



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

April 11, 1984

OFFICE OF
THE ADMINISTRATOR

Honorable William D. Ruckelshaus
Administrator
U. S. Environmental Protection Agency
401 M Street SW
Washington, D. C. 20460

Dear Mr. Ruckelshaus:

The Environmental Health Committee of the Science Advisory Board has completed its review of a revised Draft Cancer Risk Assessment Document for Coke Oven Emissions prepared by the Agency's Office of Research and Development (ORD). The major conclusion of the document was that coke oven emissions are carcinogenic to humans. This conclusion is based on a number of scientific studies including an extensive series of occupational epidemiology studies of coke oven workers and evaluation of individual coke oven constituent responses in experimental animals. The Committee unanimously concurs with this conclusion.

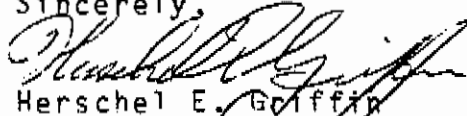
Several risk models were evaluated by ORD's Cancer Assessment Group (CAG) staff to develop a quantitative risk assessment for this pollutant. The dose-response relationship in the epidemiological studies is non-linear in the range of past occupational exposure. At the much lower levels that characterize ambient exposures, the dose-response relationship is highly uncertain and several forms of the dose-response relationship can be validly hypothesized and defended. Because the available scientific evidence does not permit rejection of the hypothesis that the dose-response relationship is dominated at low doses by a linear term, a linear nonthreshold approach has therefore been used to estimate an upper bound for the incremental cancer risk from unit exposure. Non-linear Weibull and multi-stage models have been used to calculate both maximum likelihood estimates and ranges for the unit risk (one microgram of pollutant per cubic meter of air). Results from the two models were in the expected directions and did not differ greatly. The Committee was briefed by CAG on its plans to carry out additional calculations on

the modified linear nonthreshold approach; it is the Committee's expectation that it will receive the final results of such analysis when they are completed. The Committee anticipates that the modified linear nonthreshold approach will continue to be the most protective to public health, and it is assumed to be applicable in this report.

The revised Draft Cancer Risk Assessment for Coke Oven Emissions has been reviewed by the Committee following extensive briefings by Agency staff and participation by the public. CAG staff have proven responsive to previous Committee requests for revisions, particularly in the development of a quantitative risk assessment. The result has been beneficial in at least three important respects: 1) the Committee is satisfied that the September 1983 draft document presents a thorough and balanced treatment of the available scientific evidence associated with coke oven emissions; 2) the process of communication between Agency staff and the Committee has produced considerable clarification regarding the development and use of quantitative risk assessment by ORD; and 3) several recent health assessment documents developed by ORD and reviewed by the Committee, including those for acrylonitrile, carbon tetrachloride and inorganic arsenic, have incorporated the discussions regarding the use of mathematical models and quantitative methods that evolved from the review of the coke oven emissions document. These documents were of high scientific quality and, as a result, the overall review process has been considerably shortened.

Additional Committee comments and recommendations for the Draft Cancer Risk Assessment for Coke Oven Emissions are summarized in the attached report. The Committee recommends that CAG provide a formal response to the recommendations included in the attachment. The Environmental Health Committee appreciates the opportunity to provide its scientific advice on this important issue.

Sincerely,



Herschel E. Griffin
Chairman, Environmental Health
Committee



Norton Nelson
Chairman, Science Advisory Board

cc: Mr. Alvin Alm
Dr. Elizabeth Anderson
Mr. Joseph Cannon
Dr. Bernard Goldstein
Dr. Terry Yosie

Environmental Health Committee Key Findings,
Conclusions and Recommendations on the
Revised Draft Cancer Risk Assessment
for Coke Oven Emissions (September 1983)

I. Qualitative Assessment

Based upon an extensive review of epidemiological studies of coke oven workers in America, Britain, and Japan, as well as tests in experimental animals and bacteria, the following conclusions were drawn in the document:

" 1) coke oven workers have been found to be at an excess risk of mortality from cancer at all sites, lung cancer, prostate cancer, and kidney cancer as a result of exposure to coke oven emissions. These risks may possibly have been enhanced by smoking but are not believed to have been confounded by smoking. 2) Sample extract from a coke oven main and coal tar, a condensate of coke oven emissions, were found to be carcinogenic in animal skin painting studies. Animals exposed to coal tar aerosol developed lung tumors. 3) Simple extracts from coke oven topside and a coke oven main initiated tumor formation in initiation-promotion studies in mice. 4) Coke oven door emissions were found to be mutagenic in bacteria. 5) Numerous constituents of coke oven emissions are known or suspected carcinogens. The Cancer Assessment Group concluded that coke oven emissions are carcinogenic."

The Committee unanimously agrees with these conclusions.

II. Quantitative Assessment

The Committee reviewed at length the quantitative assessment section of the document and is pleased to report that numerous changes and improvements have been incorporated as the result of the Committee's advice. The body of this section of our report will address these changes.

1. Understanding of the significance of coke oven emissions as a public health issue is enhanced by the presentation of alternative quantitative estimates and the

comparison of risk estimates against other known or suspected carcinogens. This is a particularly useful means of communicating to both the scientific community as well as the general public the significance of the risk of this pollutant.

2. The Committee suggests an alternative definition of unit risk which it believes will more thoroughly explain its use in risk assessment when the linear nonthreshold model is utilized. The alternative definition should read: unit risk is defined as the maximum, lifetime incremental lung cancer risk theoretically estimated to occur in a population in which all individuals are assumed to be continuously exposed from birth to death to a one microgram per cubic meter increase of the agent in the air they breathe.

3. The discussion of the use of mathematical models in risk assessment has been considerably clarified by placing confidence limits on the estimates calculated through the use of the Weibull model and the multistage model. More caution should be exercised, however, in presenting a risk estimate to two significant figures past the decimal point. This practice implies a degree of certainty or precision which does not exist. It is also desirable to present in tabular form the results of all the models, giving at least the most likely estimator and upper confidence limits.

4. The issue of linearity vs. non-linearity in the dose response relationship is a constant subject of discussion in evaluating risk assessments. In the case of coke oven

emissions there is relatively clear evidence of non-linearity in cases of occupational exposure. This issue should be stated more forcefully in the Summary of the document. A proposed insert might read as follows:

At the much lower levels that characterize ambient exposures, the dose-response relationship is highly uncertain: the available scientific data do not permit rejection of the hypothesis that the dose-response relationship will be dominated by a linear term. EPA therefore makes upper bound calculations of risk using the conservative assumption that an essentially linear nonthreshold dose-response relationship function exists at low doses. The multistage model is used to estimate, with an upper bound 95% confidence limit, the largest linear term consistent with the occupational data. Such estimates for different lag times have been used in developing a plausible upper bound estimate of the unit risk for coke oven emissions.

5. A more careful statement is needed in the document to clarify that the cancer risk assessment for coke oven emissions uses the benzene soluble organic (BSO) portion of coke oven emissions as an indicator of the risk due to the entire complex mixture. There is discussion of other carcinogenic agents in the coke oven emissions mixture, and BSO serves as an indicator for estimating the cancer risk of the entire mixture, including these other compounds.

6. The Office of Research and Development and the Office of Air Quality Planning and Standards should jointly work to develop exposure assessment information for hazardous air pollutants. The Committee recommends that data bases related to exposure assessment be included in the risk assessments submitted for the Committee's review.

7. A statement is needed in the document with respect to the radioisotope portion in coke oven emissions that would theoretically contribute to lung cancer. This radiation component from radon or other radioisotopes that have alpha emissions has a linear term throughout the dose response curve. There are numerous studies, among uranium miners for example, for which a lung cancer incidence rate has been calculated. There is also information available on alpha emitted particles in coke oven emissions.

Additional Recommendations

1. The ultimate credibility of the Cancer Assessment Group's (CAG's) procedures in developing risk assessments will rest upon their publication in the scientific, peer reviewed literature. Many of the difficulties and confusions that arise from the application of CAG's methods are the result of not having this peer review. The Committee strongly recommends that CAG submit its risk assessment procedures, and the assumptions contained therein, for publication in applied statistics and other journals.

2. CAG has undertaken a project to establish correlations between quantitative responses in humans and in experimental animals from selected pollutants, including coke oven emissions, believed to cause cancer. The Committee has discussed this project with Agency staff and strongly recommends that the Office of Research and Development provide support to see this work through to its completion.

3. The Committee supports the CAG effort to extend the coke oven worker study through 1984. CAG intends to use data on individual coke oven workers to improve the current risk assessment model which is based on aggregate data from groups of workers.