure obligations:

> An area of potential sensitivity in our public meetings is the nature of your interactions with both the Agency and outside interests on a particular matter. At the beginning of the meeting, I will ask each person on the Committee to voluntarily discuss any such areas they wish to identify. . . . Issues of concern can include the extent to which you or your organization have received (or will receive) professional or personal benefits from any individuals, organizations or groups . . . representing any viewpoint concerning the issue(s) under consideration at this meeting.

Flaak Mem. at 3. At both IAQC public reviews, no one admitted representing industry or any other § 403(c) constituency.[15] This result was in accordance with SAB's designed purpose and the EPA ethics advisory sent to IAQC.

After reviewing the Radon Research Act, analyzing the SAB, and reviewing the actual composition of the IAQC, the court has found no evidence that the IAQC involved with the ETS Risk Assessment satisfied § 403(c) of the Radon Research Act. EPA's procedures, guidelines, and conduct in the ETS Risk Assessment clearly demonstrate that SAB and IAQC are independent bodies. EPA's argument that IAQC was a representative body is without merit. IAQC's membership did not include individuals from industry or representatives from more than one state. No members were invited to represent or admitted to representing any constituency. Rather, EPA's regulations prohibited parties with meaningful outside interests from participating. Accordingly, EPA failed to comply with the requirements of § 403(c).

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[15] See 1990 IAQC Transcript at 11-38 (JA 8,803-30); 1992 IAQC Transcript at 16-29 (JA 11,655-668).

C. The Timing of Committee Formation

EPA argues that § 403(c) is generally worded and does not make the formation of a representative advisory committee a prerequisite that must be satisfied before EPA can undertake a specific activity under the Act. There is no evidence in the record, nor does EPA argue, that EPA established the committee during or after any activity conducted under the Act. Since the committee has not been established, EPA's argument about when it could have sought the committee's assistance appears academic. However, for purposes of fashioning a remedy, § 403(c) requires EPA to seek the committee's assistance "in carrying out the research program . . . ." Congress intended consultation at least while EPA conducted research. Ongoing consultation requires more than post hoc consultation. See Morabito v. Blum, 528 F. Supp. 252, 264-66 (S.D.N.Y. 1981) (Under the Social Security Act, where consultation with a medical advisory committee is required, committee input must be sought and received before action is taken.).

D. Consequences of EPA's Procedural Failure

Plaintiffs argue EPA's actions were unlawful and the ETS Risk Assessment must be set aside. EPA argues Plaintiffs

were not prejudiced "because EPA in fact utilized extensive public participation and peer review drawing upon all of the designated constituencies in developing the ETS Risk Assessment." (Conformed Mem. Supp. EPA's Cross Mot. Part. Summ. J. at 42-43.) Further in its memorandum, however, EPA maintains it did "not have an obligation to respond to public comments in the same manner as in [an APA] section 553 rulemaking," id. at 49, and the court cannot require EPA to respond to comments because "reviewing courts are generally not free to impose additional procedural requirements if the agencies have not chosen to grant them." Id.

Even if EPA did provide a genuine opportunity for comment and SAB review, the Agency was required to carry out its research program with the assistance of an advisory group of representatives of the identified interests. EPA may not rewrite the terms of the Radon Research Act. See Environmental Defense Fund, Inc. v. EPA, 636 F.2d 1267, 1283-84 (D.C. Cir. 1980) (agency-created "de minimis" cutoff from application of statute was struck down because not in compliance with terms of statute); Alabama Power Co. v. Costle, 636 F.2d 323, 365 (D.C. Cir. 1979) (The agency is not "free to ignore the plain meaning of the statute and to substitute its policy judgment for that of

Congress."). When Congress requires specific procedures, agencies may not ignore them or fashion substitutes."[4]

A congressional directive to consult an advisory committee is more than a formality. The Court of Appeals for the District of Columbia emphasized the significance of advisory committees in explaining the procedural requirements within the Federal Coal Mine Health and Safety Act of 1969:

> The most important aspect is the requirement of consultation with knowledgeable representatives of federal and state government, industry and labor. This goes far beyond the usual requirements of public notice and opportunity for comment set forth in the Administrative Procedure Act, and represents the Congressional answer to the fears expressed by industry and labor of the prospect of unchecked federal administrative discretion in the field. These rather unique requirements of the Act are an important part of the ultimate legislative compromise, and must be given their due weight.

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[4] Even so, the IAQC was a poor proxy for industry representation. EPA sought parties near the "middle" of the spectrum when establishing SAB panels and allegedly avoided representation from either end of the spectrum. As a general rule, the tobacco industry occupies that end of the spectrum contesting the carcinogenicity of ETS and EPA's motives. A committee aspiring to represent the middle of the ETS debate necessarily suppresses the tobacco industry's perspective. Further, industry's ability to submit comments to a "neutral" committee, which itself had access to EPA, is not equivalent to industry access to EPA.

Zeigler Coal Co. v. Kleppe, 536 F.2d 398, 403 (D.C. Cir. 1976). In National Constructors Ass'n v. Marshal, 581 F.2d 960 (D.C. Cir. 1978), the Secretary of Labor was obligated to establish and consult with a specially constituted advisory committee when promulgating safety standards. The Secretary failed to do so. The Marshal court rejected the agency's effort to equate notice and comment with the required procedures and concluded that "advisory committee consultation should, but in this case did not, consist of something more than a . . . rest stop on the route between a tentative proposal . . . and the final promulgation . . . ." Id. at 971.

EPA relies on Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 558, 98 S. Ct. 1197, 1219, 55 L. Ed. 2d 460 (1978). In Vermont Yankee, the agency complied with statutory procedures, but the appeals court held the agency should have done more. The Supreme Court reversed, noting "we find absolutely nothing in the relevant statutes to justify what the court did here." Id. at 557, 98 S. Ct. at 1218. In the present action, EPA violated a statutory procedure.

At issue then is the proper remedy for agency action that is procedurally deficient. Specifically, the court must determine whether to vacate the ETS Risk Assessment. In Vermont Yankee,

the Court held "[a]dministrative decisions should be set aside . . . only for substantial procedural or substantive reasons as mandated by statute . . . ." Id. at 558, 98 S. Ct. at 1219.

In Synthetic Organic Chem. Mfrs. Ass'n v. Brennan, 506 F.2d 385, 388-89 (3d Cir. 1974), Congress gave the Secretary of Labor the option of requesting recommendations from an advisory committee prior to promulgating certain rules. If the Secretary used the committee, interested parties could submit their comments about the rule after the committee issued its report. The dispute before the Third Circuit arose when the Secretary consulted the committee but published a proposed rule before the advisory committee submitted its report. The complainants "were not given adequate time to submit comments or to prepare for the hearing after the committee's work was completed." Id. at 386. The court remanded the standards to the agency with the directive to republish them and follow the procedural requirements.

In Marshal, 581 F.2d 960, the agency was required to consult an advisory committee before promulgating the disputed standards. The court found the agency greatly deviated from required procedures and agency regulations by not meaningfully consulting the committee. The court concluded that, had the agency abided by its procedural requirements, the agency may have promulgated

different standards. Accordingly, the court remanded the standards back to the agency for consultation with the advisory committee. Because the court also found the standards as promulgated were not illegal and the administrative record did not contain any glaring deficiencies, the court ordered a minimum remand of ninety days during which the standards would remain in effect. If the committee recommended alteration, the agency would have to reevaluate the standards.

In Brennan and Marshal, the agencies failed procedural requirements in the process of promulgating agency standards. In both Brennan and Marshal, the courts remanded the disputed agency standards with directives to comply with the procedural directives. The Marshal decision left the standards intact; the Brennan decision did not.

This case is similar to Brennan and Marshal in that the ETS Risk Assessment constitutes an agency characterization promulgated without adherence to statutory procedure. However, this case is also unique. First, it is quite clear that the ETS Risk Assessment consumed significantly more resources than the promulgation of standards in Brennan and Marshal. Second, Congress' procedural requirements in the Radon Research Act adhere to the research process. Remanding the ETS Risk

Assessment for post hoc consultation could not satisfy statutory requirements of consultation during research.

To satisfy the Radon Research Act's procedural requirements, the court would have to vacate the Assessment. EPA could then conduct research on ETS with the assistance of a representative committee. However, in Vermont Yankee, the Supreme Court advised that agency action should be set aside only for substantial reason. By itself, disregarding a statutory mandate to establish and consult an advisory committee is substantial. Again, EPA expended significant resources over several years in producing an assessment which claimed to deal with public health and safety. The Assessment's subject matter and EPA's expenditures raise the threshold of what constitutes a substantial reason.

EPA's complete disregard of statutory procedure and the potential waste of significant executive branch resources dealing with health and safety each suggest a different remedy. In resolving this conflict, the court finds persuasive the rationale underlying the District of Columbia's remedy in Marshal. In addition to enforcing Congress' directive, the remedy should ameliorate the harm caused, or being caused, by EPA's procedural

violation."[17] The court is reluctant to characterize EPA's procedural deficiency substantial where EPA would simply reproduce the same ETS Risk Assessment at significant cost. In resolving the substantiality of EPA's procedural defect, the court must inquire whether EPA's procedural failure affected the Assessment. See Textile Workers Union of America v. Lincoln Mills of Alabama, 353 U.S. 448, 457, 77 S. Ct. 912, 918 (1957) (Some federal law "lack[s] express statutory sanction but will be solved by looking at the policy of the legislation and fashioning a remedy that will effectuate that policy. The range of judicial inventiveness will be determined by the nature of the problem."); United States v. Field, 193 F.2d 92, 95 (2nd Cir. 1951) ("'[I]t is fundamental that federal courts, in common with other courts, have inherent power to do all things that are reasonably necessary for the administration of justice, within the scope of their jurisdiction.'")

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[17] In deciding whether procedural compliance could have produced a different outcome, the Marshal decision also distinguished agency action that violated the law. EPA's procedural failure constitutes a violation of the law. Where significant agency resources are at stake, the court will not, however, adopt a formal, bright line rule.

V. THE ENVIRONMENTAL TOBACCO SMOKE RISK ASSESSMENT

A. Overview

The court reviews the performance of the ETS Risk Assessment to determine whether consultation with the representative group would have likely produced a different result.[18] The court also reviews the record to determine whether EPA conducted the Assessment in accordance with the Radon Research Act, aside from procedural defects. Plaintiffs contest the validity of Chapters 3, 4, and [illegible] of the final ETS Risk Assessment. A brief overview of the Assessment will elucidate the arguments.[19]

Chapter 1 summarizes the claim that ETS is a Group A carcinogen that causes approximately 3,000 lung cancer deaths per

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[18] Plaintiffs initially argue that had industry been consulted during the research process, EPA likely would not have conducted a risk assessment and carcinogen classification. Plaintiffs' argument depends on the ETS Risk Assessment being ultra vires. As already addressed, risk assessment is incidental to gathering information, researching, and disseminating the findings.

[19] The parties' arguments to the court address whether EPA's conduct was arbitrary and capricious and whether the record demonstrates reasoned decision making. The court uses the arguments to determine whether the Assessment would have been different had industry (and state) representatives addressed their concerns directly to EPA. The inquiry turns on the legitimacy of Plaintiffs' concerns.

year among nonsmokers. Chapter 2 provides an introduction and overview. EPA states the study was conducted in accordance with its Risk Assessment Guidelines. The report explains EPA did not use its Guidelines for Health and Risk Assessment of Chemical Mixtures because mainstream smoke (MS)[26] and ETS are not sufficiently similar. Specifically, using "cigarette-equivalents" to correlate ETS exposure was not conducted for several reasons.

> Although MS and ETS are qualitatively similar with respect to chemical composition (i.e., they contain most, if not all, of the same toxicants and carcinogens), the absolute and proportional quantities of the components, as well as their physical state, can differ substantially. . . . Furthermore, it is not known which of the chemicals in tobacco smoke are responsible for its carcinogenicity. Clearly, the comparison of a small number of biomarker measures cannot adequately quantify differential distributions of unknown carcinogenic compounds.
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> Another area of uncertainty in the "cigarette-equivalents" approach relates to potential metabolic differences between active and passive smokers. . . . Because of these uncertainties, the data from active smoking are more appropriate for qualitative hazard identification than for quantitative dose-response assessment.

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[26] Mainstream smoke is the smoke inhaled by the smoker.

ETS Risk Assessment at 2-7 thru 2-8. The report then states that although ETS and MS are chemically similar, "ETS is rapidly diluted into the environment, and consequently, passive smokers are exposed to much lower concentrations of these agents than are active smokers." Id. at 2-8.

Chapter 3 establishes that ETS and MS are chemically similar because: (a) ETS is composed of aged, diluted sidestream smoke (SS),[21] and aged, diluted, exhaled MS, and (b) fifty-two of the 4,000+ characterized chemical constituents of MS were found in SS, which include most of the suspected carcinogens identified in MS.

Chapter 4 states that the high relative risks (RR) for lung cancer associated with active smoking along "with no evidence of a threshold level of exposure," id. at 2-9, the chemical similarity between MS and ETS, and corroborative evidence for the carcinogenicity of tobacco smoke provided by animal bioassay and genotoxicity studies "clearly establish the biological plausibility that ETS is also a human lung carcinogen." Id. at 2-9; see also 4-27 thru 4-29. EPA asserts these observations

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[21] Sidestream smoke is the smoke emitted from a smoldering cigarette between puffs.

alone are sufficient to establish ETS as a Group A carcinogen designation.[22]

Chapter 4 concludes with recognition that EPA should examine the "vast body of epidemiologic data dealing specifically with lung cancer and exposure to ETS." Id. at 4-29. The chapter concludes this data should be examined: (1) to promote "the interest of weighing all the available evidence, as recommended by EPA's [Risk Assessment Guidelines] . . ." (2) because SS and MS rapidly dilute into the environment and ETS components change phase distributions over time, which raises questions about the carcinogenicity of ETS exposure under environmental conditions, and (3) since "active smoking data do not constitute a good basis for quantitative estimation of the health effects of passive

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[22] A substance is categorized as a Group A Human Carcinogen "only when there is sufficient evidence from epidemiologic studies to support a causal association between exposure to the agents and cancer." Risk Assessment Guidelines at 34,000.

> Three criteria must be met before a causal association can be inferred between exposure and cancer in humans: 1. There is no identified bias that could explain the association. 2. The possibility of confounding has been considered and ruled out as explaining the association. 3. The association is unlikely to be due to chance.

Id. at 33,999.

smoking because the relative uptake and deposition between active and passive smokers of the agent(s) responsible for these effects are not known . . . ." Id.

Chapter 5 analyzes thirty-one epidemiologic studies of nonsmoking women married to smoking spouses (spousal smoking studies). Chapter 5 combines the spousal smoking studies data into six statistical "meta-analysis" based on geographic origin. Chapter 5 also analyzes high-exposure groups in the studies, conducts a trend analysis, and categorizes studies into four tiers based on their perceived utility for assessing an ETS/lung cancer association. The analysis within Chapter 5 utilizes one-tailed tests of significance and 90% confidence intervals. "The justification for this usage is based on the a priori hypothesis [from the theory of biological plausibility] that a positive association exists between exposure to ETS and lung cancer." Id. at 5-2.

Chapter 6 conducts an exposure assessment in an attempt to quantify the threat posed by ETS. Chapter 6 concludes that MS and ETS are too dissimilar to use data about MS to assess the risks of ETS exposure. Id. at 6-6. Chapter 6 thus bases its exposure assessment on data from the spousal smoking studies and

asserts that ETS exposure causes approximately 3,000 nonsmoker lung cancer deaths each year.[21]

The Addendum addresses large U.S. spousal smoking studies published in 1992. It claims "these new studies are generally consistent with this report's conclusions . . . ." Id. at ADD-1. Appendix A reviews the thirty-one spousal smoking studies and explains how the studies were assigned to tiers based on their perceived utility. Appendix B explains how EPA adjusted the data used in Chapter 5's meta-analysis to address the effects of smoker misclassification bias.

There are two issues. The first is whether EPA's consulting a representative committee, on which industry's concerns were represented during the research process, likely would have caused EPA to change the conduct or conclusions of its ETS assessment. The key to this determination is whether industry representatives could have presented meritable criticism and advice. The second issue is whether EPA's conduct was otherwise in accordance with the Radon Research Act.

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[21] Chapters 7 and 8 do not involve the carcinogenicity of ETS.

B. Biological Plausibility

1. Industry Criticism

Plaintiffs argue EPA's "biological plausibility" analysis is flawed because the Agency disregarded evidence that MS and ETS are not similar, failed to identify the criteria used in equating MS and ETS, and disregarded evidence that MS has a no-effect threshold. The importance of Plaintiffs' arguments is that the biological plausibility analysis establishes Chapter 5's "a priori hypothesis" that ETS is a Group A carcinogen. EPA uses this hypothesis to justify the use of one-tailed significance tests, which the Agency in turn relies upon to switch from a 95% to 90% confidence interval.

Plaintiffs assert the record does not explain why EPA ignored record evidence and EPA's own findings in the chemical similarity analysis of Chapter 3. Plaintiffs point out that EPA analyzed the similarity of MS and ETS three times and reached three different conclusions. Chapter 6 establishes ETS and MS were too dissimilar to use MS data to establish the carcinogenic risk of ETS, and Chapter 2 states the similarity of ETS to MS was too indeterminate to assess risk according to EPA's Guidelines for the Health Risk Assessment of Chemical Mixtures. Chapter 3, however, uses the chemical similarities of ETS and MS to

establish ETS as a known human carcinogen.

Chapter 3's similarity analysis fails for three reasons: (1) the chapter ignored Assessment findings about the differences between MS and ETS; (2) EPA ignored evidence rejecting any chemical similarity; and (3) EPA did not define the criteria used to reach conclusions about the similarity/dissimilarity/indeterminacy of MS and ETS.

Plaintiffs point out Chapter 3's similarity analysis is contradicted by the explanation at the end of Chapter 4 for analyzing epidemiologic data. Specifically, "[t]he rapid dilution of both SS and exhaled MS into the environment and changing phase distributions of ETS components over time raise some questions about the carcinogenic potential of ETS under actual environmental exposure conditions." ETS Risk Assessment at 4-29.

In rejecting using a "cigarette-equivalents" correlation, Chapter 2 states that although MS and ETS are qualitatively similar, the absolute and proportional quantities of the components, as well as their physical state, differ substantially. EPA also rejects this equivalents analysis because it does not know which tobacco smoke chemicals cause cancer nor the effect metabolic differences between active and

passive smokers have on carcinogenicity. See id. at 2-7 thru 2-9. Chapter 6 bases its rejection of an equivalents analysis on the differences between MS and SS:

> The basic assumption of cigarette-equivalents procedures is that the lung cancer risks in passive and active smokers are equivalently indexed by the common measure of exposure to tobacco smoke, i.e., a common value of the surrogate measure of exposure in an active and a passive smoker would imply the same lung cancer risk in both. This assumption may not be tenable, however, as MS and SS differ in the relative composition of carcinogens and other components identified in tobacco smoke and in their physicochemical properties in general: the lung and systemic distribution of chemical agents common to MS and SS are affected by their relative distribution between the vapor and particle phases, which differs between MS and SS and changes with SS as it ages. Active and passive smoking also differ in characteristics of intake . . . which may affect deposition and systemic distribution of various tobacco smoke components as well.

Id. at 6-6. EPA further revealed that such differences affect carcinogenicity: "Pipe and cigar smokers, who inhale less deeply than cigarette smokers, have lower risks of lung cancer than cigarette smokers." Id. at 4-10.

In a draft response to comments, Kenneth Brown, the primary author of Chapters 5 and 6, and Appendices C and D, rejects using a cigarette-equivalents analysis because "there are differences between active and passive smoking that may affect carcinogenic

risk that are not fully understood." Kenneth G. Brown, Draft Report Responses to Public Comments on the First EPA Draft Risk Assessment of ETS with Discussion of Revisions that Appear in the Second Draft Report, Response To Comment 3.1.4, at 16 (June 1992) (JA 6,457) (Draft Responses). The author agrees "that active and passive smoking are vastly dissimilar with regard to exposure," id., and states,

> [a]lthough it would be of interest to know more about the physicochemical properties of ETS, the distribution of exposure concentration, exposure duration, and other characteristics, these things do not need to be fully understood to conclude that ETS is a carcinogen. . . . If the unknown characteristics regarding the properties of ETS or exposure to ETS nullified the carcinogenic potential in fresh sidestream smoke, then we would not expect to see an association of ETS exposure with increased lung cancer, as the study data indicate.

Id., Response To 3.1.2, at 14 (JA 6,455).

Plaintiffs assert EPA's statements impact EPA's biological plausibility analysis. Regarding EPA's a priori hypothesis, Plaintiffs conclude: (1) ETS cannot be a known carcinogen if dilution and aging raise unresolved questions about its potential carcinogenicity, and (2) ETS and MS are not "sufficiently similar" carcinogens if they are "vastly dissimilar" as to exposure.

Plaintiffs next point to comments submitted by scientists[24] and by the tobacco industry citing scientific literature[25] that reject EPA's similarity conclusions. Plaintiffs contend EPA selectively cites or ignores certain studies, depending on whether the Agency is explaining or disclaiming similarities between ETS and MS. Plaintiffs also point out that none of the eleven U.S. epidemiologic studies analyzed in the ETS Risk Assessment, as reported by their authors, shows an overall statistically significant association between ETS and lung cancer.

Plaintiffs also argue EPA failed to identify the criteria used to determine chemical similarity. Plaintiffs insist the criteria EPA used to analyze similarity must be precise for two reasons. First, at different times in the same ETS Risk Assessment, EPA concluded that MS and ETS are similar,

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[24] See, e.g., Comments of Cronan (JA 6,188); Comments of Gori (JA 10,839); Comments of Todhunter (JA 10,072); Comments of Flamm (JA 10,633-34); Comments of Newell (JA 10,660-61); Comments of Reasor (JA 10,786).

[25] See, e.g., Comments of The Tobacco Institute (JA 9,537-38, 9,543); Comments of Reasor (JA 10,789-90); Comments of R.J. Reynolds (JA 5,841-58); Comments of Philip Morris (JA 10,012, 10,024).

dissimilar, and of indeterminate similarity.[24] Second, EPA's chemical similarity analysis is inconsistent with the Agency's prior risk assessment practices. See Risk Assessment Guidelines at 33,992 (listing "consistency of carcinogen risk assessments" as an EPA goal). Plaintiffs then provide evidence that, previously, EPA did not classify agents in Group A because they contain the same constituents as other Group A carcinogens. See Tennessee Gas Pipelines Co. v. F.E.R.C., 926 F.2d 1206, 1211 (D.C. Cir. 1991) (When an agency decision is inconsistent with prior decisions, it must explain the change.).

As their final argument against EPA's biological plausibility hypothesis, Plaintiffs dispute EPA's conclusion that ETS exposure causes lung cancer because "[a] clear dose-response relationship exists between lung cancer and amount of exposure [to MS], without any evidence of a threshold level." ETS Risk Assessment at 4-1. EPA's "no threshold" finding means EPA

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[24] See Dithiocarbamate Task Force v. EPA, 98 F.3d 1394, 1404-05 (D.C. Cir. 1996) (vacating EPA's listing of a carbamate as a "K waste" because EPA could not employ a highly discretionary and unarticulated "environmental concern" standard and then fail to explain why that carbamate failed to meet that standard); see also Toler v. Eastern Assoc. Coal Co., 43 F.3d 109, 115-16 (4th Cir. 1995) (review of denial of medical benefits, requiring an ALJ to identify specific and persuasive reasons to justify seemingly paradoxical reasoning).

purported to find no concentration level at which MS ceases to be carcinogenic. This finding was critical because Plaintiffs assert that nonsmokers are exposed to only minute concentrations of ETS. If EPA had found a threshold for exposure to MS, then one would have to be established for ETS. Evidence of an MS exposure threshold would jeopardize EPA's biological plausibility analysis since ETS is substantially more dilute than MS. Plaintiffs point to comments and evidence in the record of thresholds in human, animal, and genotoxicity studies. Again, Plaintiffs point to EPA's selective use of studies and failure to consider or respond to contrary evidence.

2. EPA's Response

In response to Plaintiffs' claim that EPA failed to respond to certain public comments, EPA asserts that it did not have an obligation to respond to public comments in the same manner as in formal rulemaking. EPA further reminds that it is not the province of the court to impose additional procedural requirements outside those mandated by Congress.

In assessing the health risk of ETS, EPA claims it used a "total weight of the evidence" approach, see Risk Assessment Guidelines at 33,996, 33,999-34,000, and the Agency's conclusions

rely upon all of the available evidence, not on any single analysis or theory. EPA offers two reasons the ETS Risk Assessment is unique. First, the database of evidence concerning ETS is large and derived from human data. "The use of human evidence eliminates the uncertainties that normally arise when one has to base hazard identification on the results of high-dose animal experiments." ETS Risk Assessment at 2-7. Second, the evidence consists of exposure at environmental levels people are exposed to in everyday life. EPA states such data are rare in risk assessments and obviate the need to extrapolate a response from high to low exposures. The available data being unique, EPA asserts "the guidelines themselves stress that risk analysis is not subject to hard and fast rules, but rather must be 'conducted on a case-by-case basis, giving consideration to all relevant scientific information.'" (Conformed Mem. Supp. EPA's Cross Mot. Part. Summ. J. at 47; quoting Risk Assessment Guidelines at 33,992.)

EPA explains that its biological plausibility findings rest on three considerations. First, active smoking causes lung cancer in humans, and MS is chemically similar to ETS. Second, considerable evidence exists that nonsmokers exposed to ETS absorb and metabolize significant amounts of ETS, including

carcinogenic compounds. Third, laboratory studies show ETS can cause cancer in animals and damage DNA, which scientists recognize as being an instrumental mechanism for cancer development. Further, EPA argues that its bioplausibility theory alone need not be sufficient to support the Assessment's conclusion, because the theory is confirmed by the findings from the epidemiologic studies.

EPA defends its Chapter 3 findings of chemical similarity by stating the Agency never suggested ETS and MS are identical compounds. Rather, EPA found that ETS and MS are similar in some respects and can be compared in terms of carcinogenicity. Differences between the compounds were not disregarded by the Agency. EPA cites to the many portions in the ETS Risk Assessment where EPA discusses the dissimilarities between MS and ETS.[37]

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[37] EPA also relies upon IAQC's finding:

> There are substantial differences in the relative composition of the smoke formed between mainstream and sidestream smoke, . . . but there is no reason to suppose that the qualitative toxicities of ETS and MS are substantively different. In comparing these two agents the differences are largely ones of dose and duration of exposure rather than fundamental differences in the toxicity or carcinogenicity of the agent in question.

(continued...)

EPA asserts the Assessment specifically discusses dilution in ambient air, aging, and exposure characteristics. Review of EPA's citations reveals very limited discussion. The discussions primarily admit that these are areas of uncertainty. See ETS Risk Assessment at 3-10 ("Detailed chemical characterizations of ETS emissions . . . are limited. As a result, the impact on ETS of factors such as the rapid dilution of SS emissions, adsorption and remission of contaminants, and exhaled MS is not well understood."); see also id. at 3-14 (ETS concentration is the result of a complex interaction of at least 13 variables; studies show large variations in contaminant concentrations.). EPA asserts that despite these uncertainties, nonsmokers' lungs are nevertheless exposed to and absorb contaminants, including carcinogens, and that exposure can be at significant levels relative to active smokers.

EPA characterizes Plaintiffs' contrasting the Agency's differing conclusions on ETS-MS similarities as nothing more than obfuscating the differences between qualitative and quantitative assessments. EPA claims the first issue (hazard identification)

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[27](...continued)
EPA, An SAB Report: Review of Draft Passive Smoking Health Effects Document, EPA/SAB/IAQC/93/003, at 11, November 20, 1992.

in the risk assessment process is a qualitative determination as to whether a substance is carcinogenic. See Risk Assessment Guidelines at 33,993 ("The hazard identification component qualitatively answers the question of how likely an agent is to be a human carcinogen."). EPA asserts that if the substance is identified as a hazard, the second question is a quantitative assessment as to how dangerous a carcinogenic substance is to humans. See id. (Quantitative risk assessment is a general term to describe all or parts of dose-response assessment, exposure assessment, and risk characterization.).

EPA also claims it explained four criteria for finding MS and ETS chemically similar: (1) the process resulting in the generation of MS and SS; (2) the identity of toxins and carcinogens in the two substances; (3) the relative toxicity and carcinogenicity of SS and MS per cigarette smoke; and (4) the demonstrated exposure to and absorption by the body of significant levels of carcinogens and other toxins. In response to the charge that it changed its approach in evaluating biological plausibility vis-a-vis other Group A carcinogen determinations, EPA states risk assessments are conducted on a case-by-case basis. Thus, comparison to other EPA Group A determinations are not relevant. EPA then re-explains the basis

for its plausibility hypothesis and states no other EPA Group A determination involves comparison with a substance whose carcinogenicity is as potent and as well documented as MS.

EPA asserts the epidemiologic studies reviewed in Chapter 4 establish MS as a human carcinogen. In defense of chemical similarity, EPA recites the similarities between SS and MS. Both compounds contain the same carcinogenic compounds, moreover, EPA asserts "there is voluminous record evidence demonstrating that SS is more toxic per cigarette smoked than the carcinogenic MS." (Conformed Mem. Supp. EPA's Cross Mot. Part. Summ. J. at 62.)

In recognizing that ETS is rapidly diluted into the environment, EPA explains that it analyzed the extent to which nonsmokers actually absorb and metabolize ETS. First, EPA examined the extent of nonsmokers' actual exposure to ETS in a variety of indoor environments. The studies EPA reviewed showed measurable carcinogens and toxins in ETS at levels that varied but consistently exceeded background levels. Second, EPA reviewed biomarker studies which showed at least some of the carcinogens in ETS are absorbed by the body at a higher rate than nicotine. The human carcinogen 4-aminobiphenyl (4-ABP), which is emitted at concentrations 31 times greater in SS than MS, was present in the blood of nonsmokers exposed to ETS in

concentrations of one-tenth to one-fifth of that found in active smokers. These studies lead EPA to conclude that nonsmokers exposed to ETS absorb and metabolize ETS, including carcinogenic compounds.

EPA asserts that Plaintiffs' arguments are simply attacks on the uncertainties inherent in the risk assessment process. A risk assessment, by its very nature, is not a final determination about the health effects of a substance but is instead an assessment that makes the best judgments possible based upon the available evidence. Ethyl Corp. v. EPA, 541 F.2d 1, 24 (D.C. Cir. 1976). In conducting risk assessments, an agency must adopt inference options and point out where evidence and scientific knowledge are incomplete. NRC Redbook, at 18, 28.

Finally, EPA defends its determination that there is no safe level of exposure to MS by referring to several studies that found a risk of lung cancer at the lowest levels of exposure to MS. EPA also relies upon SAB's finding it plausible that prolonged inhalation of ETS results in some increase of lung cancer. Finally, EPA asserts the record rebuts Plaintiffs' argument that nonsmokers are exposed only to small amounts of ETS.

3. Analysis

EPA offers three assertions as the foundation for its biological plausibility hypothesis. Plaintiffs contest EPA's first assertion that MS and ETS are similar. In support of its second assertion, EPA points to evidence in the record that some components of ETS are absorbed by nonsmokers. EPA does not, however, direct the court to evidence in the record demonstrating that the observed absorption of ETS constituents answers the questions of carcinogenicity raised elsewhere in EPA's analysis.

There is limited evidence in the record supporting EPA's final basis for its plausibility hypothesis. The animal laboratory studies used by EPA present some evidence supporting EPA's hypothesis. EPA conducted no animal lifetime inhalation studies of ETS but did conduct cigarette smoke inhalation studies on Syrian golden hamsters. The studies detected no evidence of lung cancer but did detect evidence of cancer of the upper larynx and a dose-response relationship. The record does not state whether the substance analyzed, air-diluted cigarette smoke (1:15), replicated MS, SS, or ETS. The remaining studies, upon which EPA relies, involve analysis of SS condensates from smoking machines. The Assessment does not explain, nor does EPA direct

the court to any evidence within the record explaining, how SS condensate demonstrates similarities between MS and ETS.

The court is disturbed that EPA and Kenneth Brown buttress the bioplausibility theory with the epidemiology studies. EPA's theory must be independently plausible. EPA relied upon similarities between MS and ETS to conclude that it is biologically plausible that ETS causes cancer. EPA terms this theory its "a priori hypothesis" in justifying Chapter 5's methodology. Chapter 5's methodology allowed EPA to demonstrate a statistically significant association between ETS exposure and lung cancer. See Federal Judicial Center, Reference Manual on Scientific Evidence 154-55, (1994) (Narrowing the confidence intervals makes it more likely that a study will be found to be statistically significant.). Chapter 5's analysis rests on the validity of the biological plausibility theory. It is circular for EPA to now argue the epidemiology studies support the Agency's a priori theory. Without the theory, the studies would likely have done no such thing.

The record also does not support EPA's argument that contrasting EPA's three positions on ETS-MS similarities constitutes obfuscation. EPA's Risk Assessment Guidelines establish a distinction between qualitative and quantitative

analysis. However, for purposes of EPA's biplausibility theory, neither the ETS Risk Assessment or administrative record demonstrates a difference or attempt the explanation which EPA now offers the court. Quantity versus quality may be a relevant distinction in certain situations, e.g., the amount of arsenic naturally occurring in an apple. Plaintiffs assert that since ETS is a gas, considering the evidence regarding ETS' physicochemical properties and the characteristics of the particles and gases comprising ETS is necessary to determine the quality of ETS. This suggests an analytical process combining qualitative and quantitative analysis, which is also what EPA's Risk Assessment Guidelines suggest.

EPA's Risk Assessment Guidelines do not support the Agency's argument that risk assessment is a bifurcated, quantitative then qualitative, analysis. To the contrary, "[r]isk assessment includes one or more of the following components: hazard identification, dose-response assessment, exposure assessment, and risk characterization (NRC 1983)." Risk Assessment Guidelines at 33,993 (emphasis added). "[Q]uantitative risk assessment has been used as an inclusive term to describe all or parts of dose-response assessment, exposure assessment, and risk characterization. . . . [However,] the more explicit terminology

developed by the NRC (1983) is usually preferred." Id. Neither the Assessment or the administrative record explains why physicochemical inquiries require a bifurcated analysis instead of a combined analysis as per the Guidelines, or why MS and ETS are similar for purposes of hazard identification, but not for purposes of quantitative risk assessments. Since Chapter 2 found ETS and MS not sufficiently similar, Chapter 3 found them similar, and Chapter 6 found them dissimilar, EPA apparently used a different risk assessment methodology for each chapter. Again, neither the Assessment nor the record explains the risk assessment components used in the different chapters, why methodologies varied between chapters, or why ETS and MS were or were not similar using each methodology.

The court is faced with the ugly possibility that EPA adopted a methodology for each chapter, without explanation, based on the outcome sought in that chapter. This possibility is most potent where EPA rejected MS-ETS similarities to avoid a "cigarette-equivalents" analysis in determining carcinogenicity of ETS exposure. Use of cigarette-equivalents analysis may have lead to a conclusion that ETS is not a Group A carcinogen.[26] It

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[26] [S]ome persons suggest a dosimetric approach

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is striking that MS and ETS were similar only where such a conclusion promoted finding ETS a carcinogen.

EPA's assertion that "EPA did explain the numerous criteria it used in assessing similarity . . . ," (Conformed Mem. Supp. EPA's Cross Mot. Part. Summ. J. at 73), is without merit. EPA merely parrots the findings made in Chapter 3 of the ETS Risk Assessment. The record presents no evidence of EPA establishing similarity criteria before the Assessment.[39] Nor did the

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[38](...continued)
(called "cigarette-equivalents" in the Report) to estimate lung cancer risk from ETS exposure from data on active smoking. An average ETS exposure is determined to be equivalent to actively smoking some percentage of one cigarette per day. Extrapolating downward on a does-response [sic] curve for active smoking at that level suggests a "negligible" lung cancer risk.

Kenneth G. Brown, Draft Report Responses to Public Comments on the First EPA Draft Risk Assessment of ETS with Discussion of Revisions that Appear in the Second Draft Report, Comment 3.1.4. at 15 (June 25, 1992) (JA 6,456) (Draft Responses). Dr. Brown's response does not rebut the asserted consequences of a cigarette equivalents analysis.

[39] See Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 395 (D.C. Cir. 1973) ("A troublesome aspect of this case is the identification of what, in fact, formed the basis for the standards promulgated by EPA - a question that must be probed prior to consideration of whether the basis or bases for the standards is reliable."); see also Independent U.S. Tankex Owners Comm. v. Lewis, 690 F.2d 908, 920 (D.C. Cir. 1982) (noting that when agency action is undertaken prior to disclosure of the basis (continued...)

scientists on IAQC's final review panel identify the criteria used to determine similarity.[32] EPA's citations reveal only summaries of findings on MS-SS similarities and ETS biomarkers.[33]

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[32](...continued)
of the action, "[t]here is an overwhelming institutional bias in favor of justifying the result in any way possible.")

[33] The data in Chapter 3 "do not . . . adequately support the conclusion that the two are chemically similar. . . . [T]he data that are in there, speaking as a chemist, they simply don't make the case." 1992 IAQC Review at II-41 (Dr. Daisey) (JA 11,969). "That also brings you to an issue of what you mean by 'chemically similar,' which is not so simple to discuss. . . . [P]erhaps we don't have to consider it. But in a broader sense, the chapter often talks about sort of vague quantitative terms . . . ." Id. at II-43 (JA 11,971). "What does it mean? What is the test for chemical similarity?" Id. at II-51 (Dr. Hammond) (JA 11,979). "[T]he data . . . simply do not demonstrate that they are similar. There are simply not enough data. . . . [Y]ou're not going to have that data, and even if you did, you'd have to decide on criteria for what constitutes similarity and what does not constitute similarity." Id. at II-77 (Dr. Daisey) (JA 12,005).

[34] Instead of explaining the criteria used to make findings, EPA's citations reveal more uncertainty. "Standardized testing protocols for assessing the physical and chemical nature of SS emissions . . . do not exist, and data on SS are not as extensive as those for MS emissions." ETS Risk Assessment at 3-2.

> Although ETS is a major source of indoor air contaminants, the actual contribution of ETS to indoor air is difficult to assess due to the background levels of many contaminants contributed from a variety of other indoor and outdoor sources. Relatively few of the individual constituents of the ETS mix have been identified and characterized. In addition, little is known about the role of individual ETS constituents in

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The record does not support EPA's arguments that EPA took MS-ETS differences into account and, despite them, concluded ETS is a known human carcinogen because nonsmokers are exposed to and absorb carcinogens. EPA conceded that dilution, aging, and exposure characteristics fundamentally distinguish ETS from mainstream smoke, and "raise . . . questions about the carcinogenic potential of ETS." ETS Risk Assessment at 2-7 thru 2-8, 4-29, 6-6. See also Draft Responses at 14-16 (JA 6,455-57). The record does not explain how, after raising these questions, EPA could classify ETS a known human carcinogen based on similarities between SS and MS. The record also fails to explain whether or how EPA determined that, because some components of ETS may be absorbed, questions raised in other areas of the assessment about the carcinogenic potential of ETS were no longer relevant.

Finally, both sides cite to independent studies on ETS, done by third parties, to support their arguments. Both sides often lay claim to the same studies. The studies predominantly contain

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11 (...continued)
eliciting the adverse health and nuisance effects observed.

Id. at 3-18.

information useful to both sides, and often conflict with one another. The court finds one review particularly relevant, a review conducted within EPA on the ETS Risk Assessment. EPA's Risk Criteria Office, a group of EPA risk assessment experts, concluded that EPA failed to reasonably explain how all relevant data on ETS, evaluated according to EPA Risk Assessment Guidelines' causality criteria, can support a Group A classification. Acting Director Chris DeRosa advised EPA that the evidence "support[ed] the conclusion that ETS be classified as a Group B1 carcinogen."[33] EPA Toxicologist Larry Glass concluded, "it is recommended that the [epidemiological] evidence be summarized as being limited . . . . This would classify ETS into a weight-of-the-evidence Group B1."[34] Office Director Terry Harvey also concluded that the ETS Classification's analysis violated EPA's Risk Assessment Guidelines: "[l]ike it or not,

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[33] EPA Memorandum from Chris DeRosa, Acting Director Environmental Criteria and Assessment Office, to William H. Farland, Director, Office of Health and Environmental Assessment (OHEA) 1 (April 27, 1990) (JA 6,651).

[34] Id. at 4-5 (JA 6,654-55). The same author recognizes "tremendous scientific, regulatory, and political ramifications of categorizing a substance as a Group A carcinogen. . . . [G]iven the inherent limitations of the data, and the comparative novelty of the approach used to interpret the data I would recommend that this approach not be used as the basis of a Group A classification." Id. at 4 (JA 6,654).

EPA should live within its own categorization framework or clearly explain why we chose not to do so."[31]

In summary, Plaintiffs raise legitimate questions not addressed in the record regarding EPA's bioplausibility theory. If confronted by a representative committee that voiced industry concerns, EPA would likely have had to resolve these issues in the record. It is not clear whether EPA could have or can do so. These issues are more than periphery. If EPA's a priori hypothesis fails, EPA has no justification for manipulating the Agency's standard scientific methodology.

C. EPA's Choice of Epidemiological Studies.

By the time EPA released the ETS Risk Assessment in 1993, 33 studies had analyzed the lung cancer risk of nonsmoking females married to smoking spouses. 12 studies had analyzed the risk of females exposed to ETS in the workplace, and 13 studies had analyzed the risk of females exposed to ETS in childhood. Six of the 58 analyses (10.3%) reported a statistically significant association between ETS exposure and lung cancer for

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[31] EPA Memorandum from Terry Harvey, Director, Environmental Criteria and Assessment Office, to Linda Bailey, Technical Information Staff, OHEA 2 (March 24, 1992) (emphasis added) (JA 6,661).

nonsmoking females; two of 13 analyses for male nonsmokers were significant. EPA chose 31 of the 33 studies done on nonsmoking females married to smoking spouses. Of the 33 studies completed in 1993, three large U.S. studies were not completed at the time EPA conducted its second IAQC review. EPA used interim results from one of the three, the Fontham study, and did not include the other two in its overall assessment. EPA did not draw its conclusions directly from the 31 studies it chose. Instead, EPA pooled the results of the studies and arranged the data into categories by geographic region and exposure level. EPA then organized and analyzed the studies by the quality of their methodology. This technique of synthesizing findings across related studies is known as meta-analysis.

The Risk Assessment gives short notice to why the childhood or workplace studies were not evaluated. The assessment states,

> [t]he use of a more homogenous group allows more confidence in the results of combined study analyses. . . . Some [studies] also provide information on childhood and/or workplace exposure, but there is far less information on these exposures; therefore, in order to develop one large database for analysis, only the female exposures from spousal smoking are considered.

ETS Risk Assessment at 5-1. The Assessment's overview explains only that childhood and workplace studies are fewer, represent

fewer cases, and are generally excluded from EPA's analysis. Id. at 1-8. The Addendum mentions the two large U.S. female nonsmoker studies but does not explain why the two were excluded but the Fontham study included.

In its first review, IAQC stated that one of four criteria necessary to conduct a meta-analysis is a "precise definition of criteria used to include (or exclude) studies." EPA, An SAB Report: Review of Draft Environmental Tobacco Smoke Health Effects Document, EPA/SAB/IAQC/91/007 at 32-33 (1991) (SAB 1991 Review) (JA 9,497-98). Regarding the studies chosen for the ETS Risk Assessment, IAQC stated,

> [s]pecific criteria for including studies was not provided. The importance of this was reinforced at the Committee meeting when a reanalysis was presented on a different set of studies than those in the report. This resulted in a change in the overall risk estimate. Decisions as to study inclusion should be made prior to analysis, based on clearly stated criteria. It is also desirable to evaluate the impact on conclusions of closely related, but excluded, studies.

Id. at 33 (first emphasis added) (JA 9,498). In its 1992 review, neither EPA or IAQC addressed again the criteria used to determine which studies were included in the meta-analysis. IAQC stated that the combination of studies used provided a scientifically defensible basis for estimating the relative risk

of lung cancer associated with ETS among American women who have never smoked cigarettes. IAQC also supported EPA's general meta-analysis categorization of the studies which EPA had chosen. See EPA, An SAB Report: Review of Draft Passive Smoking Health Effects Document, EPA/SAB/IAQC/93/003 at 3-4, 22 (1992) (IAQC review which EPA now misrepresents as a full explanation of EPA's database choice with express IAQC support) (JA 12,207-08, 12,276).

Plaintiffs contest that EPA excluded studies and data on workplace and childhood exposure to ETS, as well as the "two largest and most recent" U.S. spousal smoking studies, because inclusion would have undermined EPA's claim of a causal association between ETS exposure and lung cancer.[35] (Conformed Mem. Supp. Pls.' Mot. Summ. J. at 66.) In its memorandum before this court, EPA offers four reasons for excluding the workplace and childhood data.

"First, such data are less extensive and therefore less reliable." (Conformed Mem. Supp. EPA's Cross Mot. Part. Summ. J. at 88.) EPA's three citations to the record do not support this

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[35] Plaintiffs also argue EPA included workplace data that affirmed the Agency's a priori hypothesis. The court does not find it necessary to reach the merits of this assertion.

assertion. All three citations state there is less information in the disputed studies. One of Dr. Brown's draft responses also calls the disputed studies inadequate, without reason or explanation. IAQC also recognized the disputed studies contained less information, however, IAQC concluded "the report should review and comment on the data that do exist . . . ." SAB 1991 Review at 5 (JA 9,470). The court has also found no record support or reason for the assertion that smaller studies are less reliable for purposes of meta-analysis. The purpose of meta-analysis is utilization of smaller studies.

Similarly, EPA's second assertion that workplace studies were excluded because of potential confounders is without record support. As evidence explaining why EPA excluded workplace studies from the meta-analysis, EPA cites IAQC's 1991 Review discussing limitations on EPA's reliance on spousal smoking as an indicator of ETS exposure. IAQC discussed that the structure of peoples' homes, where they live and work, the climate, and even parental influences impact spousal assessments. SAB 1991 Review at 30. The report cited by EPA does not state workplace data should be disregarded. If at all relevant, the discussion now cited by EPA supports the opposite conclusion.

EPA also claims that workplace exposure data were disregarded because only two studies made an attempt to classify by amount of exposure. Again, EPA's explanation appears nowhere in that portion of the Risk Assessment cited by the Agency. Further, EPA's explanation appears targeted only at workplace data contained within the spousal smoking studies and does not address the Agency's decision to disregard workplace and childhood exposure data reported outside spousal studies.

EPA's final proffer is that childhood studies rely upon distant memories and more limited lifetime exposure. Again, the record does not reveal that EPA used this as a selection criteria. Rather, an assessment on ETS and lung cancer on which EPA now relies states, "No consistent association has been reported for lung cancer and exposure to ETS in childhood, which might be expected to exert a greater effect . . . . Of course, recall of ETS exposure in childhood is more difficult than recall of such exposure in adulthood." E.L. Wynder & G.C. Kabat, Environmental Tobacco Smoke and Lung Cancer: A Critical Assessment, ORD.C.1 S59-1 (JA 5,020). Nowhere in the Assessment is there a suggestion that childhood exposure data should be ignored.

EPA claims it excluded the latest two U.S. spousal smoking studies because they were submitted after the close of the comment period, and EPA already had a considerable database. EPA claims the Fontham study was used because it published interim results, was the largest U.S. ETS study, and its methodology was superior to any other study. The record contains discussion of the Fontham study, even testimony by Dr. Fontham. However, the evidence is not relevant to Plaintiffs' assertion. There being no indication of study criteria, it is not possible to determine whether or why the Fontham study was "superior." Even if EPA provided criteria, comparison would not be possible since EPA provides no discussion on the two U.S. spousal studies excluded. In summary, EPA's claim of having clearly established criteria is without merit. See Bowen v. Georgetown University Hosp., 488 U.S. 204, 212, 109 S. Ct. 468, 474, 102 L. Ed. 2d 493 (1988) ("The courts may not accept appellate counsel's post hoc rationalizations for agency [orders]."); American Trucking Ass'n v. Federal Highway Admin., 51 F.3d 405, 411 (4th Cir. 1995) (If agency action is to withstand judicial review, the agency's "actual reasoning . . . must prove reasonable, not the post hoc rationalization devised during litigation.").

EPA's study selection is disturbing. First, there is evidence in the record supporting the accusation that EPA "cherry-picked" its data. Without criteria for pooling studies into a meta-analysis, the court cannot determine whether the exclusion of studies likely to disprove EPA's a priori hypothesis was coincidence or intentional. Second, EPA's excluding nearly half of the available studies directly conflicts with EPA's purported purpose for analyzing the epidemiological studies and conflicts with EPA's Risk Assessment Guidelines. See ETS Risk Assessment at 4-29 ("These data should also be examined in the interest of weighing all the available evidence, as recommended by EPA's carcinogen risk assessment guidelines (U.S. EPA, 1986a) . . . ." (emphasis added)). Third, EPA's selective use of data conflicts with the Radon Research Act. The Act states EPA's program shall "gather data and information on all aspects of indoor air quality . . . ." Radon Research Act § 403(a)(1) (emphasis added). In conducting a risk assessment under the Act, EPA deliberately refused to assess information on all aspects of indoor air quality.

At the outset, the court concluded risk assessments were incidental to collecting information and making findings. EPA steps outside the court's analysis when information collection

becomes incidental to conducting a risk assessment. In making a study choice, consultation with an advisory committee voicing these concerns would have resulted, at a minimum, in a record that explained EPA's selective use of available information. From such record, a reviewing court could then determine whether EPA "cherry picked" its data, and whether EPA exceeded its statutory authority.

D. EPA's Epidemiologic Methodology

Plaintiffs raise a list of objections asserting that EPA deviated from accepted scientific procedure and its own Risk Assessment Guidelines in a manner designed to ensure a preordained outcome. Given the ETS Risk Assessment shortcomings already discussed, it is neither necessary or desirable to delve further into EPA's epidemiological web. However, two of Plaintiffs' arguments require mention.[36] The first contention is

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[36] The court finds it unnecessary to resolve Plaintiffs' remaining methodological contentions: (1) EPA inexplicably departed from its stated procedure for selecting risk estimates from the spousal smoking studies when that allowed the Agency to increase its summary risk estimate for particular studies; (2) EPA did not include certain studies and data in its meta-analysis in order to exclude the possibility that confounders explain the association between ETS and cancer; (3) EPA adopted statistical testing methods rejected by epidemiologists, ignored the

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EPA switched, without explanation, from using standard 95% confidence intervals to 90% confidence intervals to enhance the likelihood that its meta-analysis would appear statistically significant. This shift assisted EPA in obtaining statistically significant results. Studies that are not statistically significant are "null studies"; they cannot support a Group A classification. See Brock v. Merrell Dow Pharm., Inc., 874 F.2d 307, 312 (5th Cir. 1989) ("If the confidence interval is so great that it includes the number 1.0, then the study will be said to show no statistically significant association between the factor and the disease.").

EPA used a 95% confidence interval in the 1990 Draft ETS Risk Assessment, but later switched to a 90% confidence interval. Most prominently, this drew criticism from IAQC's epidemiologist who was also a contributor to the ETS Risk Assessment:

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[36](...continued)
possibility that more than one confounder interacting jointly could explain the claimed association, and inconsistently interpreted the results of confounding analysis to promote finding an association; (4) EPA switched from a peer-reviewed methodology to an unpublished one in excluding study bias as an explanation for the claimed association; and (5) to create critical ETS dose-response evidence, EPA inexplicably used a trend analysis that included unexposed (i.e., control) subjects, in violation of EPA's Risk Assessment Guidelines and standard epidemiologic practice.

> The use of 90% confidence intervals, instead of the conventionally used 95% confidence intervals, is to be discouraged. It looks like a[n] attempt to achieve statistical significance for a result which otherwise would not achieve significance.

Geoffrey Kabat, Comments on EPA's Draft Report: "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders", II.SAB.9.15 at 6 (July 28, 1992) (JA 12,185).

Plaintiffs argue that established epidemiologic practice is to use 95% confidence intervals. As evidence, Plaintiffs point out EPA's prior risk assessments, including the 1990 ETS draft, consistently used 95% confidence intervals, as did previous ETS analyses by IARC, NRC, and the Surgeon General.

ETS Risk Assessment Chapter 5 states:

> Throughout this chapter, one-tailed tests of significance (p=0.05) are used, which increases the statistical ability (power) to detect an effect. The 90% confidence intervals used for the analyses performed are consistent with the use of the one-tailed test. The justification for this usage is based on the a priori hypothesis . . . that a positive association exists between exposure to ETS and lung cancer.

ETS Risk Assessment at 5-2. Before this court, EPA explains the "use of the 95 percent confidence interval with the one-tailed test . . . would have produced an apparent discrepancy: study results that were statistically significant using the standard p-value of .05 might nevertheless have a 95 percent confidence

interval that included a relative risk of 1." (Conformed Mem. Supp. EPA's Cross Mot. Part. Summ. J. at 56.)

Plaintiffs' second methodological argument requiring comment states, EPA based ETS' Group A classification in large part on a resulting relative risk of only 1.19, without adequately explaining why the Agency had required every other Group A carcinogen to exhibit a much higher relative risk, or why it had recently found relative risks of 1.6 and 3.0 insufficient to classify other agents in Group A. All of the 15 chemicals or mixtures previously classified by EPA as Group A carcinogens have higher relative risks than ETS. See, e.g., ETS Risk Assessment at 4-15, 16 & 22 (Risk assessments on cigarette smoking demonstrate relative risks between 7 and 14.9 for lung cancer, and relative risks between 26 and 60 for undifferentiated carcinoma.); see also EPA Review Draft, Evaluation of the Potential Carcinogenicity of Electromagnetic Fields, EPA/600/6-901/005B at 6-2 (October 1990) (JA 1,562) (declining classifying EMF as carcinogenic for lack of strong association with cancer where relative risks in studies seldom exceeded 3.0). IAQC epidemiologist Dr. Kabat observed, "An association is generally considered weak if the odds ratio [relative risk] is under 3.0 and particularly when it is under 2.0, as is the case in the

relationship of ETS and lung cancer." E.L. Wynder & G.C. Kabat, Environmental Tobacco Smoke and Lung Cancer: A Critical Assessment, I.SAB.7.1 at 6 (JA 7,216).

EPA responds that the most impressive evidence from the epidemiologic studies is the consistent results of many studies showing increased risk, and the dose-response relationships showing the most risk to the most exposed nonsmokers. EPA explains that ETS' diluted concentration in the atmosphere accounts for the low strength of association.

The record and EPA's explanations to the court make it clear that using standard methodology, EPA could not produce statistically significant results with its selected studies. Analysis conducted with a .05 significance level and 95% confidence level included relative risks of 1. Accordingly, these results did not confirm EPA's controversial a priori hypothesis. In order to confirm its hypothesis, EPA maintained its standard significance level but lowered the confidence interval to 90%. This allowed EPA to confirm its hypothesis by finding a relative risk of 1.19, albeit a very weak association.

EPA's conduct raises several concerns besides whether a relative risk of 1.19 is credible evidence supporting a Group A classification. First, with such a weak showing, if even a

fraction of Plaintiffs' allegations regarding study selection or methodology is true, EPA cannot show a statistically significant association between ETS and lung cancer.

Second, the court's conclusions regarding EPA's motive for reducing the confidence level are based upon EPA's litigation explanations and circumstantial evidence from the record. EPA does not provide explanation in the ETS Risk Assessment or administrative record. When an agency changes its methodology mid-stream, as EPA did here, it has an obligation to explain why. See Western States Petroleum Ass'n v. EPA, 87 F.3d 280, 284 (9th Cir. 1996) ("EPA 'may not depart, sub silento, from its usual rules of decision to reach a different, unexplained result in a single case.'"); Natural Resources Defense Council, Inc. v. EPA, 859 F.2d 156, 205-11 (D.C. Cir. 1988) (invalidating an EPA rule because EPA failed to explain its mid-proceeding switch on the utility of an upset defense); see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. EPA, 768 F.2d 385, 399 (D.C. Cir. 1985) (EPA failed to explain why it departed from "established specific statistical criteria for determining whether a fuel will cause a vehicle to exceed emission standards . . . .").

Finally, when an agency conducts activities under an act authorizing information collection and dissemination of findings,

the agency has a duty to disseminate the findings made. EPA did not disclose in the record or in the Assessment: its inability to demonstrate a statistically significant relationship under normal methodology; the reasoning behind adopting a one-tailed test, or that only after adjusting the Agency's methodology could a weak relative risk be demonstrated. Instead of disclosing information, the Agency withheld significant portions of its findings and reasoning in striving to confirm its a priori hypothesis.

E. Summary of the Assessment and Record

In reviewing the parties' arguments, the court has given the benefit of many doubts to EPA by allowing the Agency to adopt third party statements, such as IAQC reviews, as Agency reasoning. EPA, the decision maker, not IAQC, the independent adviser, has the duty to demonstrate reasoned decision making on the record. See SEC v. Chenery Corp., 332 U.S. 194, 196, 67 S. Ct. 1575, 1577, 91 L. Ed. 1995 (1947) ("[A] reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency."); Motor Vehicle Mfr. Ass'n of the United States v. State Farm Mut. Auto.

Ins. Co., 463 U.S. 29, 50, 103 S. Ct. 2856, 2870, 77 L. Ed. 2d 443 (1983) ([A]n "agency's action must be upheld, if at all, on the basis articulated by the agency itself."); see also H.R. Rep. No. 95-722, 95th Cong., 1st Sess., 16 (1977), reprinted in 1977 U.S.C.C.A.N. 3283, 3295 (JA 652-53) (The SAB "is intended to be advisory only. The Administrator will still have the responsibility for making the decisions required of him by law."). If EPA's appendages speak on behalf of the Administrator, the opposing conclusions reached between IAQC and the EPA Risk Criteria Office would demonstrate schizophrenia. Even allowing EPA the benefit of now adopting IAQC reasoning, the record does not provide answers to Plaintiffs' questions.

EPA determined it was biologically plausible that ETS causes lung cancer. In doing so, EPA recognized problems with its theory, namely the dissimilarities between MS and ETS. In other areas of the Assessment, EPA relied on these dissimilarities in justifying its methodology. EPA did not explain much of the criteria and assertions upon which EPA's theory relies. EPA claimed selected epidemiologic studies would affirm its plausibility theory. The studies EPA selected did not include a significant number of studies and data which demonstrated no association between ETS and cancer. EPA did not explain its

criteria for study selection, thus leaving itself open to allegations of "cherry picking."

Using its normal methodology and its selected studies, EPA did not demonstrate a statistically significant association between ETS and lung cancer. This should have caused EPA to reevaluate the inference options used in establishing its plausibility theory. A risk assessment is supposed to entail the best judgment possible based upon the available evidence. See Ethyl, 541 F.2d at 24. Instead, EPA changed its methodology to find a statistically significant association. EPA claimed, but did not explain how, its theory justified changing the Agency's methodology. With the changed methodology and selected studies, EPA established evidence of a weak statistically significant association between ETS and lung cancer.

VI. MOTION TO SUPPLEMENT THE PLEADINGS

Plaintiffs have moved to supplement the pleadings pursuant to Fed. R. Civ. P. 15(d). Plaintiffs' Supplemental Pleading seeks declaratory and injunctive relief against EPA relating to the Agency's alleged unlawful efforts to regulate indoor air,