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Lorillard
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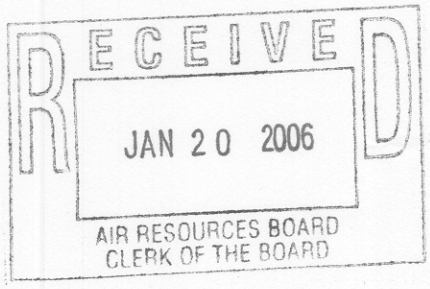


Clerk of the Board
Air Resources Board
1001 I Street, 23rd Floor
Sacramento, CA 95814

Re: Proposed Regulatory Amendment Identifying Environmental Tobacco Smoke (ETS) as a Toxic Air Contaminant (TAC)

Dear Sir:

Lorillard Tobacco Company submits the following comments in response to the Air Resources Board (ARB) Staff Initial Statement of Reasons (ISOR) and Proposed Regulatory Amendment Identifying ETS as a TAC. The Proposed Amendment and ISOR are based on the Office of Environmental Health Hazard Assessment (OEHHA) evaluation of the health effects of ETS, the ARB staff exposure assessment of ETS and the ARB Scientific Review Panel's (SRP's) findings.

On March 25, 2004, Lorillard submitted detailed comments in response to the Draft Technical Support Document for the Proposed Identification of ETS as a TAC. Those comments, together with comments submitted by other parties, demonstrated that the available scientific evidence does not support listing ETS as a TAC. In particular, the prior comments established that (1) the ARB's authority is limited to outdoor air; (2) the ARB's draft exposure assessment did not demonstrate a meaningful level of outdoor ETS exposure; (3) the Draft Support Document did not directly link outdoor ETS exposure levels in California to any adverse

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health effects and (4) all prior TAC listings have been based on more extensive and reliable exposure data than that available for ETS.

The ISOR and final Technical Support Documents (June 24, 2005) fail to rectify the fatal deficiencies in the prior draft, and the ARB/OEHHA responses to public comments (June 24, 2005) are inadequate. The rulemaking record does not provide an adequate basis for listing ETS as a TAC.

## I. OEHHA'S CONCLUSIONS REGARDING THE ADVERSE HEALTH EFFECTS OF ETS ARE NOT SUPPORTED BY THE AVAILABLE SCIENTIFIC EVIDENCE.

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 of 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 analysis and ETS risk assessment, including OEHHA's failure independently to evaluate the 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 EPA 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.

Lorillard stands by, but does not revisit here, its objections to OEHHA's ETS health effects assessment. Although the OEHHA ETS health assessment remains defective, there is an independent basis for rejecting the proposal to list ETS as a TAC. Regardless of the purported adverse health effects of ETS in the studies reviewed in the OEHHA assessment, the ISOR and Technical Support Documents do not demonstrate that ETS poses a health risk at current levels of exposure in outdoor air in California.

## II. THE ISOR AND TECHNICAL SUPPORT DOCUMENTS DO NOT PROVIDE AN ADEQUATE BASIS TO LIST ETS AS A TAC.

### A. The ARB Staff Has Failed to Demonstrate a Meaningful Level of Outdoor ETS Exposure.

The ARB Staff acknowledges that "ETS emissions and exposures are very localized" and "only very limited data on outdoor ETS levels are available" (ISOR, p. 9). This is a critical data gap that distinguishes the proposed listing of ETS from all prior TAC listings. The ARB staff attempts to circumvent this significant deficiency by relying upon a very limited 2003 ARB air monitoring study and a questionable "scenario-based approach" to ETS exposure assessment. As fully documented in Lorillard's earlier comments, neither the 2003 ARB air monitoring study

nor the ARB's scenario-based exposure assessment provides an adequate basis to list ETS as a TAC. Contrary to all prior TAC listings, the ARB staff has made no effort to determine the concentration, frequency or duration of ETS exposure in the outdoor air in California, nor has it calculated the number of people potentially exposed to ETS in the ambient air. In the absence of such data, there is an insufficient basis to list ETS as a TAC.

In its prior comments, Lorillard pointed out that the ARB staff's ETS exposure evaluation is inconsistent with the U.S. EPA's Final Guidelines for Exposure Assessment (EPA 1992). The EPA Guidelines provide that an exposure assessment should describe the intensity, frequency and duration of contact with the substance under review (Section 2), that personal monitoring is the preferred method of exposure measurement (Section 2.2.1), that time of contact should be accurately characterized by demographic data, survey statistics, behavior observation, or the like (Section 2.2.2), and that it is important to link the time an individual is in contact with a chemical to the concentration of the chemical to which the individual is exposed (Section 4.3). The ARB exposure assessment fails to satisfy any of these criteria. The ARB staff's only defense is that the "State is not required to follow U.S. EPA's Guidelines for Exposure Assessment" (Technical Report, Part C, p. 6). This misses the point. Lorillard does not contend that the ARB is legally bound by the EPA Guidelines. Indeed, even EPA is not legally obligated to follow the Guidelines. Rather, the EPA Guidelines are an authoritative compilation of well accepted exposure assessment criteria, and the ARB staff's failure to satisfy <u>any</u> of these criteria, or

adequately to explain the basis for deviating from the criteria, casts strong doubt on the staff's analysis.

In its prior comments, Lorillard provided evidence that the 2003 ARB ETS air monitoring study does not provide a reliable basis to calculate outdoor ETS exposure for a number of independent reasons, including that (1) only a few, unrepresentative outdoor venues were chosen for monitoring; (2) monitoring was conducted only in, or immediately downwind and adjacent to, designated smoking areas, which can be readily avoided by non-smokers and, thus, are not representative of typical ETS exposures in the ambient air, and (3) the ARB study was an area monitoring study that did not measure exposure duration or the level of exposure to particular individuals, whereas contemporary scientific standards reflect a strong preference for personal monitoring data over area sampling (NIOSH).

In responding to the Lorillard comments, the ARB acknowledges that its 2003 study only gathered ambient data and did not measure individual exposures and that all monitoring was conducted adjacent to designated smoking area (C-3 & 4). The ARB's only explanation for conducting monitoring at sites designed to represent maximum potential exposures is that such "sites were selected to represent a variety of outdoor exposures near ETS" (C-3). The ARB has failed to justify the design of the 2003 study, or to show that the study results can be validly extrapolated to likely exposures scenarios in outdoor air in California.

The ISOR contains an ARB staff estimate of outdoor annual average ambient ETS particle concentration for the Los Angeles air for 2003. This estimate is based largely on the Rogge study. In its prior comments, Lorillard showed that the Rogge study (1994), involving fine particulate matter samples collected in the Los Angeles area in 1982, does not provide a sound basis for calculating ETS exposure levels in outdoor air. Two critical flaws in the Rogge study are that the authors (1) calculated maximum, rather than likely, ETS exposure and (2) selected marker compounds that substantially overstated ambient ETS levels. For these reasons, together with others documented in the March 2004 Lorillard comments, the ARB's reliance on the Rogge study is unjustified.

The SRP findings do not address any of the shortcomings of the ARB exposure assessment and provide no independent support for the ARB's speculation that people are exposed to sufficient levels of ETS in outdoor air in California to justify listing ETS as a TAC.

In its March 2004 comments, Lorillard showed that all prior TAC listings were based on more extensive and reliable outdoor exposure data than that available for ETS. In particular, for all prior TAC listings, the ARB has relied either upon statewide population-weighted background exposure levels, average continuous exposure levels for a significant subset of the population residing near a particular emissions "hot spot", or evidence demonstrating that significant portions of the California population is exposed to a substance on a continuous basis.

In its response, the ARB admits that "[its ETS] approach differs from previous TAC exposure assessments, which were based on California population-weighted exposures to outdoor average ambient concentrations" and that "ETS is not monitored at ambient monitoring stations like most previously identified TACs" (C-5). However, the ARB argues that "[T]his is not the first time the ARB has taken this approach. For example, there is no population weighted exposure assessment for vinyl chloride" (C-7). Contrary to the ARB's contention, the listing of vinyl chloride as a TAC is distinguishable from, and does not support, the proposed listing of ETS. Vinyl chloride was listed as a TAC based on (1) continuous exposure measurements, (2) population-weighted long-term exposure estimates for people living near landfills in California and (3) a cancer risk assessment linked to actual outdoor exposure levels. By contrast, for ETS, there are no reliable outdoor exposure measurements, and the ARB staff's ETS attributable risk calculations are not linked to actual outdoor exposure levels in California. Outdoor ETS exposure is sporadic, discontinuous and largely avoidable, and has not been adequately measured or characterized by the ARB staff. Moreover, the ARB was required to list vinyl chloride as a TAC because vinyl chloride is listed as a hazardous air pollutant by the federal government pursuant to Section 7412 of Title 40 of the U.S. Code. This is not the case for ETS.

## B. The ARB Staff Has Failed to Show that ETS Exposure in Outdoor Air in California Poses a Health Risk

### 1. The ARB's authority is limited to outdoor air.

As fully explained in Lorillard's March 2004 comments, the ARB's authority to regulate TACs is limited to ambient or outdoor air. The ARB has no authority to regulate indoor air or to rely upon indoor air as a basis for regulation of outdoor air. The ARB's authority extends only to those substances emitted into the "ambient air". The term "ambient air" encompasses only outdoor, not indoor, air. Health & Safety Code, § 39657 ("the state board shall identify toxic air contaminants which are emitted into the ambient air of the state"). Because the ARB has no regulatory responsibility for indoor air, it cannot rely upon indoor exposure levels or health risks associated with indoor exposure as the basis for identifying or regulating a TAC.

**2. The ARB's Attributable Risk Calculations do not pertain to outdoor ETS exposure in California.**

Table 6 of the ISOR presents morbidity and mortality estimates for health effects causally associated with ETS exposure. These attributable risk calculations have no direct relevance to outdoor ETS exposure in California, which is the sole statutory basis for a TAC listing. The Table 6 figures are based exclusively on epidemiologic studies involving residential and/or workplace exposures, or exposures outside California.[1] These attributable risk estimates (even assuming they are accurate) do not establish potential risks from ETS exposure in outdoor air in California.[2]

Respectfully submitted,

Brian J. McGinn

[1] The ISOR acknowledges that California smoking rates and ETS exposure levels are significantly lower than in the rest of the United States (ISOR, p. 7).

[2] One of the largest and most recent ETS epidemiologic studies, based solely on California-exposed populations, reported no casual association between ETS exposure and lung cancer or heart disease (Enstrom, James E. and Kabat, Geoffrey C., Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians, 1960-98; *BMJ*, 326:1057-66 (2003)).