Occupational Health Priorities for Health Standards: The Current NIOSH Approach

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Abstract: Government agencies responsible for protecting the public from the adverse effects of toxic chemicals must set priorities for research, regulatory action, protocol testing, and monitoring due to the vast number of toxic chemicals and the limited resources available to these agencies The National Institute for Occupational Safety and Health (NIOSH) must set priorities for research on hazards encountered in the workplace Priorities are also utilized by NIOSH in preparing criteria for recommended occupational standards which are forwarded to the Occupational Safety and Health Administration (OSHA), U S Department of Labor, for possible promulgation For various reasons, including rapidly changing conditions in the American workplace, NIOSH has instituted a revised priorities program In the future, NIOSH research and recommended standards activities will focus not only on individual chemicals, but also on industries, occupations, chemical classes, and general industrial processes NIOSH has also implemented a new program which will allow recommended control procedures for certain chemicals to be forwarded to OSHA in a shorter time period than has been experienced previously (Am J Public Health 69 444-449, 1979)

Limits and constraints on budget and manpower are the major reasons for assessment of priorities Whether in government private enterprise, or academia, an orderly and systematic approach to the allocation of resources is necessary For health-oriented government agencies, such as the National Institute for Occupational Safety and Health (NIOSH), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), priorities for assessing the possible health effects of toxic chemicals are a primary concern More than 9,000 chemicals were commercially produced in the United States in 1970 [1] Currently the NIOSH Registry of Toxic Effects of Chemical Substances contains over 28,000 chemical entries [a] The Chemical Abstracting Service (CAS) has now registered more than 4,000,000 chemicals, and new CAS entries are being made at the rate of 21 000 per month [b] Clearly, these health agencies are faced with a monumental task in developing priorities for research, protocol testing, monitoring, and regulatory action

Ideally, the assessment of each chemical should be based on several factors Toxicity, which may include predicted or documented adverse health effects, and the population at risk including the extent of that risk, are the most important factors Other factors with varying degrees of importance include production levels, trends in use, environmental conversion or fate, adequacy of previous research, testing, or standards setting attempts, and physical characteristics such as volatility or physical state Unfortunately, the data needed to assess the priority of each chemical are not always available For example, production data are available for only a small percentage of chemicals due to the current proprietary nature of the information [2] Under provisions of the 1976 Toxic Substances Control Act,[3] production data should become available to certain agencies for the purpose of establishing priorities for evaluation and regulation of chemical substances

The two most important factors used in establishing priorities, i e , toxicity and population at risk, are also the most difficult to assess Methods used for assessing toxicity have varied considerably Stephenson[4] used the "Delphi" method, a modified version of which was used by NIOSH as will be subsequently described In the Delphi approach,[5] a panel of experts rank a series of chemicals with or without the aid

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[a] Unpublished data *Registry of Toxic Effects of Chemical Substances*, NIOSH May 1978

[b] Personnel communication Chemical Abstract Service, P O Box 3012 Columbus OH 43210, March 24, 1978

of supporting data The goal is to reach a consensus agreement, or at least a narrowing of opinion, through an iterative process which allows each participant to see how his views fit with those of the group This method works best if the number of chemicals to be ranked is limited and well defined For example, Stephenson ranked 80 chemicals, while NIOSH ranked 475 Brown[6] assessed the hazardousness of industries in Allegheny County, Pennsylvania, using reported data indicating the incidence of occupational illness This method is simple and straightforward, however, occupational illness data should not be relied upon as a sole factor, as the current adequacy and accuracy of illness reporting is poor and sometimes can be misleading.[7]

The population at risk factor includes level of exposure and duration or length of time of exposure. These variables are extremely difficult to assess. Early attempts to gain knowledge about chemical exposures in occupational populations[8 9] did not include an assessment of airborne concentration or time of exposure The 1974 NIOSH National Occupational Hazard Survey (NOHS)[10] defined exposure time as either full-time or part-time, part-time designating four hours or less of exposure per day No attempt to assess concentration was made To simply state that 2,000,000 people are occupationally exposed to benzene does not address the complex issues of time and concentration Although these variables can be determined, the effort to do so for several thousand chemicals would be a time-consuming and costly task Consequently, simple population at risk estimates, such as those made using NOHS data, normally have to be used but their limitations should be understood

Obviously, differences exist in the data that each federal agency uses for assessment of chemical priorities The EPA must consider environmental fate and the possibility of environmental release NIOSH is concerned with occupational populations The FDA must consider therapeutic vs toxic effects of drugs Nevertheless, the major parameters evaluated by each agency for assessing chemical priorities usually include population at risk and toxicity, and each agency must concern itself with an enormous number of chemicals

Development of the NIOSH Approach

As required by the Occupational Safety and Health Act of 1970, NIOSH has attempted to remain cognizant of the large number of commercial chemicals to which varying numbers of workers are exposed Among other provisions, the Act directs NIOSH to develop and conduct research and experiments which will yield criteria for identifying toxic substances and for developing recommended occupational safety and health standards These recommended standards, or criteria documents, describe, among other items, safe exposure levels and working conditions designed to ensure that "no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of the work experience "[11] Recommended standards are forwarded to the U S Department of Labor, Occupational Safety and Health Administration (OSHA), for promulgation and are also available to employers, employees, and government agencies as guides for voluntary compliance

NIOSH's commitment to setting priorities is based on the belief that such a systematic approach is necessary to ensure the effective utilization of limited resources, thereby having the greatest cost-effective impact on the health and safety problems facing the working population Priorities are established for the selection of subjects, for the preparation of criteria for recommended occupational standards, and for the conduct of laboratory research These are not necessarily independent, as much of the NIOSH research is related to providing necessary information for effective preparation of criteria documents Currently NIOSH prepares 20 to 24 criteria documents per year The subjects may include individual chemical or chemical or physical agents, classes or groups of agents, industries, occupations, or specific processes within an industry (see Appendices Tables 1 and 2)

From 1972 until 1975, NIOSH compiled three priority lists While different variables were utilized in compiling each list, population at risk and toxicity of the agent were used as a minimum in all three lists The 1972 priority list[12] contained 19 sets of substances each set consisting of five or six subjects having equal priority Listed were individual toxic agents, including chemicals, mineral dusts, and physical agents

The 1972 priority list was based on a system developed by the staff of the former Bureau of Occupational Safety and Health, which became NIOSH in 1971 Subjective rankings were made by Bureau staff and field industrial hygienists using population at risk, relative toxicity of the hazard, incidence of occupational illness, quantity produced, and trend in use Unfortunately, many of the data were not available for every agent, thereby dictating the use of subjective judgments

In March 1973, a new NIOSH priority list was developed using population at risk and severity of toxic effect as the only criteria The product of these two numerical factors represented the overall priority factor for each chemical Criteria documents were to be developed on each subject in the order that it occurred on the list. Estimates of population at risk for each of the 475 agents listed were obtained using national estimates extrapolated from the 1970 Occupational Hazard Safety of the Chicago Metropolitan Area.[8]

As noted earlier, the approach was modeled after the Delphi process, but because of time and resource constraints a modified approach was used Under contract, a toxicity severity rating was developed for each of the 475 agents based on a series of subjective judgments by a panel of 50 occupational health professionals Although the severity ratings were to include carcinogenicity and other delayed toxicities, it is probable that the rankings were based more on classical or acute toxicologic factors Data regarding carcinogenicity were not as readily available or abundant in 1972 as at present Consequently, agents with notable chronic effects, such as vinyl chloride received low toxicity ratings Lack of knowledge as to possible delayed toxic effects constantly plagues the assessment of the overall toxicity of chemicals

Based on the 1973 priority list, a third list was prepared in 1975 by NIOSH staff Three new factors were considered:

suspected carcinogenicity or other serious delayed effects, the lack of a federal occupational standard, and new or revised information regarding the potential hazard of the 475 agents on the 1973 list The top 50 hazardous agents were subjectively ranked, and those remaining agents which were positive for at least one of the new factors were placed in an unranked category Those agents which were negative for all of the three new factors were deleted This list was used by NIOSH until 1977

The three NIOSH priority lists, while serving NIOSH relatively well, have had the following deficiencies

- The scope of NIOSH priorities has been too limited While the 1973 list was the largest, it contained only 475 agents, one industrial process, and several physical agents There was no attempt to group structurally related chemical compounds.
- The methods used to generate some data could be improved, e g , the "Delphi" method used to generate severity rankings for the 1973 list While subjective opinions are sometimes necessary, they should be avoided whenever objective data are available.
- Greater involvement of affected groups, including industry, unions, and other government agencies, was needed Such involvement, assuming it came from experienced sources, would provide a broader consideration of the need to develop new or revised standards and would help to ensure that NIOSH priorities reflected priorities of other knowledgeable groups and affected parties
- There was a need for better cooperation between OSHA and NIOSH in the preparation of priority lists.
- A formalized process with a schedule of events was not used for priority assessment, which in turn did not allow for efficient, orderly planning of research or allocation of funds for that research.
- Priorities for criteria documents were not identified far enough in advance to allow the NIOSH research and grants program to identify significant research activities, the successful accomplishment of which would result in better recommended standards
- Toxicity ratings did not place enough emphasis on chronic or delayed aspects of hazardous agents and, consequently, did not reflect the best estimate of the need for a standard based on potential harm to workers.

The Current Situation

Based on the above, NIOSH decided in 1976 that if a new approach to setting priorities was to work, the problems of past priority systems would have to be thoroughly evaluated and future problems anticipated and resolved as early as possible Assessment of chemical priorities would have to be undertaken with consideration of at least three new and important factors

First, industry is using more and more compounds which are unevaluated as to toxic potential Hopefully the implementation by EPA of the Toxic Substances Control Act will have some impact on the availability of information for substances in use as well as new ones However, it will take many years to develop the necessary information to adequately evaluate the potential hazard of the thousands of chemicals now in use

Second, the hazardous properties of most compounds for which there are large populations at risk (greater than 100,000 workers) have been documented by NIOSH Future work involves updating these documents with new information and where necessary revising the recommendations through a separate effort Many of the chemicals NIOSH must now consider are specialty chemicals involving relatively small numbers of exposed current

Third population at risk estimates are not available for all commercial chemicals and where estimates are available, they are difficult to keep current

To address these problems, NIOSH has determined that criteria documents and recommended standards should be prepared for classes of toxicologically and structurally related compounds, and for processes, occupations, or specific industries Also, a new document, the Special or Emergency Occupational Hazard Review will be prepared when the population at risk factor is not large enough to warrant a criteria document, or when a response in a shorter time period is required These new documents will emphasize methods of controlling exposure rather than environmental (workplace air) limits

These new initiatives will accomplish several important goals Preparation of criteria documents on chemical classes will increase the population at risk covered by the recommended standard and result in a more efficient use of NIOSH resources By preparing recommended standards for specific industries processes, and occupations, the health and safety of those workers will be more efficiently protected, and standards will be made less burdensome than if several recommended standards were written for only a percentage of the hazardous agents in a particular industry Coverage of an entire industry will alleviate some compliance problems—both for industry and OSHA Preparation of Special or Emergency Occupational Hazard Reviews concentrating on work practices will alert employers and employees more rapidly to newly discovered hazards of chemicals being used or produced in the workplace.

The current NIOSH priorities program involves a multistep process which includes the use of several data sources and input from various groups Criteria document subjects are selected three to four years in advance of their preparation so that the planning and conduct of laboratory research can occur This is especially important if delayed toxicity or epidemiologic studies are needed Consequently, during 1979, subjects for criteria documents to be completed in 1983 will be selected and it is anticipated that this approximate four-year lead time will be maintained

Figure 1 illustrates the procedures and steps followed in setting priorities for a given year Nominations from numerous sources are solicited Information profiles which contain data relating to exposure, toxicity, production, previous regulation process engineering, chemical use and other items deemed necessary for establishing priorities are then developed (see Table 1) Comments are requested via notice in the *Federal Register* and special letters to interested groups

TABLE 1—Selection Criteria and Information Reported in Profiles

Occupational Exposure Patterns Number workers exposed, Duration of exposure, Level of exposure, Exposure to multiple hazards
Chemical/Physical Properties Physical state, Form, volatility, stability Reactivity, Structural similarity to known hazards
Biological Effects Chronic toxicity, Acute toxicity, Metabolism and fate in body, Organ system(s) involved
Production/Use Trends Extent of production, Method of use, Probability of continued or expanded use
Need for a New or Revised Exposure Standard

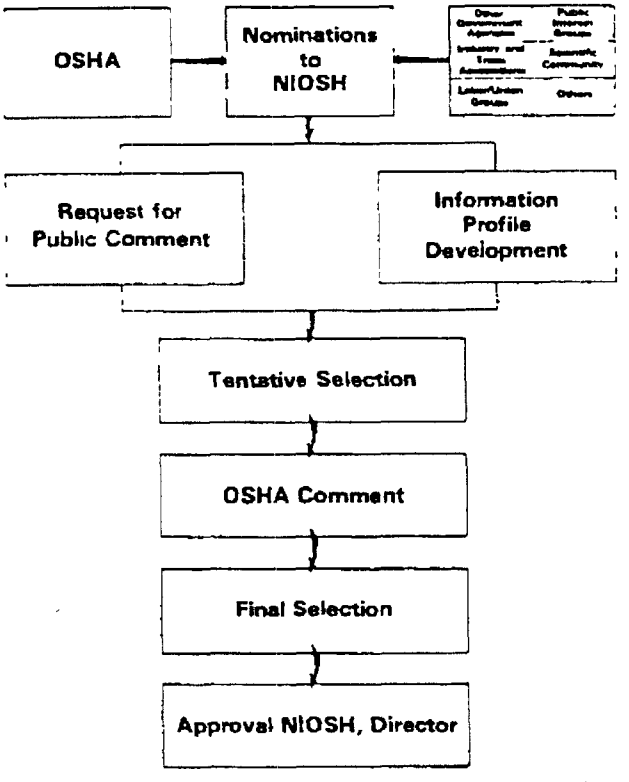

FIGURE 1—Procedures to Select and Priority Rank Subjects for Criteria Document Development

Many useful suggestions including additional subjects for consideration, are usually obtained from this solicitation effort, especially from other government agencies

After consultation with OSHA, NIOSH then selects 24 criteria document subjects which include classes of chemicals, individual chemicals and physical agents processes, industries, and occupations The task of selecting a process, industry, or occupation is considerably more complex than that associated with a single chemical or even a class of chemicals The primary issues are possible complexities of exposure to multiple hazards and clear identification of the intended scope of the criteria document Examples of process standards are the recently promulgated OSHA standard on coke ovens and the current OSHA/NIOSH joint effort for the manufacture and formulation of pesticides

Summary

Setting priorities is a difficult task, requiring good information coupled with astute scientific judgment The most important factors to be considered are occupational exposure patterns and biological effects of exposure NIOSH has prepared and recommended to OSHA more than 100 occupational health standards covering more than 200 substances including 1500 registered pesticides[1] Of the 20 to 24 recommended standards to be prepared each year in the future, an approximately even distribution for chemical classes, individual chemical or physical agents, and occupations or industries is anticipated Priorities for fiscal year (FY) 1983 are currently being developed NIOSH expects to continuously improve its priority program in order to keep abreast of the rapid changes in the problems facing the American worker

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[1]Summary listing of recommendations including plans for future documents is available from NIOSH (DCDSD), Room 8A-53, 5600 Fishers Lane, Rockville MD 20857

APPENDIX TABLE 1—Criteria Documents and Recommended Standards Transmitted to the U.S. Department of Labor

Document Name

Acetylene
Acrylamide
Acrylonitrile (Emergency Hazard Review)
Aldrin/Dieldrin (Special Occupational Hazard Review)
Alkanes
Allyl Cloride
Ammonia
Anesthetic Gases
Antimony
Arsenic
Arsenic (revised)
Asbestos
Asbestos (revised)
Asphalt Fumes
Benzene
Benzene (revised)
Benzoyl Peroxide
Benzyl Chloride
Beryllium
Boron Trifluoride
Cadmium
Carbaryl
Carbon Black
Carbon Dioxide
Carbon Disulfide
Carbon Monoxide
Carbon Tetrachloride
Carbon Tetrachloride (revised)
Chlorine
Chloroform
Chloroform (revised)
Chloroprene
Chromic Acid
Chromium VI
Chrysene (Special Occupational Hazard Review)
Coal Gasification
Coal Tar Products
Coke Oven Emissions
Cotton Dust
Cresol and Cresylic Acid
Decomposition Products of Fluorocarbon Polymers
Dibromochloropropane (Emergency Hazard Review)
Dinitro-o-cresol
Diisocyanates
Dioxane
DDT (Special Occupational Hazard Review)
Epichlorohydrin
Ethylene Dibromide
Ethylene Dichloride
Ethylene Oxide (Special Occupational Hazard Review)
Fibrous Glass
Fluorides
Formaldehyde
Glycidyl Ethers
Hazardous Materials
Hot Environments
Hydrazines
Hydrogen Fluoride
Hydrogen Sulfide
Hydroquinone
Inorganic Cyanides
Inorganic Lead
Inorganic Lead (revised)
Inorganic Mercury
Inorganic Nickel
Isopropyl Alcohol
Kepone (Emergency Hazard Review)
Ketones
Logging
Malathion
Methyl Alcohol
4,4'-Methylenebis (2-chloroaniline) (Special Occupational Hazard Review)
Methyl Parathion
Methylene Chloride
n-Alkane Mono Thiols, Cyclohexanethiol, and Benzenethiol
Nickel Carbonyl (Special Occupational Hazard Review)
Nitric Acid
Nitriles
Nitroglycerine and EGD
Noise
Organo-isocyanates
Organotin Compounds
o-Tolidine
Oxides of Nitrogen
Parathion
Pesticides Manufacture and Formulation of
Phenol
Phosgene
Polychlorinated Biphenyls
Refined Petroleum Solvents
Silica
Sodium Hydroxide
Sulfur Dioxide
Sulfuric Acid
1,1 2,2-Tetrachloroethane
Tetrachloroethylene
Toluene
Toluene Diisocyanate
1,1,1-Trichloroethane
Trichloroethylene
Trichloroethylene (Special Occupational Hazard Review)
Tungsten Compounds
Ultraviolet Radiation
Vanadium Compounds
Vinyl Acetate
Vinyl Chloride (Emergency Hazard Review)
Vinyl Halides
Xylene
Zinc Oxide

APPENDIX TABLE 2—Criteria Documents and Recommended Standards to be Transmitted to the U.S. Department of Labor

FY 1979 Document Name	FY 1980 Document Name	FY 1981 Document Name	FY 1982 Document Name
Aliphatic Primary Monoamines	Aliphatic di and polyamines	Alkanolamines	Aliphatic Amines
Brominated Aromatics	Aromatic amines	Aluminum Compounds	Aluminum Reduction
Chlorinated Benzenes	Brominated aliphatics	Caisson and Tunnel Workers	Bisphenol A
Coal Liquefaction	Dichloropropane	Cement Manufacturing and Use	Copper and its Inorganic Compounds
Cobalt Compounds	Diesel Emissions	Chlorophenols	Dimethyl Sulfoxide
Fluorocarbons	Dyeing and Finishing Textiles	Epoxides	Electroplating
Foundries	Hexachlorobutadiene	Glycol Ethers	Ethyl Benzene
Furfuryl Alcohol	Hexachloroethane	Glycols	Ethoxyethanol
Methyl Chloride	Infrared Radiation	Grain Handlers	Explosives and Fireworks Manufacture
Nitrobenzenes	Manufacture of Non-metallic Pigments and Dyes	Hexachlorocyclopentadiene	Lithium and Compounds
Nitrotoluenes	Monochloracetic Acid	Inorganic Azides	Mercaptobenzothiazoles
Oil Mists	Monochloroethane	Inorganic Chromium (non-hexavalent)	Nitroparaffins
Oxalic Acid	Pentachloroethane	Iron Compounds	Petroleum Refineries
Paint and Allied Products Manufacturing	Pulp and Paper Mills	Manganese Compounds	Photographic Processing
Plastics and Resins Manufacturing	Secondary aliphatic monoamines	Methyl Ethyl Ketone Peroxide	Platinum and Compounds
Printing Industry	Tertiary aliphatic monoamines	Naphthalene	Selenium
Radiofrequency and Microwave Radiation	Tetrahydrofuran	Nitrophenols	Solder (Manufacture and Use)
Roofing Industry	Trichloropropane	Organic Anhydrides	Spray Painting/Coating
Slaughtering and Rendering Plants	Ultrasonics	Organophosphosphorus compounds (excluding pesticides and fire-retardants)	Tellurium
Styrene	Vibration, whole body	Phthalates	Thioureas
Synthetic Rubber Manufacturing	Wood Preserving	Tire Manufacturing	Titanium and Compounds
Talc		Vinyl Cyclohexene Dioxide	Trimethyl benzenes
Welding and Brazing			Vinyl Toluene
Wood Dust			Xylenols