

State of California
AIR RESOURCES BOARD

Resolution 97-17

April 24, 1997

Agenda Item No.: 97-3-2

WHEREAS, sections 39600 and 39601 of the Health and Safety Code authorize the Air Resources Board (the "Board") to adopt standards, rules and regulations and to do such acts as may be necessary for the proper execution of the powers and duties granted to and imposed upon the Board by law;

WHEREAS, Chapter 3.5 (commencing with section 39650) of Part 2 of Division 26 of the Health and Safety Code establishes procedures for the identification of toxic air contaminants by the Board;

WHEREAS, section 39655 of the Health and Safety Code defines a "toxic air contaminant" as an air pollutant which may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health;

WHEREAS, section 39662 of the Health and Safety Code directs the Board to list, by regulation, substances determined to be toxic air contaminants, and to specify for each substance listed a threshold exposure level, if any, below which no significant adverse health effects are anticipated;

WHEREAS, inorganic lead is a potential toxic air contaminant which has been monitored in the ambient air in California;

WHEREAS, in California, the major identified sources of ambient inorganic lead are stationary point and area source fuel combustion, small aircraft fuel combustion, industrial metal melting, autobody refinishing, cement manufacturing, and incineration;

WHEREAS, inorganic lead emissions may deposit, accumulate in soil for many years, and be re-entrained by wind and agricultural activities;

WHEREAS, pursuant to the request of the Board, the Office of Environmental Health Hazard Assessment (OEHHA) evaluated the health effects of inorganic lead in accordance with Section 39660 of the Health and Safety Code;

WHEREAS, the OEHHA concluded that inorganic lead is an air pollutant which may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health because it is a suspected human carcinogen;

WHEREAS, based on OEHHA's analysis of studies of neurodevelopmental effects, a potential mean decrease of 1.39 intelligence quotient (IQ) points could occur per microgram per cubic meter of air lead exposed;

WHEREAS, based on OEHHA's analysis, increases in both systolic and diastolic blood pressure and cardiovascular effects have been correlated with lead exposure. There are many large population-based studies that examine the relationship between blood lead levels and hypertension (diastolic blood pressure greater than or equal to 90 millimeters of mercury). In addition, scientific evidence indicates a consistent association between increases in blood pressure and increases in more serious cardiovascular outcomes;

WHEREAS, the OEHHA concluded that the noncancer neurodevelopmental effects in children and increases in blood pressure and related cardiovascular conditions in adults are likely to have the most public health significance;

WHEREAS, based on the upper 95 percent confidence limit of potency, the estimated range of lifetime (70-year) excess cancer risk from continuous exposure to 1 microgram per cubic meter of lead is from 1.2×10^{-5} to 6.5×10^{-5} ; and that the OEHHA best value for the upper 95 percent confidence limit of cancer unit risk for inorganic lead is 1.2×10^{-5} based upon the latest and best animal study data set;

WHEREAS, based on the OEHHA's best value cancer unit risk factor of 1.2×10^{-5} per microgram per cubic meter and the corresponding concentration for ambient exposure, the number of potential excess cancer cases due to ambient exposure to inorganic lead is estimated to be 0.7 per million people for a 70-year lifetime which corresponds to a potential excess cancer burden of 24 among the 34 million residents of California over a 70-year period;

WHEREAS, for the reasons set forth in its evaluation, the OEHHA treats inorganic lead-induced non-carcinogenesis and carcinogenesis as nonthreshold phenomena because the OEHHA found no evidence that there are threshold levels for inorganic lead;

WHEREAS, upon receipt of the OEHHA evaluation, the staff of the Board prepared a report including, and in consideration of, the OEHHA evaluation and recommendations and in the form required by section 39661 of the Health and Safety Code and, in accordance with the provisions of that section, made the report available to the public and submitted it for review to the Scientific Review Panel (SRP) established pursuant to section 39670 of the Health and Safety Code;

WHEREAS, in accordance with section 39661 of the Health and Safety Code, the SRP reviewed the staff report, including the scientific procedures and methods used to support the data in the report, the data itself, and the conclusions and assessments on which the report was based; considered the public comments received regarding the report; and on October 31, 1996, adopted, for submittal to the Board, findings which include the following quoted material:

1. Lead is known to cause significant noncancer health effects. The two noncancer health effects of most concern at low blood lead levels are neurodevelopmental effects in children, and increase in blood pressure and related cardiovascular effects in adults. The neurodevelopmental and cardiovascular effects likely have the most public health significance.
2. There is relatively little uncertainty in the risk assessments for the noncancer endpoints for lead, including neurodevelopmental and blood pressure effects compared to the cancer endpoint. Four major uncertainties associated with most risk assessments are animal-to-human extrapolation, high-to-low dose extrapolation, full consideration of sensitive members of the human population, and studies with small numbers of subjects. The uncertainty for the noncancer risk assessment for lead is small because it includes human and low dosage data, full consideration of sensitive members of the human population, and studies that contain numerous subjects.
3. Scientific studies have indicated that, at low to moderate blood lead levels, neurodevelopmental effects include: decreased intelligence, short term memory loss, reading and spelling underachievement, impairment of visual motor functioning, poor perception integration, disruptive classroom behavior, and impaired reaction time.
4. The data on the effects of lead on measures of intelligence are particularly compelling. Evidence from three prospective cohort studies show a relationship between blood lead levels and intelligence in children up to 7 years of age. The effects on intelligence appear to occur above and possibly below the 10 micrograms per deciliter "level of concern" identified by the Centers for Disease Control (CDC) and the National Academy of Sciences. A threshold for neurodevelopmental effects from lead exposure has not been identified. Based on scientific evidence for neurodevelopmental effects, an increase of 1 microgram per cubic meter of lead in ambient air inhaled would, on average, lead to a decrease of approximately 1.39 intelligence quotient (IQ) points for children below the age of 7. Based on an evaluation of peer-reviewed evidence, it is estimated that there would be a mean decrease of 0.08 IQ points for children below the age of 7 exposed to the mean annual 1990-91 population-weighted exposure of 0.06 micrograms per cubic meter

of airborne lead. While this effect may seem insignificant at the individual level, it would result in a downward shift in the distribution in IQ points for children in an exposed community. For example, at the ambient average air lead concentration of 0.06 micrograms per cubic meter, the models predict that 4,700 additional children in California have IQ levels below 80 relative to a zero air lead level.

5. Based on current scientific evidence and using blood lead data provided by the recent National Health and Nutrition Examination Survey (NHANES III), the percent of children that would move above the 10 micrograms per deciliter blood level of concern established by the CDC and accepted by OEHHA can be calculated. The evidence suggests that at the mean annual 1990-91 statewide population-weighted air lead exposure of 0.06 micrograms per cubic meter, relative to a zero air lead level, an additional 0.6 to 2.3 percent of children between the ages of 1 and 2 could move above 10 micrograms per deciliter. This amounts to between 7,200 and 27,600 children in California. At an air lead concentration of 0.25 micrograms per cubic meter, the models indicate that an additional 5 to 13 percent of the children in this age group would move above 10 micrograms per deciliter.
6. Increases in both systolic and diastolic blood pressure and cardiovascular effects have been correlated with lead exposure. There are many large population-based studies that examine the relationship between blood lead levels and hypertension (diastolic blood pressure greater than or equal to 90 millimeters of mercury). In addition, scientific evidence indicates a consistent association between increases in blood pressure and increases in more serious cardiovascular outcomes.
7. Based on this evidence, exposure to the mean annual 1990-91 statewide population-weighted airborne lead exposure of 0.06 micrograms per cubic meter is estimated to lead to 26,000 (with a 95 percent confidence interval of 6,100 to 60,800) additional cases of hypertension (diastolic blood pressure greater than or equal to 90 millimeters of mercury) among the 7.92 million adults in California between the ages of 40 and 59. In addition, the exposure to 0.06 micrograms per cubic meter of air lead is estimated to result in 72 (with a 95 percent confidence interval of 12 to 164) fatal and non-fatal heart attacks per year and 74 (with a 95 percent confidence interval of 9 to 218) deaths from all cardiovascular related disease per year among the 8 million adults between the ages of 40 and 59. These values equate to a unit risk for mortality from cardiovascular disease of 4.6×10^{-4} per microgram per cubic meter (Table 1).

8. The risk assessment for potential near source exposure to inorganic lead at the annual average ambient concentration of 0.24 micrograms per cubic meter could result in a 4-fold increase in risk for neurodevelopmental effects, increased blood pressure and related cardiovascular effects, and cancer.
9. The current federal ambient air quality standard for lead developed by the United States Environmental Protection Agency (U.S. EPA) is 1.5 micrograms per cubic meter. This standard was based on preventing blood lead levels in 99.5 percent of children from exceeding 30 micrograms per deciliter, a level of concern that dates from 1978. The CDC has established a level of concern for children at blood lead levels of 10 micrograms per deciliter. At an air lead level of 1.5 micrograms per cubic meter, approximately one-half of California children would be expected to exceed the CDC guideline. Unfortunately, even if all airborne exposure to lead were eliminated, 10.9 percent of California children would exceed the CDC guideline of 10 micrograms per deciliter. With current air lead levels (0.06 micrograms per cubic meter), the percentage of children exceeding the CDC guideline of 10 micrograms per deciliter is anticipated to be 11.5 percent, 0.6 percent more children than if there were no lead in the air.
10. Lead compounds (which include organic and inorganic lead compounds) are listed as federal hazardous air pollutants (HAPs) and, therefore, were identified as toxic air contaminants (TACs) by the Board on April 8, 1993. However, the federal HAPs list does not include elemental lead in the definition of lead compounds. For this process, elemental lead is included in the ARB/OEHHA definition of inorganic lead and is, therefore, being considered for identification under the state's air toxics program.
11. The major sources of inorganic lead in ambient outdoor air are estimated to emit approximately 180 tons per year. Aircraft fuel combustion is the primary source of emissions at 149 tons per year. Other sources include autobody refinishing, battery manufacturing facilities, cement manufacturing, cogeneration, sawmills, paperboard mills, foundries and steel mills, stationary source fuel combustion, incineration, paint and coatings manufacturers, sand and gravel facilities, and secondary lead recycling facilities. Inorganic lead previously emitted from such sources may be re-entrained as windblown dust; it is expected to contribute 390 tons per year into the atmosphere. Ambient levels of inorganic lead can be much higher near sources which emit lead such as those listed above.
12. Based on air monitoring data collected by the ARB's criteria pollutant monitoring network, the 1990-91 statewide population-weighted exposure is estimated to be 0.06 micrograms per cubic meter. Current *statewide* population-weighted exposure

is expected to be lower due to the ban on the use of leaded fuel for on-road vehicles in California effective January 1992, the implementation of a South Coast Air Quality Management District emission standard on lead (Rule 1420), and an air toxic control measure limiting lead emissions from stationary sources. The 1992-93 *near-source* annual average ambient concentration is 0.24 micrograms per cubic meter taken one-third of a mile away from a specific secondary lead recycling facility.

13. Lead associated with particles may remain suspended in the atmosphere for up to 30 days. These particles are removed by wet and dry deposition.
14. Indoor concentrations are generally lower than outdoor concentrations; indoor/outdoor ratios range from 0.3:1 to 1:1.
15. Inhalation is not the only route of exposure to lead. Airborne lead that deposits on soil, water, and food can be ingested.
16. Most cases of lead poisoning in children are caused by ingestion of lead-based paint. Lead poisoning is also caused by the use of lead-containing traditional medicines from different cultures.
17. Scientific evidence suggests that a 1 microgram per cubic meter increase in atmospheric lead corresponds to 4.2 micrograms per deciliter (with a 95 percent confidence interval of 3.3 - 5.2 micrograms per deciliter) increase of blood lead over time for children and a 2 microgram per deciliter increase of blood lead for adults. The estimates have been developed using both an aggregate model and the U.S. EPA's Integrated Exposure Uptake Biokinetic Model (IEUBK) which incorporate the impacts of air lead emissions through all potential pathways.
18. California ambient air monitoring data from the mid 1970's to 1991 show a substantial decrease in ambient lead concentrations. This is primarily due to leaded fuel regulations that have eliminated the use of lead in automobile fuels and the introduction of catalyst equipped vehicles.
19. The International Agency for Research on Cancer (IARC) has listed lead and inorganic lead compounds in class 2B (1980), possibly carcinogenic to humans, based on sufficient animal carcinogenicity and inadequate human carcinogenicity data. The United States Environmental Protection Agency (U.S. EPA) has placed

lead compounds in category B2 (1986), probable human carcinogen, on the basis of sufficient evidence of carcinogenicity in animals, but inadequate or no data from human epidemiological studies.

20. Scientific studies show that lead can cause gene mutation and cell transformation in culture, and can interfere with DNA synthesis. Rodents that have ingested high doses of lead show increased occurrences of kidney tumors.
21. Based on a health protective interpretation of the available scientific information, the upper-bound of the lifetime excess unit cancer risk resulting from inorganic lead exposure ranges from 1.2×10^{-5} to 6.5×10^{-5} per microgram per cubic meter. This estimate of unit cancer risk was based on rodent data because there are inadequate data in humans. The best value for unit cancer risk is 1.2×10^{-5} per microgram per cubic meter, and is based on the largest data set available for quantitative assessment.
22. Based on the best value for potential unit cancer risk of 1.2×10^{-5} per microgram per cubic meter and the mean annual 1990-91 statewide population-weighted average of 0.06 micrograms per cubic meter, there could be 0.7 potential cancer cases per million people over a 70-year lifetime. Based on a population of 34 million California residents, the cancer burden is estimated to be 24 potential cancer cases.
23. Table 2, attached to these Findings, compares the best value of upper-bound unit cancer risk for inorganic lead with those of other compounds reviewed by the SRP. These 95 percent upper-bound lifetime risk estimates are health-protective estimates; the actual risk may be much lower.
24. Based on available information, there is no evidence for a threshold for neurotoxicity, increased blood pressure and related cardiovascular effects, or cancer.
25. Based on available scientific evidence, we concluded that inorganic lead should be identified as a toxic air contaminant.

WHEREAS, a table in the SRP findings, which depicts a noncancer potency value based on the predicted number of cardiovascular deaths for adults ages 40 to 59, is set forth as Table 1 to this resolution and incorporated by reference herein;

WHEREAS, a table in the SRP findings, which compares the best value of upper-bound inorganic lead cancer unit risk with those of other compounds, is set forth as Table 2 to this resolution and incorporated by reference herein;

WHEREAS, the SRP did not find that the staff report is not based upon sound scientific knowledge, methods, or practices, agreed with the staff recommendation that inorganic lead should be listed by the Air Resources Board as a toxic air contaminant, and found that, based on available scientific information, an inorganic lead exposure level below which carcinogenic effects are not expected to occur cannot be identified;

WHEREAS, the Board recognizes that the state's unleaded gasoline program has produced remarkable results, lowering the statewide ambient average concentration of inorganic lead well below the state and federal ambient standards, but that near-source concentrations may pose a public health concern to children at risk with high blood lead levels;

WHEREAS, the Board further recognizes the challenges of risk management of inorganic lead because there are multiple sources of exposure and directs the staff to work with affected parties, OEHHA and the air pollution control districts on risk management guidance;

WHEREAS, the California Environmental Quality Act and Board regulations require that no project which may have significant adverse environmental impacts be adopted as originally proposed if feasible alternatives or mitigation measures are available to reduce or eliminate such impacts;

WHEREAS, a public hearing and other administrative proceedings have been held in accordance with the provisions of Chapter 3.5 (commencing with section 11340), Part 1, Division 3, Title 2 of the Government Code;

WHEREAS, the Board has reviewed the Staff Report and Scientific Review Panel (SRP) Findings in the matter of the *Proposed Identification of Inorganic Lead as a Toxic Air Contaminant*. Based upon this review, the Board acknowledges and agrees with the SRP and the staffs of the ARB and the Office of Environmental Health Hazard Assessment that uncertainty exists when dealing with the quantitative correlation of potential health effects (neurodevelopmental effects in children, cardiovascular effects in adults, and potential carcinogenicity) at exposure to low levels of air concentrations of inorganic lead. The information contained in the report forms the basis for the identification of inorganic lead as a Toxic Air Contaminant. No controls or risk management decisions are made in this report. As risk management guidelines are developed, the uncertainties will be taken into account and the science updated as appropriate. Further, given the complexity of the models and the limitations of interpretation of the tests of Intelligence Quotient (IQ) used to correlate the neurodevelopmental effects to low air concentrations of air lead, the reader needs to be aware that the fractional IQ measurements related to the low statewide ambient air lead concentrations are given as an example of directional effects and involves uncertainty and should not be viewed as definitive; and

WHEREAS, in consideration of the staff report, including the OEHHA's evaluation and recommendations, the available evidence, the findings of the SRP, and the written comments and public testimony it has received, the Board finds that:

1. There is evidence that exposure to inorganic lead produces serious cancer and noncancer health effects.
2. Noncancer health effects are expected to be more serious than cancer effects.
3. The OEHHA and the SRP agree, and the Board concurs, that the best value of unit risk for mortality from cardiovascular disease is 4.6×10^{-4} per microgram per cubic meter (Table 1).
4. The OEHHA and the SRP agree, and the Board concurs, that the best value of unit cancer risk for inorganic lead is 1.2×10^{-5} per microgram per cubic meter (Table 2).
5. Inorganic lead is an air pollutant which, because of its noncancer and cancer effects, may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health.
6. There is not sufficient available scientific evidence to support the identification of a threshold exposure level for inorganic lead.
7. This regulatory action does not impose any control measures or reporting requirements on any person or business and will not result in any costs of compliance for California small businesses or for private persons or other businesses.
8. At such time as control measures are proposed for emissions of inorganic lead, information regarding the cost of compliance with the proposed regulations will be developed and made available for review and comment by interested persons and businesses prior to consideration by the Board at a public hearing.
9. Given the scientific basis of the Board's action, no alternative to identifying inorganic lead as a toxic air contaminant would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.
10. This regulation action will have no significant adverse impact on the environment.

NOW, THEREFORE, BE IT RESOLVED that the Board hereby identifies inorganic lead as a toxic air contaminant and adopts the proposed regulatory amendment to section 93000, Title 17, California Code of Regulations, as set forth in Attachment A hereto.

BE IT FURTHER RESOLVED, that the Board directs the Executive Officer to forward all available data on indoor exposure to inorganic lead to the Department of Health Services, Division of Occupational Safety and Health of the Department of Industrial Relations, the State Energy Resources Conservation and Development Commission, the Department of Housing and Community Development, the Department of Education, and the Department of Consumer Affairs.

I hereby certify that the above is a true and correct copy of Resolution 96-17, as adopted by the Air Resources Board.

Pat Hutchens, Clerk of the Board

**** Use following two clauses if there are 15-day changes ****

NOW, THEREFORE, BE IT RESOLVED that the Board hereby approves section[s] ____ [**and** ____], Title[s] __ [**and** __], California Code of Regulations, as set forth in Attachment A hereto.

BE IT FURTHER RESOLVED that the Board directs the Executive Officer to adopt section[s] ____ [**and** ____], Title[s] __ [**and** __], California Code of Regulations, after making the modified regulatory language [**and additional supporting documents and information**] available for public comment for a period of 15 days, provided that the Executive Officer shall consider such written comments regarding the modification [**and additional supporting documents and information**] as may be submitted during this period, shall make modifications as may be appropriate in light of the comments received, and shall present the regulations to the Board for further consideration if he determines that this is warranted.

ATTACHMENT A

1. Adopt section ____, Title[s] __ [**and** __], California Code of Regulations, to read as follows:¹

[section no]. If the original proposal is shown in italics, 15-day changes should be indicated as follows: Additions to the original proposal are shown by underline; deletions from the original proposal are shown by ~~slashes~~.

NOTE: Authority cited: section[s] [39600][, 39601][, ____ and ____], Health and Safety Code. Reference: section[s] [39002][, 39003][, ____ and ____], Health and Safety Code [; section ____, [Vehicle] Code].

2. Amend section ____, Title[s] __ [**and** __], California Code of Regulation, to read as follows:

[section no]. If the original proposal used italics and ~~strikeout~~, the 15-day changes should be indicated in the same manner as described above, i.e., underline and ~~slashes~~. If the original proposal used underline to show new language, the modifications should be indicated using *italics* and ~~slashes~~, and the footnote describing how the modifications are indicated should be amended as appropriate.

NOTE: Authority cited: sections [39600, ~~and~~ 39601 and 39605], Health and Safety Code. Reference: section [____], Health and Safety Code[; section[s] ____ [**and** ____], [Government] Code].

¹ The original proposal to shown in *italics* to indicate additions to and ~~strikeout~~ to indicate deletions from existing regulation. The modifications approved by the Board are shown by underline to indicate additions to and ~~slashes~~ to indicate deletions from the original proposal.