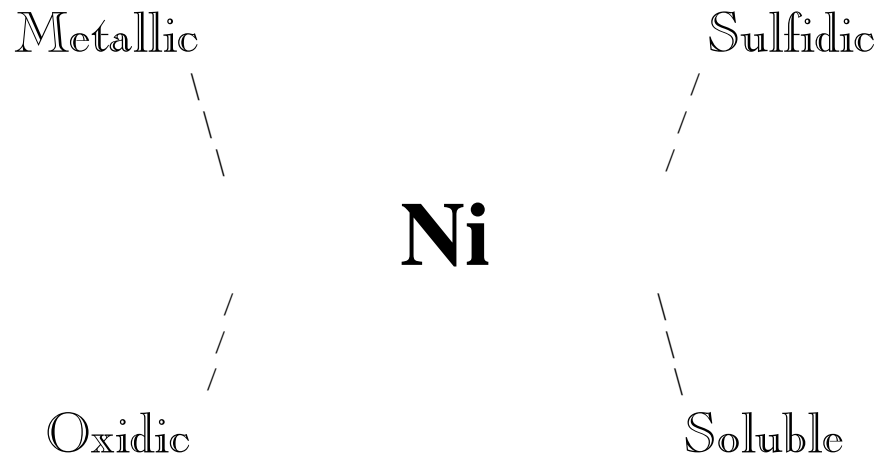


# INITIAL STATEMENT OF REASONS FOR RULEMAKING

## PROPOSED IDENTIFICATION OF NICKEL AS A TOXIC AIR CONTAMINANT



Staff Report / Executive Summary

State of California  
Air Resources Board

June 1991  
INITIAL STATEMENT OF REASONS

PROPOSED IDENTIFICATION OF NICKEL  
AS A TOXIC AIR CONTAMINANT

STAFF REPORT/EXECUTIVE SUMMARY

Prepared by the Staffs of  
The Air Resources Board and  
The Department of Health Services

June 1991

This report has been reviewed by the staffs of the California Air Resources Board and the Department of Health Services and approved for publication. Approval does not signify that the contents necessarily reflect the views and policies of the Air Resources Board or the Department of Health Services, nor does mention of trade names of commercial products constitute endorsement or recommendation for use.

## EXECUTIVE SUMMARY

### WHAT IS A TOXIC AIR CONTAMINANT?

According to section 39655 of the California Health and Safety Code, a toxic air contaminant 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." In addition, "substances which have been identified as hazardous air pollutants pursuant to Section 7412 of Title 42 of the United States Code shall be identified by the state board as toxic air contaminants."

### WHAT IS NICKEL?

Nickel is a silvery white, soft metal that is highly resistant to atmospheric corrosion and retains a high polish<sup>1</sup>. Nickel is used for the production of various metal alloys, cast irons, and electroplated goods. Evidence suggests that some forms of nickel may be essential in the human diet.

### AS A TOXIC AIR CONTAMINANT?

Yes. The staffs of the Air Resources Board (ARB) and the Department of Health Services (DHS) have reviewed the available scientific evidence on the presence of nickel in the atmosphere of California and its potential adverse effect on public health. Based on findings of carcinogenicity and the results of risk and exposure assessment, the ARB and OHS staffs recommend that nickel and nickel compounds be identified as a toxic air contaminant.

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1. Throughout this document, if not otherwise indicated, the word "nickel" refers to metallic nickel or inorganic compounds of nickel, and the words "nickel compounds" refer to inorganic compounds of nickel.

## **WHY DOES THE ARB STAFF RECOMMEND NICKEL BE IDENTIFIED AS A TOXIC AIR CONTAMINANT?**

Nickel is emitted from a variety of sources and can be detected in the ambient air throughout California. Nickel is not removed from the atmosphere at a rate that would significantly reduce public exposure.

The International Agency for Research on Cancer (IARC) has found sufficient evidence of carcinogenicity in humans to classify nickel compounds in Group 1, which includes the chemicals and group of chemicals which are "causally associated with cancer in humans. The IARC classifies metallic nickel in Group 2B or "possibly carcinogenic to humans."

The Environmental Protection Agency (EPA) concludes that there is sufficient evidence of carcinogenicity in humans to place nickel refinery dust and nickel subsulfide in Group A (known human carcinogens). EPA has also concluded that there is sufficient evidence of carcinogenicity in animals to classify nickel carbonyl, the most toxic form of nickel in Group B2 (probable human carcinogens).

The DHS staff found that all nickel compounds should be considered potentially carcinogenic to humans by inhalation. The DHS staff reports that several studies of nickel refinery workers have demonstrated that there is an "association between respiratory cancer mortality and nickel exposure." The DHS staff found this association to be consistent, replicable, of substantiable magnitude, and having a clear dose-response relationship with high statistical significance.

## **WHAT ARE THE SOURCES OF NICKEL EMISSIONS?**

Natural sources of ambient nickel are windblown dusts and volcanic activity. The major anthropogenic source of ambient nickel emissions in California is fossil fuel combustion. The

other sources are: asbestos mining and milling, secondary smelting, municipal refuse and sewage sludge incineration, electroplating, and cement manufacturing.

### **HOW MUCH NICKEL IS RELEASED INTO CALIFORNIA'S AIR?**

Total anthropogenic nickel emissions in California are estimated to range from 23 to 360 tons per year. Fuel combustion (residual oil, distillate oil, coke and coal) is responsible for the majority of the total statewide emissions of nickel. The particles which result from combustion are typically less than 1 um in diameter. Since nickel concentrations are inversely proportional to the particle size, nickel from combustion most effectively enters the deep regions of the lung and then into the bloodstream.

### **HOW LONG DOES NICKEL REMAIN IN THE ATMOSPHERE?**

The average atmospheric lifetime of nickel is estimated to be one week. Nickel particulate matter is removed from the atmosphere by either wet or dry deposition. Wet deposition is deposition by rain, snow, sleet, etc., while dry deposition is gravitational settling.

### **WHAT ARE THE AMBIENT CONCENTRATIONS OF NICKEL IN THE STATE?**

Nickel has been detected in samples collected at the 20 monitoring stations of the ARB's ambient toxic air contaminant monitoring network. The estimated mean nickel concentrations for the years of 1985 and 1986 ranged from 2.8 nanograms per cubic meter (a nanogram is one billionth of a gram) in the Sacramento Valley Air Basin to 11.0 nanograms per cubic meter in the San Joaquin Valley Air Basin. The estimated mean statewide population-weighted exposure to nickel for the 20.3 million people represented by the ARB's monitoring network is 7.3 nanograms per cubic meter.

### **ARE THERE “HOT SPOT” EMISSIONS OF NICKEL IN THE STATE?**

Yes. People that live near facilities which emit nickel may be exposed to above ambient concentrations of nickel. The ARB staff modeled emissions from fuel oil combustion sources in central Kern County. The average hot spot exposures are most likely to be about 10 times above the statewide ambient average concentrations of 7.3 nanograms per cubic meter.

### **IS THERE EVIDENCE OF INDOOR AIR EXPOSURE TO NICKEL?**

Yes. The major source of indoor exposure to nickel is tobacco smoke. Other sources of indoor nickel are wood smoke and suspended soil particles. Indoor concentrations of respirable, suspended particulates, which contain particles of nickel, often exceed outdoor concentrations. At this time we are unable to estimate the indoor contribution of nickel to total exposure. However, research is underway to investigate indoor concentrations of nickel in California.

### **ARE THERE OTHER ROUTES OF EXPOSURE TO NICKEL?**

Yes. In addition to inhalation of nickel, exposure can also occur from ingestion of water and food, skin absorption, and iatrogenic (leaching from implanted medical devices) absorption. The average nickel content of drinking water in California is 10 micrograms (a microgram is one millionth of a gram) per liter. Plants that are grown in nickel rich soil may bioconcentrate the element. Nickel has been detected in foods such as nuts, legumes, and chocolate.

### **WHAT ARE THE HEALTH EFFECTS OF NICKEL EXPOSURE?**

Three types of adverse health impacts can occur as a result of exposure to nickel: cancer, acute health effects, and chronic noncancer health effects. Acute health effects generally result from short term exposure to high concentrations of pollutants. Chronic noncancer health effects may result from long-term exposure to relatively low concentrations of pollutants.

The major route of exposure to nickel is inhalation and the staff of the DHS finds the overall evidence for development of respiratory cancer in humans due to inhaled nickel compounds is strong. This is based on epidemiological studies, carcinogenicity studies in animals, and information on the mechanism of toxic action by nickel compounds. Nickel and nickel compounds are localized in the smallest particles (i.e., those less than 2.5 microns), a size which penetrates deepest into the human pulmonary tract. The OHS was unable to determine if nickel is carcinogenic when ingested.

Acute and chronic noncancer effects have been observed after exposure to elevated levels of nickel. Acute health effects include irritation and allergic sensitization. Chronic noncancer effects from exposure to nickel include asthma and other respiratory effects. Acute and chronic noncancer effects are not expected to occur at statewide ambient population-weighted exposure levels (7.3 nanogram per cubic meter).

#### **IS THERE A THRESHOLD LEVEL FOR NICKEL?**

Since nickel is carcinogenic and mutagenic and there is not sufficient evidence at this time to support the designation of an exposure level below which no significant adverse health impacts are anticipated, the DHS staff recommend that nickel be treated as having no threshold exposure level.

#### **WHAT IS THE RISK OF CANCER FROM EXPOSURE TO OUTDOOR AMBIENT CONCENTRATIONS OF NICKEL?**

The DHS has estimated factors for estimating the risk of contracting lung cancer from a lifetime of exposure to a unit of air with a specified amount of nickel. The estimated unit risk for continuous lifetime exposure to 1 microgram per cubic meter of nickel compounds ranges from  $2.1 \times 10^{-4}$  to  $37 \times 10^{-4}$ . The DHS best value unit risk factor is  $2.6 \times 10^{-4}$ .

Using population-weighted annual exposure of 7.3 nanograms per cubic meter for the 20.3 million people represented by the toxic air contaminant network, the DHS staff estimates the excess carcinogenic risk from a lifetime exposure to be from 1.4 to 27 cancer cases per million. Assuming California's population of 30 million, an excess of 42 to 810 potential respiratory cancer cases might result from 70 years of exposure to the population-weighted annual exposure calculated for California.

Using the DHS best value and population-weighted exposure of 7.3 nanograms per cubic meter, the DHS staff estimates the excess carcinogenic risk from a lifetime exposure is 2 excess cancer cases per million and, assuming a population of 30 million people, 60 excess cancer cases statewide. Hot spot exposures near fuel combustion facilities are likely to be about 10 times above the statewide average. The Air Toxics Hot Spots program is expected to provide further assessments of these potential elevated near source exposures.

#### **DOES THE NICKEL CANCER RISK ESTIMATE APPLY TO ALL NICKEL COMPOUNDS?**

IARC (1990) and the International Committee on Nickel Carcinogenesis in Man (ICNCM, 1990) indicated that the epidemiological evidence points to insoluble and soluble nickel compounds as contributing to the cancers seen in occupationally exposed persons. Both soluble and insoluble nickel compounds are genotoxic in a wide variety of assays. Evidence is available indicating that the Ni 2+ ion is the genotoxic agent and probably the carcinogenic agent as well. The DHS staff conclude that based on available genotoxicity data, carcinogenicity data and physicochemical properties of metallic nickel and inorganic nickel compounds should be considered potentially carcinogenic to humans by inhalation and total nickel should be considered when evaluating the risk by inhalation.



**WHAT IS THE POTENTIAL FOR ACUTE OR CHRONIC NON-CARCINOGENIC HEALTH EFFECTS FROM EXPOSURE TO AMBIENT CONCENTRATIONS OF NICKEL?**

The DHS staff concluded that it is unlikely that noncarcinogenic adverse health effects would be caused at the levels of nickel currently found in the ambient air. However, nickel concentrations could be significantly higher near emission sources. Further investigations of near emission sources would help identify any potential health impact.

**WHAT ARE THE ALTERNATIVES TO IDENTIFYING NICKEL AS A TOXIC AIR CONTAMINANT?**

Government Code Section 11346.14 requires agencies to describe alternatives to the regulation considered by the agency and the agency's reasons for rejecting those alternatives. The only alternative to identifying nickel as a toxic air contaminant is to not identify it as such. The ARB staff is not recommending this alternative because nickel meets the statutory definition of a toxic air contaminant and nickel compounds are listed as a hazardous air pollutant by the federal government pursuant to Section 7412 of Title 42 of the United States Code; therefore, pursuant to section 39655, nickel is required to be identified as a toxic air contaminant.

**WHAT WOULD BE THE ENVIRONMENTAL IMPACTS OF THE IDENTIFICATION OF NICKEL AS A TOXIC AIR CONTAMINANT?**

The identification of nickel as a toxic air contaminant by the Board not in itself expected to result in any adverse environmental impacts. The identification of nickel as a toxic air contaminant may result in the Board and air pollution control districts adopting control measures in accordance with the provisions of Health and Safety Code sections 39665 and 39666. Any toxic control measures would reduce nickel ambient concentrations and the associated health risk. Therefore, the identification of nickel as a toxic air contaminant could result in environmental benefits. Additional potential environmental impacts, if any, will be addressed in the development of specific control measures pursuant to Health and Safety Code sections 39665 and 39666.

## **WHAT ARE THE FINDINGS OF THE SCIENTIFIC REVIEW PANEL?**

In accordance with the provisions of Health and Safety Code section 39661, the Scientific Review Panel (SRP) has reviewed the report of the staffs of the ARB and DHS on the public exposure and biological and health effects of nickel, and the public comments on this report. Based on this review, the SRP finds that the report is without serious deficiencies and agrees with the staff of the ARB and DHS that:

1. The evidence for carcinogenicity in humans from inhaled nickel is strong. In 1984, the U.S. Environmental Protection Agency (EPA) concluded that nickel refinery dust and nickel subsulfide are human carcinogens. In 1990, the International Agency for Research on Cancer (IARC) concluded that nickel compounds are carcinogenic to humans and that metallic nickel is a possible human carcinogen. Based on available scientific data, we agree with the DHS and IARC's classification of nickel compounds as human carcinogens.
2. Nickel is present in many forms including soluble and insoluble compounds. Human epidemiology has shown that nickel sulfate and combinations of nickel subsulfide and nickel oxides are carcinogens in humans. Several nickel compounds are genotoxic or carcinogenic in animals. While there may be differences in the potency of these different forms of nickel, available evidence does not permit quantification of separate risk estimates. As a result, a single potency has been developed.
3. Because nickel was identified as a hazardous air pollutant under Section 112 of the United States Clean Air Act, identification of nickel as a toxic air contaminant is required by California Health and Safety Code section 39655.
4. Nickel is emitted into the outdoor air by a variety of stationary sources in California.

5. Stationary sources such as fuel combustion, cement manufacturing, municipal refuse and sewage sludge incineration, secondary smelters, and electroplating contribute 18 to 353 tons per year of nickel into California's atmosphere. Mobile sources such as gasoline and diesel powered vehicles also contribute 5.4 to 7.2 tons per year of nickel emissions to the atmosphere.
6. Tobacco smoke is the major source of indoor exposure to nickel. Wood burning is another indoor source of nickel. In light of the high emissions of nickel in sidestream smoke and the amount of time most people spend indoors, it is apparent that environmental tobacco smoke may contribute much more to people's exposure to nickel than does inhaling ambient outdoor air.
7. Based on the average particle size, nickel has an estimated average atmospheric lifetime of seven days.
8. Approximately 20.3 million people in California represented by the ARB toxics monitoring network are estimated to be exposed outdoors to a population-weighted mean nickel concentration of 7.3 nanograms per cubic meter.
9. Adverse health effects other than cancer are not predicted to occur at known concentrations of nickel in ambient outdoor air.
10. Computer modeling of potential near source exposures to fuel oil combustion units indicate potential exposure to concentrations of nickel up to 10 times higher than the statewide ambient average.
11. Based on available scientific information, it is justified to assume that a nickel exposure level below which carcinogenic effects are not expected to occur cannot be identified.

12. Based on interpretation of available scientific evidence, the DHS staff estimated the range of unit risk is from  $2.1 \times 10^{-4}$  to  $37 \times 10^{-4}$  per  $\mu\text{g}/\text{m}^3$ . The lower end of this range is the human average estimate; the upper end is the 95% upper confidence bound for the animal study. We concur with the DHS staff that  $2.6 \times 10^{-4}$  per  $\mu\text{g}/\text{m}^3$  is the best value unit risk factor. Table 1 compares the best value for nickel with those of other compounds recently reviewed by the SRP.

**TABLE 1**

<b>Compound</b>	<b>Unit Risk (ppb-1)</b>	<b>Unit Risk (<math>\mu\text{g}/\text{m}^3</math>)-1</b>	<b>Approved by SRP</b>
Nickel	particulate	$2.6 \times 10^{-4}$	05/15/91
Vinyl Chloride	$20 \times 10^{-5}$	$7.8 \times 10^{-5}$	10/19/90
Chloroform	$2.6 \times 10^{-5}$	$5.3 \times 10^{-6}$	08/14/90
Trichloroethylene	$1.1 \times 10^{-5}$	$2 \times 10^{-6}$	04/16/90
Inorganic Arsenic	particulate	$3.3 \times 10^{-3}$	04/16/90
Chromium VI	particulate	$1.4 \times 10^{-1}$	09/18/85

13. Using the population-weighted annual nickel exposure concentration of 7.3 nanograms per cubic meter (California's population-weighted average ambient concentration) and the DHS value for unit risk, the DHS staff estimates 1.5 to 27 excess cancer cases per million are expected to result. Using the best value for unit risk, the DHS staff estimates the excess carcinogenic risk from a lifetime exposure is 2 cancer cases per million. Assuming that this applies to the California state population of 30 million people, this could result in up to 60 excess lifetime cancer cases statewide. Indoor exposure to nickel from tobacco smoke could add an unknown additional number of lung cancers to this risk estimate.

14. Based on the findings of nickel-induced carcinogenesis in humans and animals, as well as the results of the risk assessment, the SRP concurs with the staff of the DHS in finding that nickel compounds are air pollutants 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.