

EPA and Credible Science



- A few months ago, an Expert Panel was convened by the EPA Administrator to review how science is used at EPA and to suggest improvements. The panel's conclusions were both remarkably frank and disturbing. Among the conclusions contained in the report, "Safeguarding the Future: Credible Science, Credible Decisions," were the following:

"EPA science is of uneven quality, and the Agency's policies and regulations are frequently perceived as lacking a strong scientific foundation."

"Science should never be adjusted to fit policy, either consciously or unconsciously."

As the revised ETS risk assessment demonstrates, the EPA seems determined to ignore the Expert Panel's findings and has chosen instead to "adjust" science to "fit policy."

- In its initial review of the draft ETS risk assessment in 1990, the Science Advisory Board (SAB) concluded that the epidemiological data did not sustain the claim of increased nonsmoker lung cancer due to exposure to environmental tobacco smoke (ETS).

But then, rather than disapproving the conclusions in the risk assessment, the SAB took the extraordinary step of urging EPA to "make the case" against ETS based on active smoking data.

Even the National Academy of Sciences (NAS) has pointed out that the ETS issue cannot be resolved by turning to active smoking data. Differences in levels and routes of exposure are among the reasons cited.

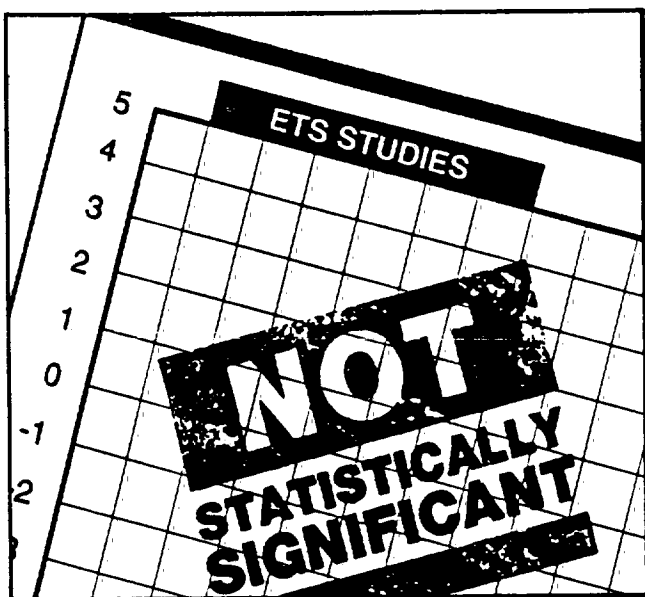
Never before has the EPA ignored such differences in proposing to classify a substance as a Group A carcinogen.

- The SAB also acknowledged that classification of ETS as a Group A carcinogen might not be possible under existing EPA guidelines.

Rather than disapproving the Group A classification, the SAB told EPA staff that "this suggests a need to revise the Guidelines."

One member of the SAB Executive Committee noted that such an effort would amount to saying that "if the data doesn't fit the guidelines, then the guidelines should be changed."

The ETS Science



- A previously released draft of the EPA ETS risk assessment acknowledged that the U.S. studies of lung cancer in nonsmokers did not report increased risk of lung cancer from exposure to ETS.

Only by resorting to an unorthodox statistical manipulation has EPA staff been able to achieve in this latest draft a contrary conclusion using the same general body of studies.

- To date, 33 epidemiological studies of ETS and nonsmoker lung cancer have been published in the scientific literature.

Of these, two-thirds report no statistically significant relationship between exposure to ETS and lung cancer among nonsmokers.

The EPA draft reviews 26 of these studies, and relies on 17 that they consider to be of "higher quality." According to the EPA draft, only six of these 17 report a statistically significant increase in risk.

Never before has the EPA proposed to classify a substance as a Group A carcinogen on the basis of such data.

- In the previous draft, EPA conceded that the epidemiologic data were too weak and confounded to provide support for the inference that ETS causes respiratory disease in children.

The revised draft acknowledges the existence of multiple sources of bias and confounding and points out methodological weaknesses in the studies.

The revised draft then goes on to ignore the stated inconsistencies and weaknesses to make conclusions that are unwarranted based on the data.

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Nonsmoker Exposure to ETS

- The revised draft EPA risk assessment concedes repeatedly that there are substantial physical and chemical differences between the mainstream tobacco smoke to which active smokers are exposed and the ETS to which nonsmokers are exposed. The draft also concedes enormous differences in levels and routes of exposure.
- When smoking is permitted in offices, restaurants and public facilities, the level of nicotine measured has ranged between 2 ug/m³ (micrograms per cubic meter) and 20 ug/m³.

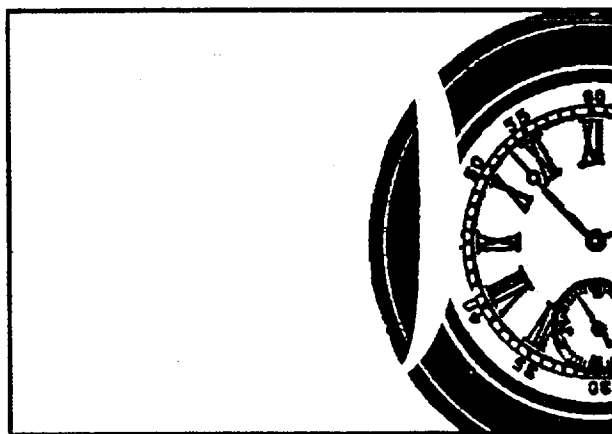
ETS is a combination of exhaled mainstream smoke (MS) and the sidestream smoke (SS) that comes off the burning end of a cigarette.

If ETS can be classified as a carcinogen on the basis used in the revised EPA report, then the air in every building and home in the United States would also qualify as a carcinogen. So too would the water we drink, as well as many of the foods we eat — hamburgers, milk, and peanut butter, for example.

- Virtually all of the substances reportedly found in ETS are found in the air from sources unrelated to smoking.

In real-life situations, ETS does not significantly affect the levels of most chemicals and compounds in the air. Other sources of these constituents generally far exceed the contribution from ETS.

At these levels, a nonsmoker would have to spend more than 100 hours to be exposed to the nicotine "equivalent" of one cigarette.



The nicotine levels found in typical indoor environments can be equated to making a gin and tonic by adding a thimble-full of gin to an Olympic-sized swimming pool.

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