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Approaches to Health Risk Assessment for
Alternative National Ambient Air Quality Standards

A Report of the Subcommittee on
Health Risk Assessment

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BACKGROUND

In 1979, the Subcommittee on Health Risk Assessment of the Science Advisory Board reviewed a methodology proposed by EPA's Office of Air Quality Planning and Standards (OAQPS) for assessing health risks associated with alternative ambient air quality standards for ozone.

The Subcommittee stated its comments, conclusions, and recommendations in a report dated September 1979.^{*/}

Briefly, the Subcommittee, among other comments and suggestions,

- commended the Office of Air Quality Planning and Standards for recognizing the need for and undertaking the development of quantitative subjective decision aids for use in the assessment of the health risks of air pollutants;
- found that the methodology developed by OAQPS ^{**/} was not ready for application in the process of establishing national ambient air quality standards;
- urged EPA to expand its efforts to develop and evaluate the use of judgmental probabilities in the process of establishing national ambient air quality standards;
- warned that under no circumstances should the use of such techniques become a replacement for the research needed to establish an objective data base for assessing health risks; and

^{*/} Review of "A Method of Assessing the Health Risks Associated With Alternative Air Quality Standards for Ozone" (Draft dated July 1978, A Report of the Subcommittee on Health Risk Assessment, EPA/SAB/79/001, September 1979)

^{**/} Subsequently referred to as the F/B Risk Assessment Method after Thomas B. Feagans, OAQPS Analyst, and Dr. William F. Biller, Consultant.

- recommended that OAQPS should formulate a plan outlining how the Agency will (a) develop the proposed methodology, including standards and protocols for application, (b) consider alternative approaches, and (c) select and establish the credibility of the best methodology.

Consistent with these recommendations, the Office of Air Quality Planning and Standards developed a "Risk Assessment Program Plan" and, with a view toward considering alternative approaches to health risk assessment, contracted with six research teams, each one to develop an integrated conceptual risk assessment procedure. This particular effort resulted in six documents which the Subcommittee reviewed in a public meeting on September 15 and 16, 1980.

SCOPE

The six documents which the Subcommittee reviewed and which are the subject of this report, are

- "Reporting of Uncertainties in Risk Analysis" by Howard Raiffa and Richard Zeckhauser, First Draft, September 1980;
- "Assessing Health Risks Associated With Ambient Air Quality Standards" by Baruch Fischhoff and Chris Whipple, July 1980;
- "A Procedure Based on Decision Analysis for Assessing the Health Risk Associated With Alternative Ambient Air Quality Standards" by M.W. Merkhofer, Preliminary Draft, July 1980;
- "Estimation of Risk of Adverse Health Effects Associated With Air Quality Standards for Pollutants" by H.O. Hartley, K.G. Manton, and M.A. Woodbury, Undated;
- "A Risk Assessment Methodology for Environmental Pollutants" by Robert L. Winkler and Rakesh K. Sarin, Draft of Final Report, July 7, 1980; and
- "A Conceptual Risk Assessment Procedure" by Richard de Neufville and Marie-Elisabeth Pate, First Revision, August 25, 1980.

Also at the September 15 and 16, 1980 meeting, the Subcommittee heard update reports on the Risk Assessment Method developed by Thomas B. Feagans and William F. Biller (the F/B method) and on contemplated next steps in the OAQPS "Risk Assessment Program Plan."

OAQPS requested that the Subcommittee, in its report, discuss each one of the suggested approaches, focus on its strengths and weaknesses, and comment on Agency plans for the further pursuit of alternative approaches.

COMMENTS AND FINDINGS

"Reporting of Uncertainties in Risk Analysis" by Howard Raiffa and Richard Zeckhauser, First Draft, September 1980

Dr. Raiffa's paper is not intended as a proposal for a specific analytical technique but rather as a general philosophical framework. It contains important insights on probabilistic methods of assessing environmental risks and provides a useful discussion of both advantages and dangers of using quantitative techniques for risk assessment in the process of regulatory decisionmaking.

The paper contains much valuable material particularly concerning the process of assessing uncertainties when working with committees of scientific experts. The paper emphasizes that communication between scientists holding disparate views and policymakers is, at best, a difficult process. It does not suggest specific mathematical techniques for aggregating scientific judgment, but rather emphasizes the need for experience and ingenuity on the part of "synthesizers" who can work with diverse experts to facilitate open, honest, and effective communication. This emphasis on communication by one of the foremost authorities on decision analysis should be carefully considered by OAQPS. It addresses implicitly a major weakness of the Feagans-Biller methodology: its focus on mathematical technique at the expense of facilitating communication.

Raiffa's argument for occasional nonseparation of risk assessment and risk evaluation also bears careful consideration.

The paper suffers somewhat from its lack of organization. It is not specific to the issues of criteria air pollutants facing OAQPS.

Dr. Raiffa has indicated that he does not wish to be considered for subsequent OAQPS contracts relating to this particular effort.

"Assessing Health Risks Associated With Ambient Air Quality Standards" by Baruch Fischhoff and Chris Whipple, July 1980

The paper by Fischhoff and Whipple provides a general philosophical framework for risk assessment and a broad set of desiderata that are useful background for developing appropriate methodology. The paper presents interesting insights on the psychology of probability assessment and on the difficulties of establishing air quality standards under the Clean Air Act. It presents virtually no analytical specifics nor an approach suited to the needs of OAQPS.

The paper's principal contributions are an emphasis upon the differing requirements and objectives of the various actors in the standard setting process and an emphasis on the psychological limitations and cognitive biases which are likely to enter the process of attempting to estimate uncertain coefficients in the form of subjective probability density function. Unfortunately, no real recommendations are provided on specifically how to incorporate these important insights into one or several quantitative tools.

OAQPS would be well advised to give these insights careful consideration as specific analytical techniques are developed for their use.

"A Procedure Based on Decision Analysis for Assessing Health Risk Associated With Alternative Ambient Air Quality Standards" by M.W. Merkhofer, Preliminary Draft, July 1980

In the view of the Subcommittee, the paper by Merkhofer clearly comes closest to providing a workable framework for risk assessment to be used in the process of setting ambient air quality standards. The technical approach is well developed, with appropriate logic and mathematics used to incorporate relevant information. Assumptions are clear and explicit, making the methodology readily comprehensible for public review. Available data on ambient levels and dose-response relationships are utilized, and uncertainties are included explicitly as their importance is assessed. The paper shows sensitivity to the specific restrictions imposed on the problem of risk assessment by the Clean Air Act and both willingness and ability to modify traditional decision analytic techniques to meet the needs of EPA.

There appears to be too much emphasis on predictive air quality models and not enough emphasis on the use of historical air quality data.

One member questioned the desirability of significance weighting, i.e., introducing value judgments which are implicit in significance weighting.

One member found the emphasis on sensitivity studies to explore the importance of alternative sources of information and the implication of varying expert opinion to be particularly appealing. The member felt that while somewhat complicated, the proposed adaptation of the ideas of value of information to this problem is useful and worthy of further exploration.

The suggested approach warrants further support for refinement of techniques and trial applications. Close collaboration with experts in air pollution other than sulfur pollutants and with experts in health, atmospheric chemistry and meteorology will be necessary and should be encouraged.

"Estimation of Risk of Adverse Health Effects Associated With Air Quality Standards for Pollutants" by H.O. Hartley, K.G. Manton, and M.A. Woodbury, Undated

The paper by Hartley, Manton, and Woodbury starts with the commendable position that risk assessment, to the extent possible, should be based directly upon health impact data and that subjective judgments should enter only to the extent necessary to interpret and compare these data. While this major emphasis on data base is absolutely correct, the proposed implementation is not satisfactory.

It is clear from the procedures proposed that the authors are thinking in terms of carcinogens and statistical studies in the context of rather large volumes of data. They propose the use of a model that emphasizes the "time of onset" of adverse chronic health effects. No evidence is presented that this model is useful or appropriate when little is known about the relation of chronic health impairment to past ambient levels or when acute or transient effects are the health impairment of concern.

The problems of obtaining epidemiological data for the proposed model are formidable. In the absence of epidemiological data, clinical and animal studies assume great importance. There is no indication how the proposed approach would make use of such data.

The Subcommittee feels that the types of techniques proposed are inappropriate for the assessment of criteria air pollutants mainly for two reasons: first, because the health effects evidence typically available for criteria air pollutants is not amenable to the kinds of statistical manipulations proposed; and, second, because typically the processes by which health effects from criteria air pollutants occur would not be well characterized by the kinds of effects model proposed, i.e., a model based on "time of onset" of a given condition or effect.

"A Risk Assessment Methodology for Environmental Pollutants"
by Robert L. Winkler and Rakesh K. Sarin, Draft of Final
Report, July 7, 1980

The Winkler and Sarin approach, while not as completely developed as Merkhofer's, impressed the Subcommittee as a clear exposition of decision analysis, a promising start tailored to the specific problem of assessing the health risks of a criteria pollutant. The approach appears well suited to making assumptions and judgments explicit, thus facilitating review by the public.

The technical approach appears generally adequate, although much less detail is presented on how air chemistry and meteorological information will be considered. The description of health effects is overly simplistic. The complexity of dose-response modeling is not fully recognized.

Some caution should be exercised regarding the use of second order probabilities and the regression approach to pollutant synergism, but the ideas expressed merit some further investigation. No procedures should be developed which would require experts to provide rather large numbers of subjective probability density functions (as might happen in the treatment of second order probabilities) or to answer questions which pose severe cognitive difficulties (as might happen with the multivariate regression procedure).

The discussion, in the paper, of aggregation of experts' judgments highlights the need to examine the basis for differing probability assessments. The authors might do well to explore procedures for displaying the sensitivity of risk assessment results to alternative expert opinions without necessarily requiring a procedure for combining those opinions.

To be implemented effectively, the Winkler and Sarin approach will require extensive familiarity with air quality models and knowledge of the details of health impacts of criteria pollutants. To be successful, air pollution and health effects experts will have to be closely involved in the further development of this approach.

"A Conceptual Risk Assessment Procedure" by Richard de Neufville and Marie-Elisabeth Pate, First Revision, August 25, 1980

The paper by de Neufville and Pate provides useful general comments on the use of risk analysis. The general philosophical position, as outlined in the main body of the paper, places heavy emphasis upon simple models and on the use of iterative procedures to reach agreement on appropriate output measures among the various parties and is excellent. OAQPS would be well advised to keep this in mind as specific analytical techniques are developed for their use.

Unfortunately, the paper is not successful in developing a specific analytical framework. An exploratory research proposal titled, "Development of a Risk Indicator for Health Effects of Air Pollution," which is included in the paper as Appendix A, while demonstrating analytical ability, suffers from a lack of familiarity with air quality literature and, in particular, the types and quality of data available.

The Subcommittee is aware of the preliminary nature of the paper under review.

"F/B Risk Assessment Method" by Thomas B. Feagans and William F. Biller

Mr. Feagans deserves much credit for his role in initiating OAQPS efforts toward formal analytic risk assessment procedures. It is with great regret, therefore, that the Subcommittee finds that the presentation at the September meeting was disappointing and did not reflect significant progress in the development of this method since the Subcommittee reviewed it and discussed its deficiencies in public session in April 1979. The Subcommittee feels strongly that the lack of progress in improving this particular approach, thought of as an "in-house" methodology, may tend to discredit the entire Risk Assessment Program and obscure the significant progress made in developing suitable methodology elsewhere in the program.

Next Steps in Risk Assessment Program Development

OAQPS indicated that the goal is, in due course, to select one or more methods for assessing health risks associated with national ambient air quality standards and to use the method or methods selected in the next scheduled review of national ambient air quality standards in 1985. As an immediate next

step toward that goal, OAQPS plans to select two or perhaps three of the methods presented for further development and sample application. The final step would be a test case where the method or methods selected would be implemented and evaluated by an independent third party.

The Subcommittee is in general agreement with this approach but warns against prematurely turning over a method or methods to a third party for trial testing. The Subcommittee feels that the party which developed a method which has been selected for further development and trial application should be given ample opportunity to refine and test try that method before it is turned over to a third party.

SUMMARY AND CONCLUSIONS

The Subcommittee commends the Office of Air Quality Planning and Standards on the conduct of its Risk Assessment Program. In the view of the Subcommittee, the program has produced clearly two and possibly three promising approaches to health risk assessment for use in developing alternative national ambient air quality standards. Regrettably, information presented on the "F/B Risk Assessment Method," in the view of the Subcommittee, did not reflect significant improvements since it was first reviewed by the Subcommittee. */

*/ It should be noted that the Subcommittee has been advised that, following the Subcommittee's recommendations, OAQPS has selected two approaches as alternatives for further development: the approach presented by M.W. Merkhofer and the one by Robert L. Winkler and Rakesh K. Sarin. With respect to the Feagans/Biller (F/B) method, the Subcommittee has been advised that OAQPS plans to complete a full report on this method within the next few weeks and then to conduct extensive in-house and external reviews of the comprehensive report. The Subcommittee will be asked to participate in that review. If the peer review indicates that further development of the F/B method is warranted, OAQPS plans to hold it in abeyance until alternative methodology can be brought into a parallel state of development. If the peer review indicates that further OAQPS support of the F/B approach is not warranted, all work on that method will be terminated except for the generally-applicable exposure analysis module. Resources designated for development of the F/B method would be applied to the alternative approach(es).