



JUL 23 1985

Committee Correspondence

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To: The HESC Planning and Budget Subcommittee
From: Steven M. Swanson
Re: Proposed Study to Collect Refinery Worker Exposure
Data on Benzene and Gasoline-Range Hydrocarbons
Date: June 13, 1985

API is preparing to participate in the OSHA hearings on benzene which are likely to be held later this year. As part of that effort, counsel and consultants have recommended that new exposure monitoring data be collected to bolster API's defenses against potential PEL's of 1.0 ppm or 0.5 ppm. This memorandum discusses the reasons why such new data are needed and describes a study to respond to those needs. If appropriate, the study can be expanded, at small additional cost, to simultaneously collect data on worker exposure to gasoline-range hydrocarbons.

THE NEED FOR SUPPLEMENTAL BENZENE EXPOSURE DATA

OSHA's draft proposed benzene standard, which is presently undergoing final OMB review and is expected to be published later this year, contains two broad findings of concern from a regulatory standpoint. First, OSHA's draft proposal concludes that workers would face a "significant" health risk even under revised benzene PEL's of 1.0 and 0.5 ppm. Second, the Agency finds that a 1.0 ppm PEL is technologically and economically "feasible" and appears ready to conclude that a 0.5 ppm PEL is also feasible in most settings. In the petroleum refining industry, for example, OSHA claims that a 1.0 ppm PEL is already being uniformly achieved and thus would impose no capital costs, and comes very close to finding that a 0.5 ppm PEL is feasible.*/*

/ In fact, OSHA's feasibility contractor purports to have identified three refineries that are consistently achieving 0.1 ppm.

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OSHA is also going to propose a 5.0 ppm short-term (15 minute) exposure limit (STEL), which is claimed to be feasible without respirator use.

API's approach to preparing for the upcoming OSHA hearings is to collect data that will support the most effective challenge that can be mounted against these conclusions on medical, technical and cost grounds. Exposure data are critical for all these purposes. To date, API's efforts to develop such a data base have included (i) an extensive survey in 1983 of historical monitoring data collected by member companies, and (ii) a statistical analysis of data supplied by four of the companies having the most extensive monitoring programs.

The preliminary results of these efforts underscore the importance of exposure data for the upcoming OSHA hearings. In particular, the data in hand suggest that occupational benzene exposures, while quite low on average, are highly variable from day to day. As a result, employers may find it necessary to reduce average exposures to levels well below any never-to-be-exceeded PEL (perhaps by a factor of four or five) to achieve reasonably consistent (e.g., 95%) compliance. This fact, if it could be adequately documented, would raise the following concerns:

- o It is far from certain that average exposures in the petroleum industry can be maintained at levels low enough to ensure reasonably consistent compliance with a never-to-be-exceeded PEL of 1.0 ppm, much less 0.5 ppm. If the preliminary conclusions of the previous efforts are confirmed by new data, OSHA's feasibility findings will be subject to serious question.
- o Even if it is technically feasible to attain a reasonable degree of compliance with a never-to-be-exceeded 1.0 ppm PEL, the tentative conclusions arising from the data in hand suggest that a potentially large number of refinery operations would be required to install engineering controls to maintain average exposures at sufficiently low levels. If substantiated, this conclusion would undercut OSHA's finding that refineries are already fully in compliance with a 1.0 ppm PEL. In addition, it would raise serious questions about the cost-effectiveness of 1.0 ppm or lower PEL's, particularly given the marginal health benefits of further reductions.

Unfortunately, our efforts to date have also shown that even the companies with the most extensive and sophisticated monitoring programs have not developed exposure data which are sufficiently coherent and systematic in collection and analysis, for their combined use to definitively support or refute conclusions like those just described. The underlying problem is that company programs have been designed to serve purposes (such as OSHA compliance) that are fundamentally different from the regulatory issues we now face. Hence, a defensible statistical analysis of the current data base is frustrated by a variety of factors, such as:

- o the use of different sampling strategies by different companies;
- o the absence of sufficient detail to relate individual measurements to engineering controls, the particular tasks being performed and the work practices used that affect analysis of the data;
- o the paucity of data sets involving multiple measurements of similarly-situated workers over a reasonable period of time; and
- o the absence of data suitable for aggregation for analysis.

Moreover, the available data base does not provide a sufficient basis for evaluating a 5.0 ppm STEL, even though that provision could well prove to have the greatest practical impact on the refining industry.

For these and other reasons, outside counsel and consultants have cautioned that our tentative conclusions doubt variability, feasibility, and compliance costs and benefits may not withstand the rigorous scrutiny that is likely to occur during the upcoming hearings. Our data must support analysis that is not only convincing but sufficient to overpower analyses of data that lead to other conclusions. Additional data confirming or refuting these tentative conclusions would therefore provide an essential supplement to the data and analysis already collected and prepared. Apart from facilitating a more defensible statistical analysis than that already completed, the collection of new data by an additional independent expert witness is likely to produce a more credible and influential submission. The additional capability to address general questions concerning the effectiveness of particular exposure controls will be of great importance in any OSHA proceeding.

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SUMMARY OF THE PROPOSED STUDY

Because of the obvious importance of API's tentative conclusions about the effects of a 1.0 ppm not-to-exceed PEL to the presentation of an effective case in the upcoming hearings, a field study designed to explore and further develop these conclusions has been developed in consultation with the group of statisticians from the University of California at Berkeley who analyzed the historical data, counsel, Radian Corporation and member-company industrial hygienists. The field study would involve about a month of field time by teams of approximately five industrial hygienists working simultaneously at each of three refineries selected to span the range of current exposure conditions. The hygienists would examine three or four units in each refinery, documenting benzene exposure controls, work practices and other parameters relevant to exposure such as weather and operating conditions.

The focus of the study would be exposure monitoring, primarily through full-shift sampling. In addition to these TWA measurements, some fifteen-minute sampling to assess the feasibility and cost of alternative possible short-term exposure limits and to aid in apportioning total worker exposure among various possible sources would be undertaken. The hygienists would follow one or two workers on each unit through their shift rotations, assembling for each of these workers the most extensive series of repeat measurements possible within the 30-day period of observation. The hygienists would also collect several five-day series of exposure measurements on other workers on the unit. As time permits, the hygienists would take selective fifteen-minute samples on workers being monitored for a full shift and collect additional full-shift samples on other workers on the unit. Preliminary plant visits will allow this general plan to be tailored to each unit to be observed.

Oversight for the project would rest with the Benzene Issue Group, staff and counsel. Responsibility for actual conduct of the project would be shared by company hygienists, and the Radian and Berkeley groups. Radian would develop the final study designs, perform the field work and coordinate sample analysis. The Berkeley group would have responsibility for analysis of the data. The final project report would be a joint Radian/Berkeley effort with provision for review by API, counsel, and the Benzene Issue Group and other company participants. In addition to the normal contract provisions for confidentiality exposure measurements and all other information would be blinded for anonymity and coded. No identification of individual companies, refineries, units, or workers would appear in the final report.

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Radian estimates that the project can be completed by November 1, 1985 if the field work is started in early August. We anticipate that the project will cost between \$550,000 and \$650,000, including the expense of additional data analysis by the Berkeley group and the time of a process-engineer who may be necessary to supplement the results of the project with additional data needed to project industry-wide costs for the installation and operation of particular exposure controls.

This proposed work has application beyond the benzene case. The cost above anticipates additional exposure analysis for a full boiling range of gasoline components, including the gasoline fractions under test in PS-53, as well as the components being considered for testing under Section 4 of TSCA.

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COMMENTS ON THE PS-7 TASK FORCE'S
PROPOSED BENZENE LIFETIME STUDIES

1. Has HSRC/SEHL reviewed the proposal to assess its risks vs. its benefits?
2. The June 19 Penick letter correctly assesses the current state of affairs both as to events in California and OSHA: data which have been in hand for more than two years, together with newer, suggestive data (e.g., the CIIT's findings on SCE and other effects at very low doses) provide information which, if used by OSHA, EPA, or state authorities, coupled with the significant latitude and mandate to exercise prudence agencies have, could well drive health-based proposals on standards to very low levels.

If the proposed study were to identify a NOEL in the 25-50 ppm range then, based either on the usual methods of extrapolation or on safety margins (1,000 - 5,000 times below the NOEL for carcinogens has been suggested) the health-related driving force toward low standards would be enhanced within OSHA, EPA, and state agencies. Doing the study thus does entail a risk, over and above that which already exists, with respect to regulation.

With respect to regulatory agencies, therefore, I propose that a study to establish the engineering and operational feasibility of controlling exposures and emissions at different levels be launched; the exposure studies now being defined could, if appropriately directed, provide invaluable data on levels, frequencies and sources of exposure and of emissions as inputs to feasibility studies. This effort needs to go forward whether the proposed inhalation studies do or not; moreover, if the inhalation studies are carried out, this study will serve to reduce the extra risk in doing the inhalation studies.

3. The area in which the inhalation studies might be most valuable is in countering extravagant adverse health effects claims. Here, a clearly established, large-study NOEL may well be important, outweighing possibly enhanced risks in the regulatory arena. This is not a sure-fire proposition, even here, since claimants can and will argue on the basis of their preferred extrapolations and/or interpretations. At the moment, however, members of the industry have too little with which to counter claims. It must be remembered, though, that even large studies entail some degree of risk of obtaining false positives at low levels.

Clearly, the relative risks and benefits need to be assessed for and by the HESC before deciding whether or not to do the inhalation studies, considering both the regulatory and the litigative factors.

4. Where in all this do the Brookhaven CBA/^C mice fit? Have all the pros and cons of this approach been explored? For example, is a mouse such as this a unique creature, or does leukemogenesis in it signify anything with respect to leukemogenesis in humans?

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5. At the March HESC meeting, the MBSD was charged with developing a program of animal studies of benzene; are the proposals now before us a complete and balanced response to that charge? Is there more to come?
6. I would suggest that the mechanistic studies mentioned might well be funded at CIIT where such benzene research is already underway.

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