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 Ethylene Oxide as a Toxic Air Contaminant

Agenda Item No.: 87-__
Scheduled for Consideration: November 12, 1987
Release Date: September 25, 1987

(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.)

EXECUTIVE SUMMARY

INTRODUCTION AND RECOMMENDATION

Health and Safety Code Section 39655 defines a toxic air contaminant is an air pollutant which the Air Resources 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." 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 ethylene oxide in the atmosphere of California and its potential adverse effect on public health. Based on the finding of carcinogenicity and the results of the risk assessment, the DHS staff finds that ethylene oxide meets the definition of a toxic air contaminant. Therefore, the staff of the Air Resources Board recommends that ethylene oxide be identified by the Board as a toxic air contaminant. In making this recommendation, the ARB and DHS staffs found that there is not sufficient available scientific evidence at this time to support the identification of an exposure level below which carcinogenic effects would not have some probability of occurring and recommend that ethylene oxide be treated as having no identified threshold.

The Scientific Review Panel (SRP), established by Health and Safety Code section 39670, reviewed the report in accordance with Health and Safety Code section 39661, and found the report to be without serious deficiency. The findings of the SRP are attached at the end of the Executive Summary.

Ethylene oxide was chosen for evaluation because: it has been identified by the International Agency for Research on Cancer (IARC) as an animal carcinogen and a probable human carcinogen; it is emitted from several sources in the state; and it will not break down at a rate that would significantly reduce the resulting public exposure.

SOURCES OF ETHYLENE OXIDE

In 1985, almost 3 million tons of ethylene oxide were produced in the United States. Most of this is for domestic use. Less than one percent of the ethylene oxide used in this country is imported and approximately one percent of production is exported. Production is expected to increase at a rate of approximately six percent per year for the next several years. The major uses of ethylene oxide are for the production of chemicals and for sterilization. Chemicals that are produced using ethylene oxide include surfactants, ethylene glycol, glycol ethers and ethanolamines. Its use as a sterilizing agent is mainly for medical and food products. Although only 0.5 percent of the total U.S. usage is as a sterilizing agent, this use accounts for over 90 percent of the identified ethylene oxide emissions in California.

The major identified source categories of ethylene oxide emissions in California are (in decreasing order of emission quantities):

1) sterilization at commercial facilities and hospitals;

2) fumigation of foods and spices;

3) surfactant manufacturing facilities; and

4) ethylene oxide distribution facilities.

Combustion of hydrocarbons may also be a significant source of ethylene oxide emissions, but not enough information is available to either determine if this could be the case, or to quantify this source of emissions.

EXPOSURE TO ETHYLENE OXIDE

In the atmosphere, ethylene oxide (EtO) is relatively stable to decomposition by gas phase processes, with an estimated lifetime* of 200 days or longer.** Its actual lifetime may be shorter due to processes such as adsorption onto particles or reactions with acid fog. Although the rates for these processes are difficult to quantify, the lifetime of ethylene oxide in the atmosphere is still expected to be on the order of at least several days. Results from dispersion modeling of emissions from all known sources within an area of Los Angeles County indicate that nearly seven million people were exposed to an estimated population-weighted annual average concentration*** of about 50 parts per trillion (ppt) (0.09 $\mu g/m^3$) of ethylene oxide in 1985. The maximum annual average concentration to which people were exposed was estimated to be 20,000 ppt (36 $\mu g/m^3$), near a large commercial emission source. Ambient air concentrations under worst-case meteorological conditions from large emission sources could range as high as four parts per million (7200 $\mu g/m^3$), on an hourly basis. Populations exposed to such concentrations cannot be calculated, but are expected to be very small. Modeling was used to estimate ambient concentrations and exposure because monitoring techniques are currently not sensitive enough to measure the concentrations to which the majority of people are probably exposed.

---

* Atmospheric lifetime is defined as the time required for a Given amount of compound to decrease l/e (0.368) of its original value at the initial time.

** This estimate is based on an assumed hydroxyl radical concentration of one million molecules per cubic centimeter.

*** The population-weighted annual average concentration is defined as the exposure level to which the average person in an area is exposed over the course of a year, in excess of any background level.

As a registered economic poison, ethylene oxide is regulated by the California Department of food and Agriculture in its use as a sterilizing or fumigating agent. Therefore, although this report includes a discussion of overall ethylene oxide exposure, emphasis has been placed on exposure from distribution and from the manufacturing of surfactants, relatively minor sources which would be subject to regulation by the Air Resources Board. From one such source, a distribution facility in Los Angeles County, it is estimated that in 1985, about a quarter of a million people living in an area of about 25 square miles near downtown Los Angeles, were exposed to an annual average ethylene oxide concentration of five ppt (O.OO9 $\mu g/m^3$) or greater. Emissions from that same facility are believed to have resulted in 13,000 people being exposed to an annual average ethylene oxide concentration of about 40 ppt (0.07 $\mu g/m^3$) or greater.

Limited data indicate that smoking and ingestion may represent significant exposure routes.

HEALTH EFFECTS OF ETHYLENE OXIDE

The health effects of ethylene oxide have been reviewed and evaluated to determine whether ethylene oxide meets the definition of a toxic air contaminant as defined by California Health and Safety Code section 39655. Inhaled ethylene oxide is rapidly distributed throughout the body. Mute and chronic exposure leads to respiratory tract irritation and central nervous system depression, as well as other pathologic changes. At high doses ethylene oxide can induce dominant lethal mutations and cause embryo toxicity in rodents. One epidemiologic study suggested an increase in spontaneous abortions due to ethylene oxide exposure. At current ambient levels of ethylene oxide estimated in this report (up to four parts per million or 7,200 $\mu g/m^3$, on an hourly basis), however, no acute or noncarcinogenic chronic effects are expected.

Ethylene oxide, presumably due to its ability to alkylate DNA, causes gene mutations in both prokaryotic and eukaryotic cells and leads to sister chromatic exchanges and chromosomal damage, including the formation of aberrations and micronuclei. Several types of tumors have

been induced in rats by ethylene oxide. Administration of ethylene oxide by savage induced tumors of the forestomach, i.e., at the site of application. Inhalational exposure led to increases in a variety of tumors. The strongest dose-dependent response was seen for peritoneal mesotheliomas in males and for mononuclear cell leukemias in females. There was also an increase in brain tumors, which are rarely seen in control animals. Epidemiologic studies of people occupationally exposed to ethylene oxide suggest that this exposure leads to increased incidences of stomach cancer and leukemia.

The International Agency for Research on Cancer (IARC) concluded that there is sufficient evidence for the carcinogenicity of ethylene oxide in animals; in humans, the evidence for carcinogenicity is limited. Overall, based on both the animal and human data, IARC considers that ethylene oxide is probably carcinogenic in people. DHS staff concurs with these conclusions. In addition, DHS staff has found no evidence of a threshold level for carcinogenicity of ethylene oxide.

RISK DUE TO ATMOSPHERIC ETHYLENE OXIDE

The DHS staff recommends that the range of risk for ambient exposure to ethylene oxide be based on the maximum likelihood estimate and upper 95% confidence limit predicted from fitting the multistage model to the animal data. The range of estimated excess lifetime cancer risks from 24-hour-per-day exposure for a lifetime to average ambient airborne concentrations, estimated to be 0.09$\mu g/m^3$ (50 ppt), is 6 to 8 cases per million persons exposed. These values were also obtained by EPA in its Health Assessment Document for Ethylene Oxide using the same data. When the risk model is applied to the human epidemiologic data to predict excess cancers, the predictions are compatible with what has actually been observed; that is, the DHS risk assessment based on animal data is compatible with the human epidemiologic evidence. Exposure to the ambient value of 0.09 $\mu g/m^3$ (50 ppt), estimated by the Air Resources Board for an area in Los Angeles County, could result in up to 55 excess lifetime cancers (Upper 95% Confidence Limit) among the 7 million residents of that area. Individuals exposed to the maximum annual

average concentration of 20,000 ppt (36 $\mu g/m^3$) for a lifetime would have a risk of developing cancer equal to one case per 330 people exposed.

Several other models proposed for cancer risk estimation by various investigators yielded an upper limit range of 52 to 417 excess lifetime cancers for 7 million people exposed to 0.09 $\mu g/m^3$ (50 ppt).

Based on the findings of carcinogenicity and the results of the risk assessment, DHS staff finds that ambient ethylene oxide 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.

ALTERNATIVES

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 ethylene oxide as a toxic air contaminant is to not identify it. ARB staff is not recommending this alternative because ARB staff believes that ethylene oxide meets the statutory definition of a toxic air contaminant. There are no alternatives considered by the ARB staff which 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 regulations.

SUMMARY OF ENVIRONMENTAL IMPACTS OF THE IDENTIFICATION OF ETHYLENE OXIDE AS A TOXIC AIR CONTAMINANT

The identification of ethylene oxide as a toxic air contaminant is not in itself expected to result in any environmental effects. The identification of ethylene oxide as a toxic air contaminant by the Board may result in the Board and air pollution control districts adopting toxic control

measures in accordance with the provisions of state law (Health and Safety Code sections 39665 and 39666). Any such toxic control measures would result in reduced emissions of ethylene oxide

to the atmosphere, resulting in reduced ambient concentrations, concurrently reducing the health risk due to ethylene oxide exposure. Therefore, the identification of ethylene oxide 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.

Amend Titles 17 and 26, California Administrative Code, Section 93000 to read as follows:

93000. **Substances Identified As Toxic Air Contaminants**

Each substance identified in this section has been determined by the state board to be a toxic air contaminant as defined in Health and Safety Code section 39655. If the state board has found there to be a threshold exposure-level below which no significant adverse health effects are anticipated from exposure to the identified substance, that level is specified as the threshold determination. If the board has found there to be no threshold exposure level below which no significant adverse health effects are anticipated from exposure to the identified substance, a determination of "no threshold" is specified. If the board has found that there is not sufficient available scientific evidence to support the identification of a threshold exposure level, the "Threshold" column specifies "None identified."

Substance	**Threshold Determination**
Benzene (C_6H_6)	None Identified
Ethylene Dibromide ($BrCH_2CH_2Br$; 1,2-dibromoethane)	None Identified
Ethylene Dichloride ($ClCH_2CH_2Cl$; 1,2-dichloroethane)	None Identified
Hexavalent Chromium (Cr(VI))	None Identified
Asbestos [asbestiform varieties of serpentine (chrysotile) rebeckite (crocidolite) cummintonite-grunerite (amosite), tremolite, actinolite, and anthophyllite)	None Identified
Dibenzo-p-dioxins and Dibenzofurans chlorinated in the 2,3,7 and 8 positions and containing 4,5,6 or 7 chlorine atoms	None Identified
Cadmium (metallic cadmium and cadmium compounds)*	None Identified
Carbon Tetrachloride* (CCL4; tetrachloromethane)	None Identified
<u>Ethylene Oxide (1,2-epoxyethane)</u>	<u>None Identified</u>

NOTE: Authority cited: sections 39600, 39601 and 39662, Health and Safety Code. Reference: sections 39650, 39660, 39661 and 39662, Health and Safety Code.

*__Note__: Compounds identified by an asterisk have been identified as toxic air contaminants by the Air Resources Board but not yet approved by the Office of Administrative Law.

JUL 27 1987

Report of the Scientific Review Panel on
THE REPORT ON ETHYLENE OXIDE
As adopted at the Panel's July 7, 1987 Meeting

In accordance with the provisions of Health and Safety Code section 39661, the Scientific Review Panel (SRP) has reviewed the reports of the staffs of the ARB and DHS on the public exposure and biologic and health effects of ethylene oxide, and the public comments on these reports. Based on this review, the SRP finds that the reports are without serious deficiencies and further finds that:

1. Ethylene oxide has been identified as an animal carcinogen and should be regarded as a potential human carcinogen.

2. Ethylene oxide is emitted into the air by a variety of stationary sources in California. Dispersion modeling of emissions from all known sources within an area of Los Angeles County indicates that nearly 7 million people were exposed to an estimated population-weighted annual mean concentration of 50 parts per trillion (ppt) (0.09 $\mu g/m^3$) of ethylene oxide in 1985. The maximum annual average concentration to which people were exposed was estimated to be 20,000 ppt (36 $\mu g/m^3$) near a large commercial emission source.

3. Based solely on its gas-phase reactivity, ethylene oxide has an atmospheric llfet1me of approximately 200 days. Although possible reaction in solution or on surfaces could shorten this lifetime, based on available scientific evidence, ethylene oxide would still have an atmospheric lifetime of days to weeks.

4. Adverse health effects other than cancer are not known to occur at predicted concentrations of ethylene oxide in ambient outdoor air.

5. Based on available scientific loformation, an ethylene oxide exposure level below which carcinogenic effects are not expected to occur cannot be identified.

6. Based on an interpretation of available scientific evidence by DHS staff, the range of lifetime excess cancer risk from exposure to 0.56 ppb (l $\mu g/m^3$) of atmospheric ethylene oxide based on the best animal estimate of risk and the upper 95% confidence limit is estimated to be 6l to 88 cases per million people exposed. These upper bound excess lifetime risks are health-protective estimates; the actual risk is likely to be below these values.

For these reasons, we agree with the ARB staff recommendation to its Board that ethylene oxide be listed by the are as a toxic air contaminant.

I certify that the above is a true and correct copy of the findings adopted by the Scientific Review Panel on July 7, 1987.

//s//
Dr. Thomas H. Mack, Acting Chairman
Scientific Review Panel