

SCIENCES

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Health and the Environment

February 19, 1999

Dr. Joel A. Seckar
Scientific and Regulatory Affairs
RJR Tobacco Co.
Bowman Gray Hospital
950 Reynolds Boulevard
Winston-Salem, NC 27105

Dear Dr. Seckar:

Thank you for your call on behalf of the Commodity Industry Coalition for Phosphine Fumigation. It is my understanding that the Coalition is interested in retaining a consultant to provide broad assistance for your activities with an emphasis on toxicology specifically dealing with EPA's proposed decision to require a control level well below that suggested by previous evaluations, and also on issues of exposure, the justification for proposed remedial measures, and regulatory analysis. First let me provide you with some general information about our company. Sciences International, Inc. (Sciences) is a health and environmental sciences consulting firm with corporate headquarters in the Washington, D.C., metropolitan area. We specialize in the full range of critical issues involved in health and environmental risk assessment. In fact, our scientists have pioneered many of the innovative techniques used today in defining risk assessment outcomes. For example, Dr. Suresh Moolgavkar pioneered and published the biologically-based model, referred to as the MVK Model, for modeling low-dose effects. The model has been applied widely to carcinogens, reproductive toxins, and other agents. We are also currently working on a novel methodology for defining acute effects using categorical regression. Examples of other innovative work include developing a new exposure and risk model for coke ovens, demonstrating that an EPA proposed short-term SO₂ standard was inappropriate, using chemical fingerprinting analysis for source allocation, and evaluating available data on the effects of air pollution on daily morbidity and mortality and coming to conclusions somewhat different from those reached by EPA.

Sciences has extensive corporate experience evaluating toxicological data for pesticides. We have specific experience in EPA's pesticide evaluation and approval process, including preparing DER and pre-RPAR reports, reviewing pathology slides, reviewing rebuttal information, conducting pesticide risk assessment, and providing technical assistance in support of administrative hearings. Sciences has also conducted numerous projects which require the review and evaluation of toxicity data for chemicals to assess potential effects for humans,

*Joel, I hope
this copy covers the
information you need.
Please let me know if
you require any
additional information.
Betty*

including the evaluation of safe levels of exposure for non-carcinogens, dose-response relationships for carcinogens, detailed studies to establish metabolic differences between species, pharmacokinetics of a particular substance, likely modes of action, epidemiologic and biostatistical analyses, and evaluation of emerging health issues including particularly sensitive groups and childhood risk. Our work has included identifying outside experts, conducting and participating in peer reviews, convening workshops and meetings and preparing follow-up reports, and participating in and testifying before various science advisory boards and in Federal administrative hearings.

These broad capabilities provide a solid background for assisting the Coalition in responding to the recent EPA proposed actions to reduce the hazards of exposure to phosphide fumigants through a variety of risk remediation measures and their request for public input. As I told you when we spoke, our toxicology staff has worked specifically on phosphine for the past year. Likewise, our exposure and risk assessment team has been evaluating worker and community exposures and measurement techniques for phosphine. Thus, we probably bring a unique background to support the Coalition by evaluating the toxicology database, developing appropriate toxicological criteria, identifying and evaluating risk remediation measures, assisting in providing public comment on EPA's actions, and assisting in preparing for and contributing to EPA's planned stakeholder meetings. We would be happy to discuss these efforts further with you if it would be helpful. We have confirmed with our current client, FMC Corporation, that there would be no conflict with their work.

Sciences' Health and Risk Assessment Team

I typically play an active role in our health and risk assessment tasks based on my more than 20 years management experience, both government and corporate, in health and the environmental sciences and my knowledge of matters pertaining to EPA risk assessment policies and methods, regulatory policy, litigation support, and strategic planning and management. I also routinely apply this knowledge to present risk issues to the public, science advisory boards, or the courts. First, I will highlight several of my recent activities which may be helpful in negotiating with regulators and in presenting risk-related work to the public, and then I will introduce you to our key staff.

On January 1, I began a 5-year term as Editor-in-Chief of *Risk Analysis: An International Journal*, which is published by the Society for Risk Analysis and is distributed worldwide. I also recently served on the Board of Scientific Counselors, Committee to Review EPA's Laboratory Programs that support health and ecological risk assessment, was recently appointed to the External Review Committee for the Los Alamos National Laboratory, and serve as Chair for the U.S. Department of Agriculture External Review Panel for Risk Assessment. When negotiating with regulators and the public or dealing in the legal arena, my activities and similar credentials of our other senior staff provide Sciences with substantial credibility and familiarity with the likely concerns of the involved regulatory groups. I also provide technical strategies and expert testimony on risk related environmental issues. A recent example was for Rockwell International

Sciences' Relevant Project Experience

The enclosed listing—Corporate Toxicological, Exposure, and Risk Assessment Experience: a Partial Listing—describes a number of projects completed by Sciences' experts over the years. Many are particularly relevant to the Coalition's potential needs, including our current work on phosphine for the FMC Corporation, many specific chemical assessments, and development of site-specific exposure modeling techniques. As you can see from the numerous project descriptions, Sciences serves the private sector, including many trade associations, on a wide range of health and risk assessment issues. However, we are different from most other consulting firms in that we also currently serve government agencies. This government work is generally limited to furthering the sciences of toxicology and risk assessment and currently includes contracts with: the Environmental Protection Agency to provide innovative toxicological and risk assessment methodology support; the Agency for Toxic Substance and Disease Control and the Food and Drug Administration to provide state-of-the-art toxicological support; and, as noted above, the National Institute of Environmental Health Sciences to operate the Center for the Evaluation of Risks to Human Reproduction. Our experience in supporting these governmental agencies in the advancement of science gives Sciences a unique credibility to negotiate with regulators on behalf of our private sector clients, to speak authoritatively in the scientific community, and to be accepted in legal proceedings and by the public.

Summary

In addition to our broad practice in areas of toxicology, exposure assessment, and related regulatory disciplines, we have spent a good deal of time with the literature on phosphine specific issues that could be applied to the particular concerns involved in EPA's Reregistration Eligibility Decision (RED) document and subsequent request for public comment. Our work has focused on toxicology, exposure assessment, and measurement. For example, a quick first reading of the EPA RED document surfaced several issues which may be useful in a submission requesting a reconsideration of proposed new phosphine regulations. First, EPA's analysis is based entirely on animal data and does not make use of the existing human studies of phosphine exposure. It is a widely held principle in public health that human studies are preferred over animal studies in developing regulations protecting human populations. In developing guidelines for exposures to phosphine, Sciences has used a study of aluminum phosphide workers by Misra et al., 1988. Second, the approach taken by EPA in developing the 0.03 ppm level is one which would apply to chronic exposures. Our research on the mechanism of phosphine toxicity indicates that it may not be appropriate to apply such procedures to a toxicant such as phosphine. We believe that these and other issues may be effectively developed into a scientific petition requesting a reconsideration of the proposed regulation.

I have enclosed a summary of some of our recent activities, a 1999 Fee Schedule, and selected resumes. If you have questions, please feel free to call me or David Patrick of my staff at (703) 684-0123.

Sincerely,

A handwritten signature in cursive script, appearing to read "Elizabeth L. Anderson".

Elizabeth L. Anderson, Ph.D.
President

Enclosures