

Final Statement of Reasons for Rulemaking

Including Summary of Comments and Agency Responses

**PUBLIC HEARING TO CONSIDER THE IDENTIFICATION OF
ENVIRONMENTAL TOBACCO SMOKE
AS A TOXIC AIR CONTAMINANT**

Public Hearing Date: January 26, 2006
Agenda Item No.: 06-1-4

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State of California
Environmental Protection Agency
AIR RESOURCES BOARD

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I. GENERAL

In this rulemaking, the Air Resources Board (ARB or Board) is adopting a regulation order for the identification of environmental tobacco smoke (ETS) as a toxic air contaminant (TAC) as defined in Health and Safety Code section 39655. Environmental tobacco smoke will be added to title 17, section 93000, of the California Code of Regulations as a TAC with no threshold specified.

The rulemaking was initiated by the December 9, 2005, publication of a notice for a January 26, 2006, public hearing to consider the proposed identification of ETS as a TAC. A Staff Report: Initial Statement of Reasons for Rulemaking (Staff Report) was also made available for public review and comment starting December 9, 2005. The Staff Report, which is incorporated by reference herein, describes the justification for the proposal. The text of the proposed amendment to title 17, California Code of Regulations (CCR) section 93000 was included as an Appendix to the Staff Report. These documents were also posted on the ARB's website for the rulemaking at: <http://www.arb.ca.gov/regact/ets2006/ets2006.htm>.

This Final Statement of Reasons (FSOR) provides an update of the Staff Report.

A. Description of Board Action

On January 26, 2006, ARB conducted a public hearing to consider adoption of the staff recommendation to identify ETS as a TAC. At the hearing, the Board considered and unanimously adopted Resolution 06-1-4 identifying ETS as a TAC and adding ETS into the CCR, title 17, section 93000.

Written and oral comments were received on the proposed regulation from December 9, 2005 to January 26, 2006, and at the public hearing. This FSOR summarizes the written and oral comments received. ARB's responses to those comments are also set forth in Section II of this FSOR.

B. Modifications to the Original Proposal

There were no modifications to the original proposal. The Board adopted the regulation amendment as proposed.

C. Incorporation by Reference in the Regulation

This regulation order does not include any references to other regulations.

D. Fiscal Impacts to School Districts and Local Agencies

The Board has determined that the identification of ETS as a TAC will not directly have any fiscal impact on sources of ETS, as defined in Government Code section 11346.5(a)(6), to any state agency or federal funding to the state, costs or mandate to any local agency or school district whether or not reimbursable by the state pursuant to part 7 (commencing with section 17500), Division 4, title 2 of the Government Code, or other nondiscretionary costs or savings to state or local agencies. The act of identifying a TAC does not mandate any specific risk management action. Once a substance is identified, ARB is required to assess the need and appropriate degree of control for that substance. Potential control measures will be assessed and developed in a public forum in which the impact of these measures on businesses would be fully assessed.

E. Consideration of Alternatives

There are no other alternatives which would be more effective than the action taken by the Board. This rulemaking is the only way available to identify ETS as a TAC.

II. SUMMARY OF COMMENTS AND AGENCY RESPONSES

The Board received written and oral comments during the 45-day public comment period provided for the proposed identification of ETS as a TAC and at the January 26, 2006, public hearing. A list of commenters is set forth below, identifying the date and form of all comments that were timely submitted. Following the list is a summary of each objection or recommendation made regarding the proposed action, together with an explanation of how the proposed action has been changed to accommodate the objection or recommendation, or the reasons for making no change.

A. Comments Received During the 45-day Public Comment Period and Board Hearing

<u>Abbreviation</u>	<u>Commenter</u>
ACTCP	Paul Cummings, Director Alameda County, Tobacco Control Program Written Testimony: January 26, 2006
ALAC	Paul Kneprath, Vice President American Lung Association of California Written Testimony: January 20, 2006 Oral Testimony: January 26, 2006
ALASB	Shelly Brantley, Project Director American Lung Association of California, Superior Branch Written Testimony: January 24, 2006
CYHD	Steven Jensen County of Yolo Health Department Written Testimony: January 24, 2006
EL	Erica Leary, MPH Written Testimony: January 24, 2006
JRS	Jay R. Schrand Written Testimony: January 6, 2006
LLAPD	Clara Boyden, President Local Lead Agency Project Directors Association Written Testimony: January 25, 2006
LTC	Brian J. McGinn, Associate General Counsel Lorillard Tobacco Company Written Testimony: January 18, 2006
PCPHA	Henry Foley, Director of Public Health Plumas County Public Health Agency Written Testimony: December 21, 2005
PHI	Robin Salzburg, JD Staff Attorney Public Health Institute Written Testimony: January 24, 2006

<u>Abbreviation (cont.)</u>	<u>Commenter (cont.)</u>
PJ	P. Jacobs Written Testimony: January 9, 2006
RESPECT	Dian Kiser, Co-Director Resources and Education Supporting People Everywhere Controlling Tobacco Written Testimony: January 20, 2006
RJR	Mitchell Neuhauser, Senior Council R.J. Reynolds Tobacco Company Written Testimony: January 25, 2006
RP	Roger Pariseau Written Testimony: January 10, 2006
SBCTC	Robert Balgenorth, President State Building and Construction Trades Council of California Written Testimony: January 18, 2006
SFTFC	Alexandra Hernandez, Co-Chair San Francisco Tobacco Free Coalition Written Testimony: January 23, 2006

1. Comment: In general, we support the conclusions of the Staff Report and ARB's action to identify ETS as a TAC (PJ, PCPHA, SBCTC, SFTFC, CYHD, EL, LLAPD, ACTCP, ALASB, RESPECT, PHI, ALAC)

Agency Response: We appreciate this comment.

2. Comment: The assembly of the Scientific Review Panel (SRP) does not meet the requirements set forth in California Health and Safety Code 39670(b)(1), mandating that one of the SRP members is to "be qualified as a pathologist," and one of the members is "to be qualified as an oncologist." In addition, two members of the SRP have a "conflict of interest" regarding ETS and should disqualify themselves from reviewing the Staff Report (JRS, RJR)

Agency Response: We disagree with this characterization. California Health and Safety Code 39670(b) states that "the panel shall be highly qualified and professionally active or engaged in the conduct of scientific research" and that one SRP member must be a qualified pathologist and one SRP member must be a qualified oncologist. The qualified pathologist on the SRP is Dr. Charles G. Plopper, University of California Davis, and the qualified oncologist on the SRP is

Dr. Joseph R. Landolph, University of Southern California. There is no conflict of interest because no panel member has an interest in matter before the Panel that would create a conflict and the commenter does not demonstrate that such an interest or conflict exists.

3. Comment: The SRP found "...there is not sufficient available scientific evidence to support the designation of a threshold exposure level to ETS below which no significant adverse health effects are anticipated." The lower boundary is a hallmark of well done toxicological studies. If it can't be measured, it's not there. However, the SRP recommends declaring ETS a toxic contaminant anyway.

The implications of the lack of a lower threshold is that someone in San Diego (or in their private home in Chicago) might inhale a carcinogen from ETS emanating from Governor Arnolds cigar tent. (JRS)

Agency Response: Based on the scientific evidence available at this time regarding carcinogenic substances, a threshold below which there is zero cancer risk is not possible to determine, and is theoretically nonexistent for genotoxic carcinogens, of which there are many in tobacco smoke. Only zero exposure results in zero risk from a genotoxic carcinogen. Any finite dose has a risk which moves towards zero as exposure decreases to zero. There are statistical reasons why a specific toxicological threshold for any endpoint noted in well-conducted studies cannot be construed to be an absolute population threshold. The statutes authorize a finding of no threshold exposure level (Health and Safety Code section 39660(c)) and require the SRP to review this finding along with the other scientific aspects of the health effects report generated by OEHHA and the ARB (Health and Safety Code sections 39660(c) and 39661).

4. Comment: The other problem is that, of the many potential harmful carcinogenic constituents in ETS, the individual constituent(s) causing the problem have not been uniquely identified as the cause of the specific illnesses attributed to ETS. It is easier to blame ETS in general. And, of course, if the measurable constituent(s) were to be identified, they could probably be removed or reduced to an acceptable level. (JRS)

Agency Response: The unique association of identified components of ETS with specific illnesses is not a prerequisite for the recognition that ETS exposure is causally associated with specific disease outcomes. For example, the identification of specific carcinogens in ETS that also cause specific tumor types in laboratory animals supports epidemiological data indicating such an association in humans. It is true that the composition of ETS is, to some extent, altered by changes in tobacco formulations, but whether an innocuous product could be developed remains to be seen. In any event, ETS meets the statutory definition of a TAC, "an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health." Health and Safety Code section 39655(a).

5. Comment: My response to previous versions of the report indicated that the stress of Adverse Childhood Experiences (Anda) has not been adequately considered as a confounding factor in any of the studies. (JRS)

Agency Response: The study by Anda et al. (1999) in the Journal of the American Medical Association, volume 282, pages 1652 to 1658, to which the commentator refers, found an association between exposure to what he terms “adverse childhood experiences” (ACES) and the initiation of teenage smoking. Whether ACES are associated with disease outcomes is not addressed in this paper. “ACES” per se have not been identified as confounding factors in studies of ETS, however most studies adjust for socioeconomic status, marital status, and educational attainment which serve as imperfect proxies for life stresses. Exposure to ETS itself is a stressor but is not an indication of exposure to ACES. While ACES and ETS exposure may both contribute to morbidity and mortality, there is no evidence that they are not independent factors. Moreover, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound. Health and Safety Code section 39661.

6. Comment: The materials bearing on this issue seem to contain a curious mixture of science, guesstimizations and pure fallacies. Do you have links to any discrete, empirical, preferably-duplicated, real-world studies concerning the causative effect of tobacco use and lung cancer? I cannot find a single (supportable) one!

I can find plenty concerning diesel and other industrial fumes. I can find plenty establishing the causative relationship between tobacco use and emphysema, but zip for the same to lung cancer.

Likewise, I can find no supported evidence for causation between ETS and any disorder. (RP)

Agency Response: The adverse health effects of active smoking are widely accepted. For example, they are addressed in some 28 reports by the Surgeon General listed at http://www.cdc.gov/Tobacco/sgr/sgr_2004/Factsheets/11.htm. Relatively recent studies of the effects of tobacco use on lung cancer are listed in the bibliography of the 2004 Surgeon General’s report: Health Consequences of Smoking.

In addition to this and the previous California Environmental Protection Agency reports on the health effects of ETS, the 2006 report of the Surgeon General on ETS, The Health Consequences of Involuntary Exposure to Tobacco Smoke (<http://www.surgeongeneral.gov/library/secondhandsmoke/>), also provides citations of numerous studies causally linking ETS exposure and various health endpoints. Moreover, the SRP approved the health effects report, including

finding that the scientific knowledge, methods and practices it is based on are sound. Health and Safety Code section 39661. See also the response to Comment 4.

7. Comment: "I've written everyone from WHO to NIH to the EPA and on and on. None of them can come up with an empirical, real-world study that eliminates any other possible causative contaminants in the air." (RP)

Agency Response: Studies that compare two well-matched groups whose only demonstrable difference is the presence or absence of ETS exposure effectively eliminate other air contaminants as causative agents since both groups are exposed to the same contaminants. An example of a "real-world" study of this type is that of Sargent et al. (2004), which is part of the record in Part B: Health Effects, Chapter 8 - Cardiovascular Health Effects, that recorded a drop in the incidence of heart disease (acute myocardial infarction) during a 6-month ban on smoking in public places compared with before and after the ban, and compared with areas outside the ban. There is no evidence of changes in any other air pollutants during this time that could explain these observations.

Sargent, R.P., R.M. Shepard and S.A. Glantz (2004). "Reduced incidence of admissions for myocardial infarction associated with public smoking ban: before and after study." BMJ **328**(7446): 977-80.

In any event, ETS meets the statutory definition of a TAC, "an air pollutant which may cause or contribute to an increase in mortality or in serious illness, or which may pose a present or potential hazard to human health." Health and Safety Code section 39655(a). Moreover, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound. Health and Safety Code section 39661.

8. Comment: OEHHA acknowledges that its analysis of the health effects of ETS in Part B of the Technical Support Document rests largely on the 1997 OEHHA report: Health Effects if Exposure to Environmental Tobacco Smoke". The tobacco industry submitted extensive comments on the 1997 OEHHA report. Those comments identified major deficiencies in the OEHHA scientific record, failure to employ objective, scientifically sound criteria; failure to follow accepted risk assessment procedures, including those recommended by federal EPA and The California Advisory Committee; and selective reliance on weak, inconsistent and unreliable studies.

The deficiencies in the 1997 OEHHA ETS Report have not been corrected, and the tobacco industry's comments on the 1997 Report remain valid. Moreover, contrary to the assertions in Part B of the Technical Support Document, scientific studies published since 1997 weaken, rather than strengthen, OEHHA's 1997 conclusions with respect to the health effects of ETS. This is explained and documented in detailed comments submitted for the record in March 2004 by

J. Daniel Heck, Ph.D. et al., and Maurice LeVois, Ph.D. (LTC)

Agency Response: OEHHA responded to the comments and concerns regarding the 1997 document at that time and similarly for this update. Please see Responses to Comments (Part C), pages 27-90 (LeVois) and 91-124 (Heck et al.) Moreover, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound. Health and Safety Code section 39661.

9. Comment: Previous comments sent to ARB include the concern that ARB failed to conduct a California risk assessment. Part of that comment indicated that the attributable risk calculations are irrelevant for California. We had responded that the comment fails to recognize that the lower smoking rates in California are factored into the calculations of attributable risks. There is no reason to believe that Californians would, in fact, not respond to ETS like other people, given the broad diversity of people present in California in terms of genetic, lifestyle, diet, and so forth.

The current comment letter goes on to note that this response “... *demonstrated a complete lack of understanding regarding the concept of attributable risk. While it is correct that the attributable risk calculations utilized by ARB took into account ‘the lower smoking rates in California,’ these calculations did not – and indeed could not – take into account the fact that exposures in California are substantially lower and occur in different venues than the exposures and corresponding venues of exposure identified in the epidemiology studies utilized in the attributable risk calculations.*” (RJR)

Agency Response: This latest comment demonstrates a lack of understanding of attributable risk calculations. The attributable risk calculations in the Cal/EPA 2005 report utilize information on smoking prevalence and prevalence of ETS exposure that is California-specific; the ETS exposures in California occur in exactly the same situations identified in the epidemiology studies, the results of which form the basis of the risk estimates used in the attributable risk calculations. Moreover, pursuant to Health and Safety Code 39661, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound.

10. Comment: ARB staff relied upon a very limited 2003 ARB air monitoring study and a questionable “scenario-based approach” to determine the ETS exposure assessment. (LTC)

Agency Response: This comment has previously been addressed in the *Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant*, “Part C – Public Comments and ARB/OEHHA Staff Responses”, p. C-7 and C-8, response to comments #14 and #15. The staff response explained that the use of a scenario-based approach for characterizing public

exposure to ETS was chosen in consideration of the way in which people are exposed to ETS and the absence of data from ambient air monitoring stations throughout the state. This approach allows for characterizing intermittent exposures that commonly occur over the course of a day, which staff believes is a better measure of personal ETS exposure than a population-weighted exposure occurring in outdoor air alone. Moreover, pursuant to Health and Safety Code section 39661, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound.

11. Comment: ARB has failed to characterize the intensity, duration or frequency of ETS exposure in outdoor air, and failed properly to characterize the exposed population. (LTC)

Agency Response: This comment has previously been addressed in the *Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant*, “Part C – Public Comments and ARB/OEHHA Staff Responses”, p. C-7 and C-8, response to comments #14, #15, and #16. The staff responses explained that ETS exposures were estimated through scenario-based activity patterns to estimate exposures under different conditions. Staff also estimated a statewide outdoor urban background level of ETS (appendix D of Part A: Exposure Assessment). Estimates of duration and level of exposure are provided in Chapter V of Part A: Exposure Assessment.

12. Comment: The ARB’s ETS exposure assessment is inconsistent with the U.S. EPA’s Final Guidelines for Exposure Assessment (U.S. EPA, 1992) and fails to satisfy any of these criteria. (LTC)

Agency Response: This comment has previously been addressed in the *Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant*, “Part C – Public Comments and ARB/OEHHA Staff Responses”, p. C-6, response to comment #11. The staff explained that the State is not required to follow U.S. EPA’s Guidelines for Exposure Assessment (see Health and Safety Code Section 39656). The two programs are separate and different both in scope and purpose. Moreover, pursuant to Health and Safety Code section 39661, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound.

13. Comment: The ARB study was an area monitoring study that did not measure exposure duration or the level of exposure to particular individuals. Personal monitoring data is preferred over area sampling. (LTC)

Agency Response: This comment has previously been addressed in the *Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant*, “Part C – Public Comments and ARB/OEHHA Staff Responses”,

p. C-3 and C-4, response to comments #5 and #6. The staff responses explained that the purpose of the monitoring study was to gather ambient data. The study was not an individual exposure assessment. The ARB ambient monitoring study included: 1) an airport smoking area outside from the baggage claim area, 2) a community college eating area outside a cafeteria, 3) two office buildings outside the exits, and 4) an amusement park smoking area, near walkways. Moreover, pursuant to Health and Safety Code section 39661, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound.

14. Comment: The Rogge et. al. (1994) study referred to in Chapter V of the exposure assessment is outdated and fundamentally flawed. Smoking rates have declined and smoking patterns have changed since the original study in 1982. (LTC)

Agency Response: This comment has previously been addressed in the *Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant*, “Part C – Public Comments and ARB/OEHHA Staff Responses”, p. C-6, response to comment #12. The staff responses explained that the information presented in the Rogge et al. study is outdated. However, this study, along with others, was used for comparison purposes and presented a source apportionment approach for estimating outdoor concentrations of ETS. ARB must consider all available data when identifying a substance as a TAC. Moreover, pursuant to Health and Safety Code section 39661, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound.

15. Comment: In almost all previous TAC exposure assessments, the ARB relied upon California population-weighted exposures to outdoor average ambient concentrations of the candidate substances. By contrast, for ETS, there are no reliable outdoor exposure measurements. (LTC)

Agency Response: This comment has previously been addressed in the *Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant*, “Part C – Public Comments and ARB/OEHHA Staff Responses”, p. C-5, C-6 and C-7, response to comments #10, #13 and #14. The staff explained that a scenario-based approach was used to characterize the range of the public’s exposure to ETS since cigarettes and cigars are the primary sources of ETS and emit pollutants near people. ARB’s ambient monitoring results from its ETS study were used as the outdoor ambient concentration input to the exposure scenarios. Toxic air contaminants from area-wide and region-wide sources, such as motor vehicles and industrial plants, used California population-weighted exposures to outdoor average ambient concentrations. Moreover, pursuant to Health and Safety Code 39661, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound.

16. Comment: The ARB is limited to regulate based on ambient or outdoor air and has no authority to regulate indoor air or to rely upon indoor air exposure levels as a basis for regulation of outdoor air. (LTC, RJR)

Agency Response: This comment has previously been addressed in the *Proposed Identification of Environmental Tobacco Smoke as a Toxic Air Contaminant*, “Part C – Public Comments and ARB/OEHHA Staff Responses”, p. C-5, response to comment #9. The staff explained that the ARB is required to evaluate the exposures in indoor environments as well as in ambient air (Health and Safety Code section 39660.5). Moreover, pursuant to Health and Safety Code 39661, the SRP approved the health effects report, including finding that the scientific knowledge, methods and practices it is based on are sound.