



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 23, 1985

Honorable Lee M. Thomas
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

OFFICE OF
THE ADMINISTRATOR

Dear Mr. Thomas:

The Acute Toxics Subcommittee of EPA's Science Advisory Board met on August 15-16, 1985 to review a draft document, "Acute Hazards List Development," prepared by the Office of Toxic Substances (OTS) and dated July 1985. The draft document describes a proposed method to develop a list of chemicals that are capable of causing serious human health effects from short-term exposures. The Subcommittee was not given a specific list of chemicals to review but was asked to comment on the scientific adequacy of the selection criteria by which such a list will be generated.

Purpose of the List

The purpose of the list was described by Agency staff as providing support for a process by which the Agency will prepare guidance documents to assist state and local authorities in identifying chemical substances that pose potential health hazards in their jurisdictions. Specific sites would require further analysis and investigation regarding use, storage or transportation of chemical substances to establish the extent of the health hazard. Where the hazard is significant, the authorities may want to carry out emergency response planning and to take steps to mitigate the hazard. In this context, the Subcommittee believes that a list can aid the planning process. However, the draft document needs to clarify the intended use of the list to avoid possible misinterpretation or misuse. The guidance documents for site-specific analysis were not provided to the Subcommittee. We recommend that EPA also obtain expert review of the guidance documents because of their importance to the decision-making process.

Because of the large number of chemicals in use as commercial products or intermediates in manufacturing, the diverse toxicities of these chemicals and their intrinsic characteristics affecting human exposure, it is not appropriate to expect that the list can provide more than a coarse screen to identify hazardous chemicals. The list is not intended as a ranking of chemical substances by their degree of hazard because the screening process categorizes substances in a simple way, as meriting further investigation. The list will be a poor predictor of the consequences or frequency of emissions of acutely toxic materials, as judged

against the impacts of past, or potential, site-specific or process-specific releases.

Unless a large number of chemicals are listed, substances likely will be omitted that do present a threat to community health (false negatives), but a large list will contain many chemicals that experience has shown present little or no health risk (false positives). Any list that is intended as a basis for regulatory action is likely to be criticized as containing errors of both types. The degree of risk that chemicals pose to human health can only be evaluated on a site-specific and process-specific basis.

Many chemical substances routinely used in commerce can pose a threat to health, but most public safety organizations know how to deal with them in emergency situations. EPA has to emphasize these more obvious hazards, because of the need for a comprehensive approach, but an acute toxics list will be most useful if it also identifies chemical substances that pose significant health risks of which local authorities are unaware, or for which they can prepare better. The Agency might describe its activity under a title such as "Acute Hazards Identification Process," to emphasize that the list is intended only as an initial step in identifying potential acute health hazards.

Data Limitations

Limited data are available to EPA on the toxicities and other characteristics of chemicals. While the Registry of Toxic Effects of Chemical Substances (RTECS) may be the most comprehensive single source of information on toxicity test results, many chemicals now used in commerce are not included in RTECS, and some information now in RTECS may be inaccurate. The Agency began to establish a list by taking chemicals for which there are data in RTECS that also occur either in the initial Toxic Substances Control Act inventory plus the 1982 cumulative supplement, or in the EPA list of active pesticide ingredients. This list will omit many chemicals that may pose an acute health risk.

Additional efforts will be required to identify other commercially available chemical substances whose toxic properties merit inclusion on the list. For example, toxicity data are available for some substances on the inventory but not on RTECS. Further, there are some intermediates, by-products, and waste products that may be important from an acute emissions perspective but that do not appear on the inventory. For those chemical substances that do appear in both RTECS and either the inventory or the pesticide ingredients list, it will be important to review the information from RTECS against other data sources to assure the accuracy of the data.

It is appropriate, therefore, to regard the main output of the Agency's current effort as the set of selection criteria for the acute toxics list rather than the list itself. The selection criteria can then be used to screen chemical substances not included in the Agency's initial list, for which information is available from chemical manufacturers and processors. These substances also will merit investigation for their potential acute health hazards. Chemicals that arise only as intermediates may fall into this

category, and information on such chemicals may be available only to the segments of industry that manufacture or process these chemicals. The Subcommittee hopes that the guidance documents being prepared by EPA will contain recommendations to utilize the available industry resources in dealing with site-specific problems.

Selection Criteria

The Subcommittee has a number of recommendations regarding the selection criteria discussed in the EPA draft document. The Agency needs to define overall criteria that predict the level at which the concentration of a chemical substance is likely to become practically dangerous to human health. The "immediately dangerous to life and health" level, used by the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH) as discussed in Section V of the draft, is one possible approach. EPA may wish to refine this criterion to provide appropriate protection for sensitive subgroups of the population not present in occupational groups, such as young children or adults with cardio-respiratory impairment.

Given the set of acute health responses that EPA defines as unacceptable, such as all irreversible effects, the Agency must choose selection factors to identify the chemical substances that could elicit such responses from members of the public as a result of a short-term exposure (such as thirty minutes). Lacking the best possible data to predict these responses, EPA will have to use surrogate information. For example, LC₅₀ and LD₅₀ data seem suitable for an initial screening procedure since they are available for many substances. The Subcommittee suggests that it is inappropriate to single out any specific health effect for special consideration at this time because the current question is whether persons are harmed, not which organ is affected.

A secondary screening procedure for exposure characteristics could identify those chemical substances for which an unacceptable concentration or dose might be delivered to the public. As proposed by the Agency, the use of boiling point data in such a secondary screen would select a chemical that can occur in gaseous form or with high vapor pressure under ambient conditions. Exposure beyond the plant fence line could occur as a result of a sudden release of the chemical into the air. However, a high boiling point does not necessarily imply the absence of a potential hazard. Rupture of containment for chemicals stored or processed at high pressure and temperature, or releases associated with a fire or explosion, could cause the formation of a cloud of liquid or solid particulates that endangers public health. The Subcommittee questions whether the flammability and reactivity selection factors proposed by the Agency will be useful as a means of identifying substances for which non-ambient releases pose a community health threat.

Interagency Cooperation

Scientists from a number of Federal agencies, in addition to EPA, have interests in the development of plans to assist state and local government agencies in dealing with potential releases of chemical

substances that pose an acute exposure health hazard. Many of these agencies have special expertise and information that will be of value to EPA. These agencies include the Departments of Labor, State, Energy, Transportation and Health and Human Services. NIOSH and OSHA have a major role in providing information for the protection of workers that is directly relevant to the protection of communities.

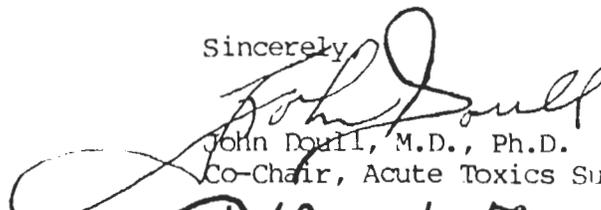
EPA has already made extensive use of NIOSH and OSHA data sources. NIOSH scientists and engineers know the limitations of their data. Further, NIOSH has updated material that is not yet available in standard publications. The Surveillance, Hazard Evaluation, and Field Studies Division of NIOSH has primary responsibility for keeping updated information on what chemicals are being used in industry, including the effectiveness of control of hazardous chemicals. Their walk-through surveys on national samples of workplaces are the only national data sources on hazardous chemicals to which workers are potentially exposed. The second national survey has not yet been published, but many of its findings could be obtained prior to publication.

Conclusion

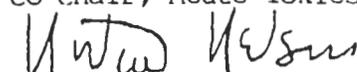
The Subcommittee believes that the Agency has made a reasonable beginning to a process that will assist state and local levels of government in dealing with chemical substances that pose a potential health hazard in their communities. The list being developed by the Agency should be a starting point for more detailed investigation of potential hazards so that appropriate mitigation and emergency preparedness actions may be taken by government and private industry. The documentation will need considerable expansion and refinement from the draft that the Science Advisory Board was given to review. The initial list that can be generated from RTECS, the toxic substances inventory, and the pesticide ingredients data will have significant limitations. This initial effort will, however, be of value.

Comments from individual members of the Subcommittee have been transmitted directly to OHS staff. We appreciate the opportunity to comment on this important public health issue and stand ready to provide any further scientific advice.

Sincerely,


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Co-Chair, Acute Toxics Subcommittee


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cc: A. James Barnes
Assistant Administrators