State of California
AIR RESOURCES BOARD

Staff Report: Initial Statement of Reasons for Proposed Rulemaking

Public Hearing to Consider the Adoption of a Regulatory Amendment Identifying Hexavalent Chromium as a Toxic Air Contaminant

Agenda Item No.: 86-1-3
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(This report has been reviewed by the staffs of the California Air Resources Board and the California 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 or commercial products constitute endorsement or recommendation for use.)

OVERVIEW AND RECOMMENDATION

I. INTRODUCTION

The Air Resources Board ("ARB" or "Board") identified toxic air contaminants and develops regulations for the control of their emissions according to the requirements of state law. A toxic air contaminant (TAC) is an air pollutant that the Board or the Department of Food and Agriculture* finds "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."** This report recommends that the Board find hexavalent chromium chromium(VI) to be a toxic air contaminant.

Section II of this Overview to the report presents the regulatory background and reviews the procedures by which the Board considers substances for the TAC designation. The Overview also summarizes the technical and toxicological information that supports the staff's recommendation. Section IIIA is a summary of Part A, which presents data on the uses of chromium, its emissions, and the public's exposure to chromium via the ambient air. Section IIIB summarizes the Department of Health Services' (DHS) analysis in Part B of the health effects of chromium. Section IV of this Overview discusses potential environmental effects of the recommended action, and Section V contains the staff's recommendation to the Board.

II. REGULATORY BACKGROUND AND PROCEDURES

Health and Safety Code (HSC) Section 39650 et seq. and Food and Agriculture Section 14021 et seq. set forth the procedure for identifying

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* See Section II.

** Health and Safety Code section 39655; all statutory references are to the Health and Safety Code, except as otherwise stated.

and controlling toxic air contaminants in California. (These provisions were enacted in September 1983 as Assembly Bill 1807; Stats 1983 ch 1047.) The Department of Food and Agriculture is responsible for identifying and controlling TACs in their pesticial uses. The ARB has authority over TACs in all their other uses.

HSC section 39650 sets forth the Legislature's findings about substances which may be TACs. The Legislature has declared:

> "That public health, safety, and welfare may be endangered by the emission into the ambient air of substances which are determined to be carcinogenic, teratogenic, mutagenic, or otherwise toxic or injurious to humans (HSC section 39650(a))."

The findings also include directives on the consideration of scientific evidence and the basis for regulatory action. With respect to the control of TACs, the Legislature has declared:

> "That it is the public policy of this state that emissions of toxic air contaminants should be controlled to levels which prevent harm to the public health." (HSC section 39650(b)).

The Legislature has further declared:

> "That, while absolute and undisputed scientific evidence may not be available to determine the exact nature and extent of risk from toxic air contaminants, it is necessary to take action to protect public health, (HSC section 39650(e))."

In the evaluation of substances, the Legislature has declared that the best available scientific evidence, gathered from both public agencies and private sources including industry, should be used. The Legislature has also determined that this information should be

reviewed by a scientific review panel, created pursuant to HSC section 39670, and by the public.

The Board's determination of whether or not a substance is a toxic air contaminant includes several steps specified in the HSC. First, we request the DHS to evaluate the health effects of a substance (HSC section 39660). The evaluation includes a comprehensive review of all available scientific data. Upon receipt of a report on health effects from DHS and in consideration of their recommendations, we prepare and submit a report to the Scientific Review Panel (SRP) for its review (HSC section 39661(a)). The report consists of the DHS report (Part B), material prepared by the ARB staff on the use, emissions and ambient concentrations of the substance (Part A), and public comments on the draft Report and responses (Part C). It serves as the basis for future regulatory action by the Board. The report is also made available to the public, which may submit comments on the report to the SRP (HSC section 39661(b)).

After receiving the SRP's written findings on the report, the Board issues a public hearing notice and a proposed regulation which includes a proposed determination as to whether or not the substance is a toxic air contaminant (HSC section 39662(a)). If, after a public hearing and other procedures to comply with Government Code Section 11340 et seq., the Board determines that a substance is a toxic air contaminant, its findings must be set forth in a regulation (section 39662). The HSC also sets forth procedures for developing and adopting control measures for substances identified as TACs (sections 39665-39667); such measures are not proposed during this proceeding.

III. EVALUATION OF CHROMIUM

Consistent with the provisions of state law, the ARB and the DHS prioritize candidate substances for evaluation and regulation as "toxic air contaminants" pursuant to HSC section 39660(f). Briefly, the selection of a substance for the Board's evaluation and

consideration as a toxic air contaminant is to be based on the risk to the public from exposure to the substance, amount or potential amount of emissions from use of the substance,manner of usage in California, atmospheric persistence, and concentration in the ambient air. After consulting with the Department of Health Services (DHS), chromium and its compounds were among candidate substances selected for consideration as a TAC.

Chromium was chosen for evaluation because it was identified by the International Agency for Research on Cancer (IARC) as a human and animal carcinogen, because chromium was found to be emitted from many sources throughout the state (both directly from processes using chromium or chromium compounds, and as a product of the combustion of coal, oil, and other chromium-containing fuels), and because its presence in the atmosphere was documented.

A. EMISSIONS, PERSISTENCE IN THE ATMOSPHERE, AND AMBIENT CONCENTRATIONS OF CHROMIUM

Data in the revised Part A are summarized in Table I.

Industrial sources of chromium may emit chromium in the hexavalent state (chromium(VI)) or the trivalent state (chromium(III)), or a mixture of the two. Chrome plating and the use of hexavalent chromium as a corrosion inhibitor in cooling towers accounted for most of the known hexavalent chromium emissions in California. Refractory (firebrick) production is a source of trivalent chromium emissions.

Combustion of oil, coal, municipal waste, and sewage sludge is a source of chromium emissions. Because historical data for these source categories refer to total chromium, rather than to one form or the other, the oxidation state of chromium emitted from these sources is not known. Available information suggests that combustion-related emissions are trivalent chromium.

Total chromium has been measured in the air at sites in many populated areas of California. Estimates of population exposure to total and hexavalent chromium are summarized in Table 1. Limited preliminary data on ambient concentrations of hexavalent chromium indicate that hexavalent chromium comprised between 3 and 8 percent of ambient total chromium. Efforts are under way to validate the analytical method and to gather more data on ambient concentrations.

Evaluation of concentrations of chromium near sources of chromium(VI) suggest that significant population exposure may occur close to sources.

The atmospheric persistence of chromium(VI) is not known. It has been suggested that chromium(VI) reacts in the atmosphere with available organic matter; however, there is no information available on the atmospheric reactions of chromium(VI) or chromium(III). Chromium is removed from the atmosphere by physical deposition processes. Measurements have shown that most chromium deposition occurs through wet deposition.

The draft of Part A was released for public review and comment. Comments and our responses are presented in Part C.

B. HEALTH EFFECTS AND RISK ASSESSMENT

Pursuant to Health and Safety Code Section 39660, we requested that the Department of Health Services conduct a health effects evaluation of chromium. The DHS evaluation was conducted in accordance with the provisions of that section, which requires that the DHS consider all available scientific data, including, but not limited to, relevant data provided by the ARB, the Department of Industrial Relations, international and federal health agencies, private industry, academic researchers, and public health and

environmental organizations. To facilitate the identification of all available data, we sent, prior to formally requesting the DHS evaluation, a letter to potential sources of chromium compounds in California and other interested members of the public requesting that they submit any information they considered pertinent to the DHS evaluation. We also conducted a reference search on the health effects of chromium and its compounds using the MEDLARS II and DIALOG Information Services and included a bibliography from that search in our request for information. The data compiled in the search were also provided to the DHS.

TABLE 1
SUMMARY OF DATA IN PART A

Emissions			
	Inventory Year	**Chromium Measured**	**Estimated Statewide Emissions, tons**
Stationary Sources			
Chrome plating	1983	Hexavalent	0.77-16
Cooling towers	1979/81	Hexavalent	0.23-9.2
Oil combustion	1983	Total	13.2-28.1
Coal combustion	1981	Total	0.02
Cement production	1981	Total	0.9
Waste incineration	1981	Total	0.02-0.16
Refractory Production	1984	Hexavalent	<0.01

Fate in the atmosphere: The half-life and reactions of chromium (VI) are unknown; chromium particulate is removed from the atmosphere through physical processes, mainly by wet disposition.

Ambient Concentrations		
Location (year)	**Form**	**Concentration nanogram/cubic meter (ng/m^3)**
San Francisco Bay Area Air Basin (partial) (1977)	Total chromium, annual average	10.8
South Coast Air Basin (1977)	Total chromium, annual average	16.9
Fresno Area (1977)	Total chromium, annual average	12.3
San Diego Area (1977)	Total chromium, annual average	11.7
San Jose Area (1977)	Total chromium, annual average	14.3
El Monte (1985)[1]	Total chromium (average of four samples)	13.2
El Monte (1985)[1]	Hexavalent chromium (average of four samples)	0.5

[1] Samplestaken during the last week of August 1985.

The DHS' draft report (Part B) was released to the public for comment. The comments received and responses are included in Part C. A revised Part B is presented to the Scientific Review Panel for review.

In meeting the requirements of section 39666 for DHS' evaluation, the DHS addresses these issues in Part B: 1) Is chromium or its compounds, or both, a human and/or animal carcinogen? 2) Does chromium have a carcinogenic threshold? 3) Are health effects other than cancer expected to occur at current ambient levels? And 4) What is the range of added lifetime cancer risk for populations continuously exposed to the ambient concentrations of chromium measured in California? In response to these issues, the DHS concludes that: 1) hexavalent chromium is a human and animal carcinogen and insufficient information exists to decide whether chromium(III) is a potential human carcinogen; 2) hexavalent chromium should be treated as a substance without a carcinogenic threshold; 3) health effects other than cancer are not expected to occur at current ambient levels with the possible exception of adverse reproductive effects, where experimental data are inadequate to assess potential human reproductive risks; and 4) the theoretical added lifetime cancer risk from a continuous 70-year exposure to atmospheric hexavalent chromium (chromium VI) exposure ranges from 12 to 146 cases per million people per nanogram per cubic meter (ng/m^3).

The DHS has found in its report that: 1) many epidemiologic studies show a strong high association between hexavalent chromium exposure in the work place and respiratory cancer; and 2) all short-term assays reported show that hexavalent chromium compounds possess genotoxic capabilities, while tests of chromium(III) compounds are generally negative or generate positive results at much higher doses than those used in chromium(VI) tests. The DHS agrees with the findings of IARC that there is sufficient evidence to demonstrate the carcinogenicity of chromium in both animals and humans. The DHS believes there are inadequate data available at this time to confirm or refute the carcinogenic potential of trivalent chromium.

To determine that a substance has a carcinogenic threshold, the DHS requires strong positive evidence that the substance acts only through mechanisms which ought to have a threshold. The DHS found that no positive evidence exists for this position with respect to chromium.

The staff of DHS recommends adopting the risk assessment performed by the Environmental Protection Agency (EPA), in which a linear nonthreshold model was applied to the epidemiologic study (Mancuso, 1975) judged to be most methodologically sound and to contain the best exposure data to derive dose-response curves for hexavalent chromium. Data from animal studies were judged to be inadequate for quantitative risk assessment by the staff of DHS.

Making certain assumptions, the DHS described dose-response curves for hexavalent chromium. Based on the results derived from application of the linear nonthreshold model and the Mancuso data, the staff of DHS recommends that the Air Resources Board consider the increased lifetime carcinogenic risk from a continuous lifetime exposure to hexavalent chromium as falling in the range of 12 to 146 cancer cases per nanogram hexavalent chromium per cubic meter of air per million people exposed (12-146 cancers/ng/m3/million). This range is illustrated in Figure A, where the solid line represents the curve based on the EPA assessment using total chromium as the exposure, the dotted line is based on the EPA assessment adjusting for the hexavalent chromium fraction of the exposure, and the dashed line was generated by taking the upper limit of the 95% confidence interval for carcinogenic risk due to chromium and adjusting for the hexavalent fraction of the workplace exposure. There are not, however, sufficient data from this or other epidemiologic studies to estimate the risk of specific hexavalent compounds for airborne exposures.

Figure A Diagram Goes Here

There is very limited information on levels of ambient hexavalent chromium in California. Preliminary data on ambient concentrations of hexavalent and total chromium at a site in the South Coast Air Basin during August 1985 indicate that 3 to 8 percent of total ambient chromium is in the hexavalent state. Although it is not known whether this ratio is representative of other sites, it is the best information available at this time.

There is a need to better characterize the concentration of chromium(VI) in the ambient air of California; we are working with the air pollution control districts and air quality management districts to gather such data. We are also carrying out emission testing of chromium sources to determine the oxidation state and magnitude of chromium emissions. Such information will be an important part of any control effort for hexavalent chromium.

IV. ENVIRONMENTAL IMPACTS

The identification of hexavalent chromium as a toxic air contaminant is not in itself expected to result in any environmental effects. The identification of hexavalent chromium as a toxic air contaminant by the Board may require that the Board and air pollution control districts adopt toxic control measures in accordance with the provisions of state law. Any such toxic control measures may result in reduced emissions of hexavalent chromium to the atmosphere, resulting in reduced ambient concentrations, concurrently reducing the health risk due to hexavalent chromium. Therefore, the identification of hexavalent chromium as a toxic air contaminant may ultimately result in environmental benefits. Environmental impacts identified with respect to specific control measures will be included in the consideration of such control measures pursuant to Health and Safety Code Sections 39665 and 39666.

V. RECOMMENDATION

Because hexavalent chromium is a known human and animal carcinogen, and is known to be emitted in California, the ARB staff recommends the listing of hexavalent chromium as a toxic air contaminant. In making this recommendation, we note that there is not sufficient available scientific evidence to support the identification of an exposure level below which carcinogenic effects would not occur.

NOV 25, 1985

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November 21, 1985

Mr. James D. Boyd, Executive Officer
State Air Resources Board
P. O. Box 2815
Sacramento, CA 95812

Dear Mr. Boyd:

The Sclentific Revlew Panel on Toxic Alr Contaminants has reviewed the BeDort to the Sclentific Revlew Panel on Chromium, and has formulated Its findings regarding the report. With this letter, I am formally submitting the Sclentific Revlew Panel's written findings to the Air Resources Board.

Kindest personal regards,

//s//
Emil M. Mrak

Enclosure

cc: Scientific Revlew Panel
Dr. John Holmes
Mr. Richard Bode

Flndings of the Scientific Review Panel

Regarding the Report on Chromium

In accordance with the provisions of the Health and Safety Code Section 39661, the Scientific Review Panel (SRP) has reviewed the September 1985 Report to the Scientific Review Panel on Chromium, and has reviewed the pubilc comments received regarding this report. The SRP finds the Report on Chromium to be adequate and sufficient.

Specifically, the SRP finds each of the following propositions to be prudent interpretations of the available evidence:

1. In epidemiologic studies, where the oxidation state of chromium was unknown (either in the hexavalent CCr(V1)] or trivalent Ccr(III)) state, chromium was shown to be a human carcinogen.

2. In other studies conducted In laboratory animals, chromium in the hexavalent state CCr(VI)] was shown to be carcinogenic. According ly, the SRP finds that hexavalent chromium (CrCVI)] should be considered a potential carcinogen in humans.

3. An exposure level below which no significant adverse health effects are anticipated could not be identified. Based on our knowledge of the pharmacokinetics, metabolism, and mode of action of chemical carcinogens like chromium, there is no scientific basis for determining an exposure level below which carcinogenic effects would not have some probability of occurring.

4. Adverse health effects other than cancer are not anticipated at current ambient chromium exposure levels.

For these reasons, we agree that hexavalent chromium CCr(VI) should be listed by the Air Resources Board as a toxic air contaminant, but we are unable to recommend an exposure level below which carcinogenic effects would not have some probability of occurring.

COMMENTS

Using extrapolation procedures recommended by the EPA and Interagency advisory groups, DHS has estimated that the added lifetime cancer risk from a 70-year exposure to 1 nanogram per cubic meter (ng/m^3) of atmospheric hexavalent chromium ranges from 12 to 146 cases per million people exposed. The SRP concurs with DHS's evaluation, but wishes to clarify several points:

1. The range of risk presented (12 to 146 cases) was derived using conservative estimation procedures.

2. Chromium may exist in several chemical states, predominately at the trivalent CCr(III)] and hexavalent CCr(VI)] states. The health effects impact of these states are not equal. Hexavalent chromium Cr(VI)] has been shown in animal tests to be carcinogenic. On the ther hand, there are inadequate data to indicate any association between trivalent chromium CCr(III)] exposure and cancer induction in animal tests, however, trivalent chromium CCr(III)] is an essential element. Chromium, as a mixture of oxidation states, has been shown to be a human carcinogen.

3. Whereas there is uncertainty associated with the absolute value of the risk estimated, the range of 12 to 146 cases is useful in comparing risk from exposure to chromium to other environmental carcinogens In ambient air.

I certify that the above is a true and correct copy of the findings adopted by the Scientific Review Panel on November 20, 1985.

//s//

Dr. Emil Mrak, Chairman
Scientific Review Panel

11/21/85
Date