DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Hazard Communication

AGENCY: Occupational Safety and Health Administation (OSHA), Labor.

ACTION: Final rule.

SUMMARY: OSHA is hereby promulgatiing a final occupational safety and health standard entitled "Hazard Communication" (29 CFR 1910.1200). The standard requires chemical manufacturers and importers to assess the hazards of chemicals which they produce or import, and all employers having workplaces in the manufacturing division, Standard Industrial Classification (SIC) codes 20 through 39, to provide information to their employees concerning hazardous chemicals by means of hazard communication programs including labels, material safety data sheets, training, and access to written records. In addition, distributors of hazardous chemicals are required to ensure that containers they distribute are properly labeled, and that a material safety data sheet is provided to their customers in the manufacturing division SIC Codes.

Implementation of this final standard will reduce the incidence of chemically-related occupational illnesses and injuries in employees of the manufacturing division. Increased availability of hazard information will assist employers in these industries to devise appropriate protective measures, and will give employees the information they need to take steps to protect themselves.

The twenty-four states with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of this publication date. These states are: Alaska, Arizona, California, Connecticut (for state and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as a state standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these states.

EFFECTIVE DATES: Chemical manufacturers and importers are required to label containers they ship and provide required material safety data sheets by November 25, 1985. Distributors are required to be in compliance by November 25, 1985. All employers covered by the standard are to be in compliance by May 25, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, U.S. Department of Labor, Occupational Safety and Health Administration, Room N3641, 200 Constitution Avenue, N.W., Washington, D.C. 20210; telephone (202) 523–8151. Copies of this document may be obtained from the Office of Public Affairs at this address and telephone number, or by contacting any OSHA regional or area Office.

SUPPLEMENTARY INFORMATION: The recordkeeping requirements in the standard have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980, Pub. L. 96–511, 44 U.S.C. 3501, *et seq.* The OMB approval number is 1218–0072.

I. Introduction.

A. The Format of This Document (the Preamble)

The preamble accompanying this final standard is divided into five parts, numbered I through V. The following is a table of contents:

Part II provides a detailed analysis of public input on the proposed standard and related issues. Part IV is a provision-by-provision discussion of the final standard, including a brief summary of each requirement and the rationale supporting it. References to the rulemaking record are in the text of the preamble, and the following abbreviations have been used:

1. Ex.: Exhibit number in Docket H–022.
2. Tr.: Transcript page number.

B. History of the Proceedings

1. *The development of the proposal.* OSHA's involvement in the issue of identification and communication of hazards in the workplace began nine years ago. In 1974, the Standards Advisory Committee on Hazardous Materials Labeling was established under Section 7(b) of the OSH Act to develop guidelines for the implementation of Section 6(b)(7) of the Act with respect to hazardous materials (Ex. 16–1). On June 6, 1975, the Committee submitted its final report which identified issues and recommended guidelines for categorizing and ranking chemical hazards (Ex. 16–2). Labels, material safety data sheets, and training programs were also recommended.

The National Institute for Occupational Safety and Health (NIOSH) published a criteria document in 1974 which recommended a standard to OSHA (Ex. 16–3). The document, entitled "A Recommended Standard * * * An Identification System for Occupationally Hazardous Materials," included provisions for labels and material safety data sheets.

On January 28, 1977, OSHA published an advance notice of proposed rulemaking on chemical labeling in the **Federal Register** (42 FR 5372). The notice requested comments from the public regarding the need for a standard that would require employers to label hazardous materials. Information was also requested regarding the provisions to be included in such a standard to assure that employees are apprised of the hazards to which they are exposed. A total of eighty-one comments were received from a variety of federal, state, and local government agencies, trade associations, businesses, and labor organizations (Ex. 2B). In general, there was support for the concept of a hazard communication standard.

On January 16, 1981, OSHA published a notice of proposed rulemaking (NPRM) entitled "Hazards Identification" (46 FR 4412). The NPRM would have required employers to assess the hazards in their workplaces using specified determination procedures. Labels including extensive information about these hazards would have been required on all containers within the workplace (including pipes), as well as on containers leaving the workplace.

OSHA withdrew the NPRM on February 12, 1981 for further consideration of regulatory alternatives (46 FR 12214).

2. *The proposal.* On March 19, 1982, OSHA published the NPRM that was the subject of this rulemaking proceeding (47 FR 12092). The notice established a sixty day period, which ended on May 18, 1982 for submission of written comments and filing of notices of intent to appear at the public hearings. The

deadline for submission of written statements and other documentary evidence to be presented during the hearings was set as June 1, 1982.

The proposed standard required chemical manufacturers to assess the hazards of all chemicals which they produce, and all employers in SIC Codes 20 through 39 to establish hazard communication programs for their employees. This communication was to be accomplished by labeling in-plant and downstream containers, through the availability of material safety data sheets, and by employee training.

The proposed standard represented OSHA's determination that rulemaking was necessary because many employers and employees in the manufacturing division are not aware of the presence of hazardous chemicals in their workplaces. This lack of knowledge increases the risk of occupationally-related chemical source illnesses and injuries, since appropriate protective measures can only be designed and implemented when the presence of a hazard is known.

3. *Response to the proposal.* OSHA received 221 written comments on the NPRM prior to the public hearing, as well as a number of late comments after the hearing began. All written evidence concerning the NPRM was entered into Docket H–022, which was established for this rulemaking proceeding.

Public hearings were conducted under OSHA's procedural regulations for rulemaking (29 CFR Part 1911). They were presided over by Administrative Law Judge Stuart A. Levin, and all participants were given the opportunity to present oral testimony and to question other witnesses. The hearings were held from June 15–24, 1982, in Washington, D.C.; July 13–14, 1982, in Houston, Texas; July 20–23, 1982, in Los Angeles, California; and July 27–31, 1982, in Detroit, Michigan. A total of 4,253 pages of transcript was generated during these nineteen days of oral testimony.

The hearing participants were permitted to submit additional information to the record until September 1, 1982. The period for submission of post-hearing comments and briefs was originally scheduled to end on October 15, 1982, but Judge Levin extended the date to November 1, 1982, in response to a request from participants (Ex. 173). Sixty-two (62) exhibits were received after the close of the hearing.

4. *The record.* The public record for the proposed rule was certified by Judge Levin on November 10, 1982. The record consists of all material submitted to the OSHA Docket Office, Docket No H–022, by either OSHA or the public, including:

(a) Comments submitted in response to the ANPR (42 FR 5372);

(b) Comments submitted in response to the NPRM (47 FR 12092);

(c) Background materials collected by OSHA;

(d) The draft regulatory impact and regulatory flexibility analysis (Ex. 17);

(e) Notices of intent to appear at the public hearings;

(f) Pre-hearing submissions of testimony and evidence;

(g) Verbatim transcripts of the public hearings;

(h) Hearing exhibits; and

(i) Post-hearing submissions.

The views of a wide range of employees, businesses, labor unions, trade associations, public interest groups, as well as state and local governments and other interested parties, are represented in the public record.

Copies of the official list of entries in the record, as well as the exhibits themselves, are available from the OSHA Docket Office, Docket No. H–022, Room S–6212, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C., 20210; telephone (202) 523–7894.

II. Overview of the Final Standard and Summary of Major Issues.

A. Overview and Purpose of the Final Standard

Although the need for apprising workers of the hazards of the chemicals they work with has long been recognized by pational safety and health professionals, as well as other representatives of industry, labor, academia, and the government, the difficulties encountered in attempting to define hazards and determine the appropriate means of communication have long delayed implementation of a systematic approach. In the interim, voluntary systems of various types have been designed and instituted in some segments of industry. Some of these systems are quite comprehensive and effective, while others incorporate a cursory approach to the problem.

The purpose of this standard is to establish uniform requirements for hazard communication in one segment of industry, the manufacturing division. Under the provisions of this final standard, each employee in the manufacturing industries who is exposed to hazardous chemicals will receive information about them through a comprehensive hazard communication program. Chemical manufacturers and importers will be required to evaluate the hazards of the chemicals they produce or import, and to transmit this information to downstream employers by means of labels on containers and material safety data sheets. In addition, all covered employers will be required to provide the information to their employees by means of labels on containers, material safety data sheets, and training.

The standard is designed to ensure that all employers receive the information they need to inform their employees properly, and to design and implement employee protection programs. In addition, it will provide necessary hazard information to employees, so that they can meaningfully participate in, and support, the protective measures instituted in their workplaces. The result of this hazard communication program will be to reduce the incidence of chemical source illnesses and injuries in the manufacturing division. In addition, once the information about these chemicals has been generated by the producers, this standard establishes the framework for future regulation, if necessary, to similarly cover other user industries where workers are also exposed to hazardous chemicals.

In the following discussions, we have summarized the major isues raised by participants during this rulemaking proceeding in response to provisions in the proposed standard. The positions of the various participants have been presented as well. In addition, we have indicated which arguments and evidence we have found to be persuasive, and what changes we have thus made to the proposed provisions in preparing the final standard.

The record for this rulemaking is extensive, and OSHA appreciates the time and effort expended by interested parties to ensure that as much information as possible was available to the Agency for purposes of making decisions on the final standard. In analyzing the record and preparing this final document, OSHA has carefully weighed all of the alternatives presented, and attempted to balance the concerns of all parties in the final provisions. Many of the decisions to be made were of a policy, rather than technical, nature. Unlike other rulemakings where scientific studies form the bases for much of the decisionmaking, this rulemaking is primarily based on the actual experience and policy recommendations presented by participants in the proceedings. OSHA's primary intent in promulgating this final standard is to ensure that employees will receive as much information as needed concerning the hazards in their workplaces, and

that this information will be presented to them in a usable, readily accessible form. The Agency's secondary intent is to write the standard in such a way that those companies who have voluntarily instituted effective programs of hazard communication for their employees may continue to use them without substantial modification. The latter goal is accomplished by presenting the provisions of the final standard in performance language wherever possible.

B. Need and Support for the Standard

Although the lack of adequate hazard information in the manufacturing industries has long been recognized, objective data quantifying the extent of the problem are not generally available.

In the NPRM, OSHA presented the findings of the National Occupational Hazards Survey (NOHS) conducted by the National Institute for Occupational Safety and Health (NIOSH) as being indicative of the broad scope of the problems addressed by the proposed standard (47 FR 12093–4). The Agency noted at the time that it was aware that criticisms have been levied by various parties concerning the conclusions and extrapolations of the NOHS. In particular, the fact that the data were collected ten years ago and may be outdated now concerns some parties. However, the NOHS remains the only comprehensive study which indicates the extent of chemical exposures in industry.

According to the NOHS data, approximately 25 million American workers, or one in four, are potentially exposed to one or more of the nearly 8,000 hazards identified by NIOSH (Exs. 16–4, 16–5, 16–6, and 16–7). As many as 40 to 50 million Americans (23 percent of the entire U.S. population) may have been exposed at some point during their lifetimes to one or more of the hazardous chemicals presently regulated by OSHA. Thus it can be concluded that chemical exposures in the occupational setting, and particularly in manufacturing, are frequent, and the need for adequate information to be given to exposed employees is critical.

Several participants in the rulemaking stated that the NOHS data should not be used to substantiate the need for the standard, due to the limitations described above (Exs. 19–44, 19–76, 19–91, and 19–147). For example, the Chemical Specialties Manufacturers Association (Ex. 19–76) stated:

> The National Occupational Hazards Survey (NOHS) data upon which OSHA relies to document the need for and calculate the benefits of this standard are not currently relevant if they ever were. It is erroneous to assume that conditions in the workplace ten years ago are still present, given the changes in chemicals used, developments in engineering controls, and advances in hazard communication practices. For example, material safety data sheets (MSDS's) did not come into use until 1970, and NOHS's failure to find them in widespread use in a survey published in 1972 is not surprising.

OSHA used the NOHS data to indicate the broad scope of chemical exposures in general, including the number of chemical products and the associated numbers of exposures involved. NOHS testified regarding the validity of using the NOHS data for this purpose (Tr. 185):

> NIOSH feels that despite the dating on the survey that it is really the only national source of information on this particular type and that it has held up well and does provide useful information if one realizes the—how the data was gathered and what the size of the data base and so forth.
>
> We feel there's no other source of data that is available that would really contradict that nor could replace that in any way.

NIOSH is in the process of doing a second study regarding the extent of hazardous exposures. Their experiences in conducting health hazard evaluations and research projects in the years since the original NOHS was undertaken have provided confirming evidence that the data collected in the survey were valid and useful (Tr. 184–6). Since no alternative sources of comparable data to indicate the magnitude of chemical exposures in the occupational setting exist, OSHA's use of NOHS is necessary and appropriate, and substantiates the need for a standard to ensure information is presented to employees in the manufacturing sector who are exposed to such chemicals.

In the NPRM, OSHA also cited statistics compiled by the Bureau of Labor Statistics concerning the occurrence of occupational illnesses resulting from workplace exposures to hazardous chemicals as an indication of the need for hazard communication (47 FR 12094). OSHA's analysis of the illness statistics for 1977 and 1978, indicated that a total of more than 174,000 illnesses were reported in those two years which were most likely caused by chemical exposures. OSHA concluded that implementation of appropriate hazard communication in these workplaces would serve to decrease the number of such incidents by providing employees with the information they need to help protect themselves, and ensure that their employers are providing them with the proper protection.

In addition to these types of objective data, OSHA also cited testimony presented by workers and health professionals during rulemaking hearings and in testimony before Congress as evidence of the need for a standard. The Agency also described a number of existing documents, including OSHA regulations, a NIOSH criteria document, voluntary consensus standards, and several Congressional reports as further indication of general recognition of this need (Exs. 16–10, 16–11, 16–12, and 16–13).

The record developed during this rulemaking overwhelmingly substantiated OSHA's conclusion that there is a critical need for a standard to ensure disclosure of hazard information to employees in the manufacturing sector. This substantiation was received from all segments of those interested in, or potentially affected by, this rulemaking. For example, the following statement was submitted by the American Petroleum Institute (Ex. 181):

> The goal of effective hazard communication can only be approached where responsible employers and responsive employees work together in developing and implementing an integrated hazard communication program. This proposed rule would require the identification and evaluation of intrinsic chemical hazards and the preparation and availability of MSDS's for hazardous substances in the workplace and, perhaps most importantly, employee training regarding chemical hazards. These and other elements of individual workplace hazard communication programs should ensure significantly improved occupational safety from chemical hazards.

This support of the need for a standard to establish comprehensive hazard communication programs in the manufacturing industries was also expressed by other industry representatives, both individual companies and trade associations. For example:

> If implemented, this standard should do more to educate the worker about potential workplace hazards than any other standard since OSHA's inception. Educated employees make safer employees.
>
> (Kaiser Aluminum and Chemical Corporation, Ex. 19–196)

> The communication of hazards which surround employees is a basic and elementary component of any successful workplace. As such, the hazard communication process is not only necessary for the prevention of many avoidable injuries and illnesses, but moreover, a cornerstone to such effort.
>
> (National Association of Manufacturers, Ex. 179)

> As a concerned and responsible employer and producer of chemicals, we desire that our own employees and those of our customers be provided with accurate information on the hazards of the chemicals they handle and are

instructed in proper work practices to minimize the risk from those hazards. We thus support OSHA's intention to develop a sound standard to support those aims.

(Celanese Corporation, Ex. 19–185)

Workers in this country are exposed to hazardous chemicals every day. The effective communication of potential hazards can help reduce the national incidence of occupational injuries and illnesses.

(Gulf Oil Chemicals Company, Ex. 19–96)

Ignorance of workplace hazards can subject employees to unacceptable risks.

(Shell Oil Company, Ex. 19–124)

The comments and the hearings have confirmed the need for an effective federal standard requiring employers to identify workplace hazards, communicate hazard information to employees, and train employees in recognizing and avoiding those hazards. The testimony of employers, employees, unions and public health officials has uniformly supported the appropriateness of a rule directed toward these ends. There has been no serious dispute of the proposition that well-structured programs for informing employees of the hazards of the workplace are beneficial and cost-effective.

(Chemical Manufacturers Association, Ex. 182)

Representatives from academia and other professionals were also supportive of the need for a federal hazard communication standard:

The proposed Hazard Communication standard is a considerable advance over present practice, and should be of great assistance in protection of workers from hazardous chemicals.

(Howard E. Ayer, University of Cincinnati Medical Center, Ex. 19–5)

The American Chemical Society recognizes the need for hazard communication and supports the concept of uniform federal guidance on hazard communication. OSHA's proposed rule (47 FR March 19, 1982) generally reflects a more realistic approach than the previous version proposed in January 1981. While the current proposal can and should be further modified, the document represents a positive contribution for which we commend OSHA.

(American Chemical Society, Ex. 19–206)

Most of the patients whom I see have not been informed of the identity or toxic nature of the materials with which they work. Some know a trade name or chemical generic name, but their knowledge ends there. They rarely have sufficient information about the material with which they work to understand the actual or potential toxicity of the chemical and to take steps to protect themselves from the effects of the material * * * (Tr. 96–7).

At the present moment, most activity on hazard communication is voluntary and subject to no standard and little regulation. Some forward-looking manufacturers and employers aware of their own use of toxic materials have developed programs which are similar to those which will be required by the proposed standard.

The proposed standard will encourage these manufacturers and employers to forge ahead with their programs. Some less forward-looking companies have been pushed into developing hazard communication programs by decisions in worker's compensation hearings, tort courts, or OSH hearings.

On the other hand, most manufacturers have done little or no work in this area. For them the standard will provide an appropriate impetus to implement toxic materials health and safety hazard communication programs * * *

(Dr. Daniel Teitelbaum, Tr. 109)

Representatives of various government entities were also vocal in their support of the need for a standard in the area of hazard communication:

My concern today is for the future and for the necessity to assure that workers have the right to know what substances they are exposed to in the workplace. If we fail to promulgate an effective hazards communication programs standard, we will assure ourselves that in the future we will continue to be puzzled and unable to determine why workers are becoming ill or dying from exposures to unkown chemicals in the workplace * * *

(Michigan Department of Labor, Ex. 114)

The Department of Defense strongly supports the intent of the proposed standard published in the **Federal Register** on March 19, 1982, to help ensure that personnel are aware of potential workplace chemical hazards and adequately protected therefrom * * *

(Department of Defense, Ex. 19–148)

Most importantly, workers and their representatives reaffirmed their need for a standard to obtain information about the hazards they are exposed to:

What we have been seeing time after time through all the work we do, is that workers simply do not know what kinds of materials they are exposed to on the job * * *

Without more comprehensive, enforceable legislation, workers can't help themselves or use our technical resources if they are in a position where they can walk into a COSH library and not even tell us what to look up or look up for themselves because they don't know what they are exposed to.

(Joan Parker, New York State Council on Occupational Safety and Health, Tr. 3454)

We feel now, testifying for a strong national right-to-know standard as we did for our state's right-to-know law, that the key to identifying and correcting health and safety hazards in the workplace lies with the workers' participation. Workers have an intimate knowledge of the conditions of work, how work is done, and what changes have been made over the years, and how conditions in the workplace affect them.

Armed with the knowledge obtained from the right-to-know legislation, workers will be made aware of acute and chronic symptoms of exposure to the toxic substances they work with, and therefore can be alerted, and enough in advance, before any serious harm can be done. Workers have a day-to-day contact with the process of production that allows for an in-depth analysis of where the problems lie. And, most importantly, with this right-to-know and increased awareness, the workers can effectively assist management and, if needed, pressure management to make necessary changes that effect their well-being.

(James Valenti, Local 12457, United Steelworkers of America, Tr. 3792–3)

I strongly feel that there is a necessity to initiate a program whereby the company will eliminate the practice of purchasing chemicals and putting them into use prior to obtaining the knowledge that can be found in the material safety data sheets.

To summarize, I'd like to add one final note. I strongly feel that the company should institute a program of chemical awareness, whereby they will personally inform the employees of: (1) The exact chemicals in use; (2) the health hazards involved in them; (3) the precautions that you take when handling them.

(James Centner, Local 2693, United Steelworkers of America, Tr. 3805)

Additional examples of statements supporting the need for a federal standard on hazard communication may be found in the record in the following exhibits: 19 (1, 2, 3, 4, 5, 6, 7, 8, 11, 14, 23, 27, 40, 43, 44, 46, 48, 50, 51, 54, 55, 57, 59, 61, 62, 64, 65, 66, 67, 69, 74, 77, 79, 82, 83, 85, 86, 88, 89, 90, 91, 92, 94, 96, 109, 111, 115, 116, 119, 122, 124, 125, 126, 131, 135, 140, 145, 146, 147, 148, 154, 156, 158, 164, 169, 170, 174, 180, 185, 193, 194, 196, 201, 204, 206, 207, 209, 210, 211, 214, 215, 217, A–6, A–9); 28; 31; 34; 35; 36; 42; 47; 48; 53; 59; 63; 64; 65; 66; 83; 161; 167; 174; 179; 180; 181; 182.

Based on this evidence, OSHA has concluded that a hazard communication standard is necessary to reduce significantly the risk of chemically-related disease which results from the current state of hazard communication practices.

Another reason many participants in the rulemaking support the need for a Federal standard is the recent proliferation of state and local right-to-know laws. Most companies in the manufacturing sector have business dealings which involve interstate commerce, and are thus subject to numerous different and potentially conflicting regulations.

For example, the National Paint and Coatings Association addressed the issue of state and local standards in their written comments as follows (Ex. 19–62):

It is NPCA's belief that a Federal OSHA Standard, rather than a variety of differing State and local requirements, best serves the interests of the private sector, labor interests, the general public and the Agency itself. While we recognize statutory limitations in

this area, we believe every effort should be made to see that such a Federal standard preempts State and local efforts.

Without a strong Federal role, individual States will enact a variety of diverse labeling rules that would hamper interstate business operations and impede worker protection. Indeed, manufacturers in interstate commerce are faced with the threat of 50 different chemical hazard warning systems mandating conflicting, overlapping, and duplicative requirements for hazard warnings * * *

Similar concerns were expressed by many of the other participants in the rulemaking (see, for example, Exs. 19–46, 19–51, 19–57, 19–91, 19–150, 136, 174, 181, and 182).

Approximately twelve states and six local governments have some type of regulation related to the identification of hazardous substances. About thirteen other states and three other local governments have introduced proposed legislation either in this legislative session or in previous sessions. They cover different lists of substances, have different reporting requirements, serve different purposes, have different labeling and material safety data sheet requirements, and have different educational and training requirements.

In discussing the enforcement of such standards in a State with relatively comprehensive regulations, Joan Parker, representing the New York State Council on Occupational Safety and Health, stated regarding the New York State Law that "* * * although the intent is admirable the problem is that there is no enforcement" (Tr. 3473). She further stated that her experience with the State Right-to-Know law indicated the need to complement this law with a strong Federal standard.

The potential for conflicting or cumulatively burdensome State and local laws has been acknowledged by industry representatives to be immense. As stated above, this subject was cited in many comments submitted prior to the hearing, in presentations made during the hearings, and in post-hearing comments.

By promulgating a Federal standard, OSHA is in a position to reduce the regulatory burden posed by multiple State laws. In the final standard, OSHA preempts State laws which deal with hazard communication requirements for employees in the manufacturing sector, except in those States with a State plan which have a standard that regulates in this area. In order to regulate with respect to hazard communication for employees in the manufacturing sector, a State will have to submit their intended requirements to OSHA for approval under section 18(b) of the Act which deals with State plans, show that they are at least as effective as the Federal standard, and that there is a compelling need for a separate standard. The Legal Authority Section of the preamble addresses the preemption issue in more detail.

OSHA realizes that the rationale favoring a single Federal standard in place of various State standards for chemicals in interstate commerce applies as well to the concept of agreed international standards for substances in international commerce. Accordingly, these regulations will be reviewed on a regular basis with regard to similar requirements which may be evolving in the United States and in foreign countries.

Although the vast majority of the participants in the proceeding explicitly supported the need for a Federal hazard communication standard, there were a few parties who did not agree that OSHA should issue such a rule (Exs. 19–87, 19–162, 19–181, 19–195, 19–200, 19A–19, and 105). For example, Master Chemical Corporation testified as follows during the Detroit session of the public hearing (Tr. 3916–17):

* * * Master Chemical rejects the need for any such rule that is being proposed. Granted, there is an artificially created need, a politically expedient need, but there is no real need in terms of protecting workers.

Master Chemical says this because we also reject the idea that the free market system has failed in providing hazard information to users of industrial chemicals.

During the past two years, there has been a steady increase in the demand for this type of information from our customers. Master Chemical has responded to this demand and our suppliers have acceded to our demands for this information, or they would have ceased to be our suppliers.

This regulation takes away from those companies that are socially responsible, which we believe to be by far the majority of business, the competitive advantage that they have worked for and earned by responding to the demands of the market.

The better the response, the better the competitive advantage.

This regulation interferes with the natural preferences of the market place, thereby interfering with the weeding out of those companies that refuse to comply with its demands.

While OSHA respects Master Chemical's philosophy regarding hazard communication, the weight of the evidence submitted by other participants in this rulemaking proceeding unfortunately does not appear to support their assertion that market responses will ensure adequate hazard information by rewarding those companies which provide the most complete information. Although their firm has undertaken toxicity testing, trains their employees, and provides detailed labels and information sheets to their customers (Ex. 105), many of the firms that will be covered by this standard do much less. For example, the Aerospace Industries of America, Inc. stated the following on their experiencs in obtaining hazard information (Ex. 19–212):

As users of large volumes of industrial chemicals and specialty chemicals, our member companies have experienced the inefficiency and burden of trying to obtain hazard information under a voluntary standard. The new standard should correct past inefficiencies by guaranteeing that chemical users will receive the information they require in a timely and routine manner.

OSHA agrees with the majority of the participants in the rulemaking that the need for a Federal standard has been amply demonstrated. Companies like Master Chemical will nonetheless benefit from their prior diligence through vastly reduced costs of complying with this standard.

C. Issues Raised by Provisions of the Proposed Standard

The following discussion will summarize the technical and policy issues raised by the proposed standard, and the evidence in the record concerning these issues:

1. *Scope and application*—a. *Industries Covered.* The proposed standard applied to the manufacturing division of the Standard Industrial Classification (SIC) Codes, 20 through 39. Although hazardous chemicals are used in other industries as well, OSHA determined that the employees in the manufacturing sector are at the greatest risk of experiencing health effects from exposure to hazardous chemicals. The Agency thus decided to exercise its authority to set priorities for standards promulgation under Section 6(g) of the Act, and limited the proposed standard's scope to the manufacturing sector.

This decision was based primarily on an Agency analysis of occupational injury and illness statistics compiled annually by the Bureau of Labor Statistics (BLS) (47 FR 12094; Exs. 16–8, 16–36, 16–37, and 17). Since the purpose of the proposed standard was ultimately to decrease the number of occupational injuries and illnesses caused by exposure to chemicals, OSHA decided to ascertain where these types of effects are occurring. Recognizing that the BLS figures, although substantial, probably only reflect a small percentage of the incidents actually occurring in exposed employees, the statistics nonetheless reveal patterns of occurrences in the various industries for which they are compiled. (The regulatory analysis for

the proposal (Ex. 17) provided a detailed discussion of the underreporting of occupational illnesses.) Table 1 indicates the industry distribution of chemical source injuries and illnesses found in the Supplementary Data System for 1976 and 1977, Subfile of Chemical Injuries and Illnesses (Ex. 16–27). As can be seen from this table, nearly half of all reported chemical source injuries and illnesses occurred in the manufacturing sector. It should be noted that it is not appropriate to compare combined injury and illness incidence rates, regardless of the cause, to assess industry effects, since this standard only deals with chemical exposures. Such aggregate rates include, for example, construction accidents and back injuries which are unrelated to chemicals and thus would not be affected by chemical hazard communication.

TABLE 1.—DISTRIBUTION OF CHEMICAL SOURCE INJURIES AND ILLNESSES BY INDUSTRY

Industry	Total number (1976)	Percent [1] of total (1976)	Total number (1977)	Percent [1] of total (1977)
Agriculture, Forestry Fisheries	535	2.8	682	3.1
Mining	325	1.7	455	2.1
Construction	1,545	8.1	1,802	8.3
Manufacturing	9,217	48.4	10,234	47.1
Transportation and Public Utilities	997	5.2	1,158	5.3
Wholesale Trade	524	2.8	610	2.8
Retail Trade	2,176	11.4	2,464	11.3
Services	2,548	13.4	3,184	14.6
Government	1,021	5.4	961	4.4
Other	171	0.9	216	1.0

[1] The percent figures may not add due to rounding.

Source: Supplementary Data System 1976 and 1977, Subfile of Chemical Injuries and Illnesses.

An examination of the industry distribution of chemical source illnesses for 1978 (Ex. 16–8) is even more telling in regards to the contribution of the manufacturing sector to the overall occurrence of chemical source occupational illnesses. Since illnesses are more likely to be due to chemical exposures than injuries are, it is in this area that the effects of hazard communication should be most apparent.

Occupational illnesses are reported to the BLS in seven categories:

1. Skin disease or disorders.
2. Dust diseases of the lungs.
3. Respiratory conditions due to toxic agents.
4. Poisoning.
5. Disorders due to physical agents.
6. Disorders associated with repeated trauma.
7. All other occupational illnesses.

In analyzing this BLS data, OSHA assumed that Categories (1) through (4) are primarily due to chemical exposures. Category (1) includes skin ailments due to handling plants, so in the agriculture sector the numbers are greater than they would be if only chemically-related skin diseases or disorders were reported. Categories (5) and (6) are obviously not related to chemical exposures. Category (7) primarily deals with biological agent diseases, but also includes benign and malignant tumors. Since the potential effect of the proposed standard in preventing occupationally-induced cancer was dealt with separately in the regulatory analysis (Ex. 17) Category (7) was not included in this analysis either.

As OSHA reported in the preamble to the proposed standard, the manufacturing sector is responsible for a disproportionately high number of these chemically-related occupational illnesses. In Table 2, the number of such cases reported in 1978 are indicated for each industry, as well as the percentage of the total number reported that these cases represent. These were the latest figures available when the preamble for the proposal was prepared. In addition, Table 2 includes the same statistics for 1981, the latest year for which statistics are now available, to show that the trend in industry occurrence is similar to 1978. The 1981 statistics became available after the public record for this rulemaking was closed, and were not used to make the decisions regarding the scope of the standard, but are merely presented as a point of comparison. A copy of the 1981 report is available in the public docket for this rulemaking.

It can be seen from Table 2 that the manufacturing sector accounts for more than half the reported cases in both years. Since the average total employment in 1978 in manufacturing was 20.5 million, or 32% of the total, this clearly indicates that manufacturing sector employees are at the greatest risk of experiencing health effects due to chemical exposures.

TABLE 2.—CHEMICAL SOURCE ILLNESSES BY INDUSTRY

Industry	Number [1] of cases 1978	Percent of total	Number [1] of cases 1981	Percent of total
Private Sector (Total)	86.7	100	69.5	100
Agriculture	2.7	3.1	3.0	4.3
Mining	1.0	1.1	1.0	1.4
Construction	5.1	5.9	4.7	6.8
Manufacturing	53.8	62.1	37.9	54.5
Transportation/ Utilities	4.8	5.5	4.3	6.2
Wholesale/Retail Trade	7.6	8.8	5.9	8.5
Finance/Insurance/ Real Estate	1.0	1.1	0.7	1.0
Services	10.9	12.6	11.8	17.0

[1] In thousands.

Source: Prepared by OSHA from: *Occupational Injuries and Illnesses in the United States by Industry*, 1978 and 1981, Bureau of Labor Statistics.

Examination of incidence rates for chemical source occupational illnesses also reveals that manufacturing employment represents a higher risk of harmful chemical exposures. The last year that the BLS reported occupational illness incidence rates by industry division and category of illness was 1977. Using the same Categories (1) through (4) as described above, the chemical source illness incidence rates per 1000 full-time workers in the private sector in 1977 were:

Industry	Incidence rate
Agriculture	5.5
Mining	0.9
Construction	1.7
Manufacturing	3.1
Transportation/Utilities	1.4
Trade	0.5
Finance, Insurance, Real Estate	0.2
Services	1.1

The only industry division which has a greater incidence rate than manufacturing is Agriculture. As noted above, since Category (1) includes effects resulting from handling plants, which is not a chemical exposure situation, occurrence of chemically-related skin illness in Agriculture is overstated. The incidence rate for this category was 4.4, or more than 80% of the total incidence reported for Agriculture. In addition, OSHA cannot regulate chemical exposures related to the field use of pesticides, which would be expected to be the most common source of chemical exposures in the Agriculture industry. (Tr. 2260–61), because EPA has exercised its jurisdiction in this area under the Federal Insecticide, Fungicide, and Rodenticide Act. Pesticide exposures would also be expected to cause a large number of the skin ailments reported for the Agriculture industry in Category 1 as well as the poisonings in Category 4 (incidence of 0.7). Therefore, it appears that manufacturing has the highest incidence rate when considering just chemical exposures, and only those which the Agency has the authority to regulate. The category which has the second highest number of reported illnesses (Table 2), Services has an incidence rate that is one third that of manufacturing. Recognizing the limitations of these data due to the effects of underreporting, it still appears that the incidence rate also support OSHA's determination that manufacturing employees have the greatest risk of experiencing health effects due to chemical exposures, since the incidence rate for manufacturing is

from about two to ten times greater than the other industries.

No evidence was submitted to the record which contradicted OSHA's finding that manufacturing employees experience the greatest number of chemical source injuries and illnesses. One participant did point out that overall injury and illness incidence rates are comparable in a number of industries (LACOSH, Tr. 3128):

> * * * One way to determine if an industry is hazardous compared to other industries is to look at injury and illness rates. And, we did that. And, the Bureau of Labor Statistics in 1980 reported that in construction, agriculture, and transportation industries the following rates of injury and illnesses were sustained for one hundred full-time workers: 15.7 in construction; 11.9 in agriculture; 9.4 in transportation. And, these rates are comparable and in one case higher than the 12.2 suffered by workers in the manufacturing sector.

However, as noted previously, these rates are not specific to chemical exposures and can therefore not be appropriately used to determine the scope of this standard.

It should be emphasized that the Agency does not believe that employees in other industries are not exposed to hazardous chemicals, or that they should not be informed of those hazards. OSHA has merely exercised its discretion to establish rulemaking priorities, and chosen to first regulate those industries with the greatest demonstrated need. The promulgation of this final standard for the manufacturing SIC Codes ensures that hazard information will be routinely generated and available. Downstream employers will be receiving labeled containers that will indicate the presence of hazardous chemicals. Although not required for those employers outside SIC codes 20–39, the increased availability of material safety data sheets will also benefit them. Thus this standard will increase the general availability of hazard information in all of industry, and will establish the informational framework upon which standards dealing with other industries can be based, if necessary.

A number of participants supported the scope of the standard as proposed (Exs. 19–48, 19–62, 19–67, 19–85, 19–96, 19–106, 19–111, 19–124, 19–177, 19–199, 19–211, 19–214, 59; 83; 167; 181). For example, the American Iron and Steel Institute stated (Ex. 167):

> All workers with known significant potential exposure to hazardous chemicals should be afforded the protection of a hazard communication standard. However because of special conditions peculiar to other industries it may be necessary to develop separate vertical standards to assure that the regulation is cost-effective and germane to their particular workplaces.

However, many of the participants, particularly workers and worker representatives, believe that the scope should be expanded to cover all industries where employees are exposed to hazardous chemicals (See, for example, Exs. 19–5, 19–74, 19–109, 19–169, 19–180, 19–206, 34, 36, 62, 64, 122, 131, 153, and 180A). These participants presented examples of exposures to hazardous chemicals in industries outside SIC codes 20–39 to support their contention that all industries should be covered in one standard (e.g. Ex. 31; Tr. 2197; 3089; 3922).

As stated previously, OSHA acknowledges that exposures to hazardous chemicals are occurring in other industries as well. A limited coverage of them is included in the final standard since all containers leaving the workplace of chemical manufacturers, importers, or distributors will be labeled, regardless of their intended destination. This will alert downstream users to the presence of hazardous chemicals, and the availability of material safety data sheets. The Agency contends that the focus of this standard should remain on the manufacturing sector since that is where the greatest number of chemical source injuries and illnesses are occurring. This focus will also serve to ensure that hazard information is being generated for chemicals produced or imported into this country, and this increased availability will benefit all industry sectors.

A few comments were received from employers in the manufacturing SIC codes, particularly the flavor and fragrance industries and the distilled spirits industry, suggesting that their facilities be exempted from the standards (e.g. Exs. 19–63, 19–68, 19–77, 19–97, and 19–197). The primary reasons offered for this recommendation were that employee exposures to hazardous chemicals are limited in their plants, the industries are regulated by other Federal agencies, and the industries have voluntarily undertaken programs to protect their own employees.

Although employees in these industries may be exposed to fewer hazardous chemicals than employees in some other segments of manufacturing, the testimony and written submissions of their representatives verify that such exposures nevertheless do take place. For example, representatives of the flavor and fragrance industries indicated that ethylene oxide and hydrochloride acid may be used in their facilities (Tr. 3425). These chemicals are both currently regulated by OSHA, and thus are considered to be hazardous under the provisions of the final standard. Likewise, employees in distilled spirits plants are exposed to ethyl alcohol (Ex. 19–68), which is also regulated by OSHA and thus considered to be hazardous under the final standard. To the extent that the numbers of hazardous chemicals are limited, the burden of complying with the standard will be reduced in comparison to the burden of compliance in other segments of the manufacturing industries where greater numbers of such chemicals are used. However, the presence of such chemicals indicates that hazard communication programs are needed.

The other Federal agencies which regulate these industries (i.e. the Food and Drug Administration and the Bureau of Alcohol, Tobacco and Firearms) do so to ensure the quality of the product for consumers, not to protect employees. OSHA has examined the potential for conflict and overlap of this final standard and regulations of these agencies. It appears that the primary area of potential concern is in the labeling requirements, and OSHA has explicitly addressed this concern in the final standard to avoid any duplication of effort or conflict. This issue will be addressed further in following sections of this preamble.

Implementation of voluntary activities in these industries is not unique since many manufacturers have indicated they have undertaken such programs (see, e.g., Exs. 19–85, 19–91, 19–124, and 19–160). In fact, OSHA assumed prior compliance for many manufacturers in its Regulatory Impact Analysis for the proposed standard (Ex. 17), and stated that companies with existing effective programs should be able to comply with the new performance standard without substantial modification of such programs (47 FR 12101). To the extent that the flavor and fragrance industries and distilled spirits plants are already providing hazard information to their employees, the burdens of complying with this standard should be minimized.

Therefore, OSHA has determined that no conclusive evidence has been provided to exclude any industries within the manufacturing SIC codes from coverage by the standard.

One significant modification to the basic scope of the standard has been made in the final document, however, based on extensive comments in the public record. Under the proposed standard, OSHA did not explicitly cover importers or distributors, and raised the issue in the preamble of whether they

should be covered by the final standard. At the time of the proposal, OSHA stated that explicit coverage may not be necessary because marketplace pressure exerted by manufacturers needing hazard information would, in fact, ensure that the importers and distributors made it available to their customers.

In response, the vast majority of the participants in the rulemaking believed that marketplace pressure would not be sufficient to ensure the availability of hazard information from importers or distributors (see, for example, Exs. 19–23, 19–51, 19–75, 19–89, 19–119, 19–143, 19–185, 36, 46, 47, 123, 125, 168, 180, 181, and L–16). Many based this conclusion on their past experiences in trying to obtain such information. For example, the Duriron Company, Inc. stated (Ex. 19–186):

> The Duriron Company, Inc. has maintained Material Safety Data Sheet (MSDS) files at all manufacturing locations for several years. Establishing these files has been very difficult. In some instances, several letters and telephone calls were required to obtain *any* information. Most of these problems have been with a middleman, especially repackagers.

The Boeing Company also addressed coverage of suppliers in their written comments (Ex. 19–109):

> * * * Marketplace pressure, as suggested in the preamble, is not an acceptable means by which to ensure that suppliers will pass on hazard warning information (specifically, Material Safety Data Sheets (MSDS's)) to users. This suggestion will only reinforce the current voluntary system which already relies on pressure from "the market", or users pressuring the suppliers and manufacturers for information. It is a cumbersome and ineffective system which we hope will not be sanctioned by OSHA under the guise of new terminology. "Suppliers" must be included in this regulation to ensure that information does flow from the manufacturer to the user * * *

The National Association of Chemical Distributors provided written comments to the record concerning their members' position regarding the responsibilities of distributors to pass on hazard information. Although they did not favor explicit coverage of distributors in the final standard, they did acknowledge responsibility for making such information available and expressed a willingness to do so (Ex. 19–213):

> NACD is submitting the following comments to help clarify the position of its members with respect to manufacturing and primary distribution versus secondary distribution particularly with regard to furnishing Material Safety Data Sheets. Where the material is repacked and sold in smaller quantities with no commingling of product, the distributor would pass on the manufacturer's safety data sheet to the end user. Where the distributor engages in blending or compounding, NACD would consider that a manufacturing process and agrees that the distributor should have the responsibility for providing the proper MSDS for the resulting product.

OSHA has determined that explicit coverage of distributors is necessary to ensure the proper transmittal of hazard information, and has included such provisions in the final standard.

The National Association of Photographic Manufacturers, Inc. expressed the views of many rulemaking participants in their comments on the coverage of importers (Ex. 19–75):

> Quite clearly, the chemical manufacturer is the best source of information as to the hazard posed by a particular chemical. This applies whether the manufacturer is domestic or foreign. There appears to us to be no significant reason why an importer cannot obtain an MSDS from a foreign chemical manufacturer and be required to provide it to his customers in the United States in the same manner as would be required of a domestic chemical manufacturer.
>
> Under the proposed standard, employers in S.I.C. codes 20 through 39 would be required to comply with the proposed rule. Those domestic employers who use imported chemicals would be seriously disadvantaged if they were not able to obtain an MSDS from an importer or directly from a foreign chemical manufacturer. In this regard, we believe requiring an MSDS could easily be made a condition for importation much as the labeling requirements of the European Economic Community as outlined on page 12100 of the **Federal Register** notice.
>
> In addition to preventing a potential breach in the Hazard Communication Program to the detriment of U.S. employees, the above action would tend to equalize the economic disadvantages that would otherwise be present if U.S. manufacturers were required to bear the cost of OSHA compliance while foreign manufacturers were exempt from that cost. U.S. manufacturers are already bearing the cost of compliance with foreign regulations, i.e. those of the EEC. Foreign manufacturers would also enjoy a competitive advantage in developing third country markets since they would not be concerned with the OSHA Hazard Communication Program.

The European Communities submitted a written comment to the record which indicated that the proposal as published could create an unnecessary obstacle to trade if applied to importers (Ex. 19–216). In particular, they noted that "the list of requirements is somewhat exhaustive and would be followed by all manufacturers in the EC. Some manufacturers in the EC supply information to their employees under the provisions of national legislation which is flexible in allowing various methods for information to be transmitted to the employee. This achieves the same objective while allowing flexibility in application and avoids the danger of creating unnecessary obstacles to trade within the terms of Art. 2.1 of the GATT Agreement on Technical Barriers." The OSHA standard is also flexible in prescribing the manner and methods of hazard communication. European Economic Community (EEC) labels will be accepted if they include the label components as required by the OSHA standard. Moreover, the importers would not be required to do anything more than is required of domestic manufacturers. Based on comments such as those submitted by the National Association of Photographic Manufacturers, this explicit requirement is necessary to ensure the safety and health of American workers. Therefore, under the final standard, importers will be required to supply the same hazard information that chemical manufacturers are required to provide to their manufacturing customers. As Dr. Myra Kartstadt reported, coverage of importers is especially appropriate since a number of chemicals in use in the United States are totally imported from abroad (Ex. 52). Some commenters suggested that this coverage will be feasible and in fact reflects current practice:

> The experience at Schering with importers has demonstrated an ability and a willingness to obtain material safety data sheets (MSDS's) from overseas manufacturers.
>
> (Schering-Plough Corporation, Ex. 19–199)

Accordingly, the OSHA standard does not constitute a barrier of trade to foreign manufacturers. However, OSHA acknowledges the long-term benefit of maximum recognition of hazard warnings, especially in the case of containers leaving the workplace which go into interstate and international commerce. The development of internationally agreed standards would make possible the broadest recognition of the indentified hazards while avoiding the creation of technical barriers to trade and reducing the costs of dissemination of hazard information by elimination of duplicative requirements which could otherwise apply to a chemical in commerce. As noted previously, these regulations will be reviewed on a regular basis with regard to similar requirements which may be evolving in the United States and in foreign countries.

b. *Laboratories.* Another issue raised by the scope of the proposal which generated significant comment was the coverage of laboratories in manufacturing facilities. In the proposed

standard, laboratories in the manufacturing SIC Codes would have been subject to the provisions with one exception. The proposal exempted "chemicals being developed and used only in research laboratories." This exemption was primarily intended to apply to new chemicals being developed in research activities, since they would not have been tested to determine their hazards, and would generally be present in the laboratory for short periods of time, in small quantities. Although some people interpreted the proposal as exempting all research laboratories, this was not, in fact what the provision stated.

A number of participants commented on the coverage of laboratories, and many favored exempting all chemicals in all laboratories (see, for example, Exs. 19–4, 19–43, 19–61, 19–111, 19–146, 19–167, 19–199, 67, 148, 181; Tr. 212, 530). These participants generally cited as reasons for exempting them from the scope of this standard the facts that laboratory environments are different from the rest of the manufacturing facility in which they are located; that laboratories are generally supervised by highly trained, technically qualified individuals; and that OSHA has previously requested comments and information on the appropriateness of promulgating a standard to cover laboratories exclusively.

Although it may be true that laboratory facilities have different types of operations than the rest of a manufacturing plant, that does not appear to be a sufficient rationale for exempting them from coverage. The fact remains that employees in these laboratories are exposed to hazardous chemicals, and are at risk of experiencing adverse health effects from such exposures. As stated by the Celanese Corporation (Ex. 19–185):

> * * * The workers in the laboratory use hazardous chemicals and need to be informed of what the hazards are and appropriate work practices to minimize the risks from these hazards * * *

The BLS statistics for the manufacturing sector's incidence of occupational illnesses cannot be broken down to separate the incidence in laboratories versus other operations. Although specific evidence concerning the incidence of injuries and illnesses in laboratories was not submitted to the public record, there is testimony that indicates that laboratories may be just as hazardous environments as manufacturing in general. For example, Mr. Frank Baird testified concerning his experience working in a research laboratory. During his employment, he was unknowingly exposed to high levels of mercury vapors and contracted mercury poisoning. As he stated (Tr. 1845):

> The mercury I worked with came in unmarked glass bottles. There were no warning labels, no markings saying poison. It didn't even have a label saying mercury. The Greeks knew that mercury was poisonous, the Romans knew that mercury was poisonous, even my employers knew that the mercury was poisonous, but they may not have known just how poisonous its vapors were or how badly my exposure exceeded the toxic limits set by the U.S. recommended standard in 1942.

Undoubtedly, the laboratory Mr. Baird worked in, which was at an academic institution, was under the supervision of highly trained, technically qualified individuals. However, the fact that such laboratory supervisors are trained in conducting chemical research or other laboratory operations does not mean that they are adequately trained in, or concerned with, the hazards of the substances they are working with. As Dr. Daniel Teitelbaum testified (Tr. 159):

> In my own experience as a university professor, having worked in research laboratories and run research projects, I can say to you that many research scientists are less than informed about the toxicity of the materials with which they work in spite of their doctoral degrees.

Furthermore, although supervisory personnel may be technically trained, there are frequently workers in laboratories who are engaged in cleaning glass containers or other tasks where they are exposed to a myriad of hazardous chemicals without appropriate training. For example, Melena Barkman of the United Steelworkers of America stated (Ex. 103):

> We strongly disagree that all laboratory workers are highly skilled and trained. Many lab workers clean the area and wash equipment with little or no instruction. Many laboratory technicians have only two years training. Even medical technologists and research chemists are not trained in safety; i.e. proper storage and ventilation.
>
> OSHA must provide protection for all laboratory workers. Even where chemicals are properly labeled, material safety data sheets must be made available at the site. In view of the recognized hazards in laboratories, anything less than inclusion would be negligence.

The third argument made for exempting laboratories from coverage is the possibility of a vertical OSHA standard for laboratories. At this time, that rulemaking is in the pre-proposal stage and the Agency has no way of definitely determining when such a standard will be completed, or what it will contain. By including laboratories in this rule, OSHA can assure more immediate protection for laboratory workers in SIC codes 20 through 39. When the laboratory standard is promulgated in final form, the Agency will assure that all laboratory facilities have the same duties in regards to hazard communication programs for employees. In the meantime, the record for this rulemaking indicates a need for hazard communication in laboratories, and the final standard includes provisions to protect these employees.

OSHA recognizes that due to the large number of small containers in laboratories, and the types of operations performed, all of the provisions of the final hazard communication standard may not be appropriately applied to those facilities. This view is supported by a videotape submitted by the Pharmaceutical Manufacturers Association (Ex. 67) and examples of laboratory containers submitted to OSHA (Ex. 68). Therefore, we have incorporated a limited coverage of laboratories in the final standard.

It appears that most containers of chemicals in laboratories are either labeled, or are under the control of someone who removes a chemical from a labeled container to put it in other vessels, and thus is aware of the identity of the substance involved (Tr. 966). Therefore, with respect to labeling, OSHA has simply required that in laboratories the employer ensure that labels on incoming containers are not removed or defaced.

A similarly limited approach has been incorporated for material safety data sheets as well. Any labeled container entering the laboratory workplace would be accompanied by an MSDS. Accordingly, the standard requires that any MSDSs received by the employer are to be maintained in the work area, and employees are to have access to them.

The employer will be required to fully implement the training provisions of the hazard communication standard for laboratory employees. Since, according to the record, much of this training is already being provided, this should not be burdensome for these employers (Tr. 220; 2300–03). The final standard permits employers to train employees with regard to general classes of hazards, as long as the substance-specific information is available to employees in written form. This type of training should be easily accomplished and yet will provide protection for laboratory workers and increase their awareness of hazards in their work areas. Training of this type is particularly important in laboratories, where employees are

typically exposed to large numbers of chemicals in small quantities.

One additional argument related to the coverage of laboratories concerned manufacturers of research chemicals. The Scientific Apparatus Manufacturers Association, for example, testified that such manufacturers should be exempted from the provisions of the standard (Tr. 215), for essentially the same reasons as they supported exemption of laboratories. Where these facilities are actually laboratories, they would be covered by the standard in the modified approach used for laboratories as already described. It should be noted that manufacturers of chemicals for use in laboratories outside the manufacturing SIC Codes—for example, in university research laboratories—would not be required to send material safety data sheets to these facilities. In addition, since the final standard allows employers to keep the required information in the work area in some other form than as an MSDS, these employers would be able to more readily meet the information requirements for their own employees. Therefore, no specific exemption has been included in the final standard for these facilities.

c. *Coverage by Other Federal Agencies.* Another issue of concern to a number of participants in the rulemaking is potentially duplicative coverage by OSHA and other Federal agencies with labeling regulations. Although OSHA stated in the preamble to the proposed standard that it did not intend to require any additional labeling for products covered by other Agencies, the proposal itself did not contain a specific exemption for such products.

Many commenters in the record did not agree with this approach, and preferred that OSHA provide specific exemptions for products labeled under other Federal laws and for manufactured articles (see, for example, Exs. 19–46, 19–63, 19–67, 19–68, 19–77, 19–81, 19–110, 19–124, 19–157, 19–158, 19–196, 163, 170, and 171).

In response to these concerns, the final standard explicitly states that its labeling requirements do not apply to certain substances. In particular, the labeling requirements of this standard do not apply to:

(1) Pesticides which are labeled in accordance with the requirements of the Environmental Protection Agency;

(2) Foods, food additives, color additives, drugs and cosmetics, including materials intended for use as ingredients in such products (e.g., flavors and fragrances), which are labeled in accordance with the requirements of the Food and Drug Administration.

(3) Distilled spirits (beverage alcohols), wines, and malt beverages intended for nonindustrial use when subject to the labeling requirements of the Bureau of Alcohol, Tobacco, and Firearms; and,

(4) Consumer products and hazardous substances which are subject to consumer product safety standards or labeling requirements of the Consumer Product Safety Commission.

The applicable definitions are those provided by the governing statutes and regulations.

In providing exemptions from the labeling requirements of this standard for these substances, OSHA is mindful of the fact that they are already being labeled pursuant to the authorities of other Federal agencies. In the case of pesticides, the purpose of such labeling is mainly the protection of workers exposed to the pesticide. In the case of the other substances, the purpose of the labels is more general consumer protection. Nevertheless, the required labels generally provide for the listing of chemical identities and, in some cases, hazard warnings as well. Because of the nature of the substances, they are regulated by the other Federal agencies to assure that they are safe for consumer use, and to the extent that workers are exposed to the substances in a manner comparable to that of ordinary consumers, there is no need for additional OSHA labeling requirements.

OSHA recognizes, however, that there may be situations where worker exposure is significantly greater than that of consumers, and that under these circumstances, substances which are safe for contemplated consumer use may pose unique hazards in the workplace. For this reason, the standard's exclusion is limited to labeling. It does not exempt employers from the material safety data sheet and training requirements of the standard with respect to any of these substances, provided of course that the substance otherwise meets the standard's definition of hazardous chemical. Moreover, it should be stressed that these labeling exclusions are for the enumerated substances only. To the extent that an employer uses other chemicals, such as in the manufacture or processing of these substances, they are fully subject to the requirements of this standard.

The standard does, however, provide complete exclusion for four categories of substances: (1) Hazardous waste, as defined and regulated by the Environmental Protection Agency; (2) tobacco and tobacco products; (3) wood and wood products; and (4) articles. The Environmental Protection Agency regulates the disposal of hazardous waste, and their rules include requirements for labeling and training. Thus OSHA has decided that when a chemical is considered to be a hazardous waste by the EPA, it will be exempt from the provisions of this standard. Tobacco and tobacco products are intended for use by consumers and are not commonly thought of as chemicals for the purposes of this kind of regulation. See, e.g., their exclusion from the Toxic Substances Control Act, 15 U.S.C. 2602(B)(iii). Wood and wood products are likewise excluded for comparable reasons. While both kinds of materials are no doubt flammable and may pose other hazards as well under some circumstances, their identity within the workplace is unmistakable and their characteristic hazards should be well known to the workers involved. Accordingly, their exclusion from this standard is appropriate. In the case of preserved wood, i.e. wood that has been impregnated by pesticides, OSHA has previously determined that while the preserved wood is not itself a pesticide, EPA is nevertheless primarily responsible for its regulation (see Ex. 19–157, Att. I, American Wood Preservers Institute). In other respects, it is not different from ordinary wood. Therefore, the wood itself will be covered by the wood exclusion, while the pesticide used to preserve it will be covered by the labeling exclusion provided for FIFRA-regulated pesticides. It should be noted again that, as with the other exclusions, non-excluded chemicals which are used in conjunction with tobacco or wood products, or are known to be present as impurities in those materials, are covered by this standard.

The final exclusion is for "articles" which are defined essentially as manufactured items which are formed into a specific shape or design for a particular end-use function and which will not release or otherwise result in exposure to a hazardous chemical under normal conditions of use. The specific definition is similar to that used by EPA for purposes of excluding articles from certain TSCA reporting requirements. See, e.g. 40 CFR 704.95(c)(1). An example of an article would be a piece of equipment or furniture. These obviously do not meet the common conception of a chemical and are not appropriate subjects for a hazard communication standard directed at chemical hazards. Of course, chemicals used in the manufacture or use of an article are

covered by this standard unless otherwise excluded.

No explicit exclusion is provided for substances regulated by the Department of Transportation under the Hazardous Materials Transportation Act. This standard is directed towards hazard communication within the workplaces of employers in SIC Codes 20–39 (i.e. manufacturers), whereas the Department of Transportation regulations are directed toward the packaging and labeling of hazardous materials while they are being transported in commerce. Therefore, although both sets of requirements necessarily apply to many, if not all, of the same substances, there should be no unnecessary duplication of regulatory effort. It is true that this standard requires chemical manufacturers and importers to provide material safety data sheets and labeled containers to downstream employers who purchase their products, and requires chemical distributors who act as middlemen in the chain of distribution to provide the same information to their industrial customers in SIC 20–39. This is necessary to assure that the required hazard information is disseminated throughout the distribution chain so that all covered workplaces may have adequate hazard communication programs. Conflict with the DOT regulations is avoided by requiring, in the labeling section of this standard, that the labeling of containers leaving the workplace shall be done in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act and regulations issued under that Act. This standard is thereby harmonized with the DOT regulations, specifically including 49 CFR 172.401(6), which states that "no person may offer for transportation and no carrier may transport a package bearing any marking or label which by its color, design, or shape could be confused with or conflict with a label prescribed by this part" (i.e. the DOT labeling requirement).

It should be noted that the Environmental Protection Agency (EPA) has statutory authority to require labeling of chemicals under the Toxic Substances Control Act (TSCA). This authority has not been exercised to date except in very limited circumstances. As long as any such labels specified in the future include the information OSHA requires, the TSCA labels would also suffice to comply with this standard's labeling provisions.

Mixtures. The final major issue involving the scope and application of the proposed standard is the coverage of mixtures. The determination of mixtures to be covered by the standard is particularly critical since most chemicals produced and used in the manufacturing sector are mixtures, not "pure" substances. In order to ensure necessary protection for employees, these mixtures must be covered by the standard. For organizational purposes, the coverage of mixtures has been moved from the "scope and application" paragraph of the standard to the newly created "hazard determination" paragraph.

Under the proposed standard, a mixture would have been covered in one of two ways. First of all, if the mixture itself had been objectively evaluated for its hazard potential, e.g. toxicity tests had been performed or the flashpoint had been determined, the results of such testing were to be used to indicate the hazard of the mixture. This requirement did not imply that manufacturers had to test the mixtures themselves. As with individual substances, the manufacturer could rely on available scientifically valid evidence published in other sources reporting the hazards of the mixture. The manufacturer was required to list on the material safety data sheet the ingredients known to contribute to the hazards that the mixture posed according to the available scientific evidence, but did not have to list ingredients which may be hazardous themselves, but do not exhibit their known hazards in the particular mixture. For example, a mixture containing small concentrations of acetone, a highly flammable liquid under most circumstances, may be tested and found to be not flammable. In this situation, the chemical manufacturer would not have been required to designate the mixture as a flammable hazard nor to list acetone because of its flammability.

Where no such objective information on the hazard of the mixture as a whole entity was available, the manufacturer was to identify which components comprising greater than one percent of the composition were hazardous in their own right, and list each of these on the material safety data sheet. In other words, where no objective scientific information existed on the mixture's hazard, it would be assumed to have the same hazards as its component parts. The proposal also included a provision indicating that the Assistant Secretary reserved the right to require ingredients to be listed when present in concentrations less than one percent when they were deemed to be particularly hazardous.

The rationale of the proposal was that when the hazard of a mixture is unknown, all hazardous ingredients should be indicated on the material safety data sheet. The user would then have the most complete information available to predict the potential hazards of the mixture. The one percent exclusion was included to absolve the employer from having to evaluate and list chemicals present in mixtures in small quantities, which are not likely to result in substantial exposures.

Considerable comments were submitted to the record on this approach. OSHA stated in the preamble to the proposed standard that the one percent cut-off was justified on the basis that it appeared to be protective and was considered to be reasonable by a number of affected parties. Some participants, such as Armco, Inc., agreed with this finding (Ex. 19–146):

> Like the OSHA proposal, Armco has used the one percent (1%) criteria for our specific chemical products whenever they have been involved in MSDS requests. We feel this is a reasonable cutoff value.

Similarly, West Point Pepperell stated that (Ex. 19–150):

> The 1% cut-off for disclosure of hazardous chemicals and hazard labeling for chemical products seems to be a reasonable and effective safeguard for a great number and variety of circumstances.

However, a number of participants felt that one percent was too high for certain chronic hazards, and that some provision should be made in the final standard for identifying such hazards in smaller quantities automatically, rather than waiting for completion so substance-specific rulemakings. For example, West Point Pepperell continued their comments on the one percent rule as follows:

> The proposed standard also provides for the imposition of lower cut-off levels by rulemaking procedures. However, there is a group of substances, most of which have already been named in rulemaking by OSHA as potential human carcinogens, which may already need lower cut-off levels. We suggest that the proposed standard require the disclosure, through the use of an MSDS, of any part of a chemical product which may contain or release some amount, no matter how small, of any substance for which OSHA has successfully completed rulemaking, naming the substance as a potential human carcinogen, toxic substance or harmful chemical agent which may cause a disease of grave and extreme consequence * * *

Other participants were concerned about the extent of protection provided by the one percent exclusion for other types of substances as well. The

Department of Defense addressed the issue as follows (Ex. 19–148):

We recognize the practical need for limiting the applicability of the standard with regard to hazardous ingredients of a mixture. We believe, however, that there is significant health risk involved when carcinogens, strong sensitizers, or other compounds with extremely low permissible exposure limits are present in mixtures in concentrations below 1%. For example, the free isocyanates present in certain paints are usually present in a concentration less than one percent, yet failure to list the isocyanates on the Material Safety Data Sheets could result in a significant hazard going unnoticed. We suggest that the standard require the disclosure of all hazardous chemicals comprising less than 1% of a mixture (by weight or volume) if those chemicals, under typical use conditions, may result in exposures above the permissible exposure limit, or if those chemicals are known to be carcinogens, mutagens, teratogens or sensitizers when in low concentrations.

Several interested parties further suggested that hazardous chemicals, or any ingredient whether hazardous or not, be listed regardless of their concentration in the mixture. For example:

Other areas of concern include Section A3 of the standard which does not require chemicals found in quantities of less than one percent to be identified as a constituent of a product. We believe that all hazardous constituents product (sic) should be identified since some materials in quantities less than one percent can pose a health hazard. A case in point would be the use of hydrazine in some sealing materials as an oxygen scavenger. Depending upon the method of application, quantities of hydrazine less than one percent of the total volume of the material can have a significant impact in determining the safe method for using that particular product.

(Caterpillar Tractor Company, Ex. 19–201)

I would like to draw an analogy if I could to death certificates. Death certificates, in the old sense, used to list merely the immediate cause of death and that was felt to be sufficient.

Now, of course, somebody could walk across the street, be hit by a car and have lung tumors. Then there was some feeling that approximate cause of death should be included. And now I think the burden of medical thinking is that all co-existing conditions should be listed so that one gets a complete picture of what is happening with an individual. We would suggest the same thing for the constituents of a formulation or a mixture and that is that particularly in the absence of knowledge about synergistic interactions between trace amounts of compounds and larger amounts, as well as an inability perhaps by all parties to appreciate the significance of chronic disease as opposed to acute conditions. That those are not judgments that should be left up to discretion.

(Dr. E. Silbergeld, Environmental Defense Fund, Tr. 2247–8)

OSHA limits the scope of its rule even further by excluding from labeling any substance that makes up less than 1% of a mixture. This exclusion based on percentage makes no sense at all. If a chemical is highly toxic, or if it causes cancer after long-term exposure to small amounts, then it may be extremely hazardous even when present in amounts far below 1%. Likewise, if workers are exposed to large amounts of a mixture, they may be exposed to considerable amounts of a toxic constituent that makes up less than 1% of the mixture. Requiring a complete rulemaking proceeding to inform workers for each case when the 1% rule provides inadequate protection is a great burden on OSHA—one that will lead to more numerous and complex regulations, rather then to clear and effective regulation. The solution must be to require inclusion of *all* known contents on the label.

(Dr. E. Bergmann, Public Citizen Health Research Group, Ex. 19–172)

Additional examples of rulemaking participants who believed the one percent exclusion was appropriate in some, if not all instances, or that the cut-off should be lowered or eliminated to permit greater disclosure, can be found in Exs. 19–51, 19–60, 19–67, 19–83, 19–89, 19–90, 19–109, 19–146, 19–148, 19–150, 19–192, 19–193, 19–214, and 167.

In contrast to these cited comments which indicated that the one percent rule incorporated by OSHA in the proposed standard was reasonable or not protective enough, several commenters stated that the one percent cut-off was too low (Exs. 19–64, 19–176). More commonly, the suggestion was made that the "cut-off" approach should be replaced by an evaluation of which chemicals "substantially contribute" to the hazard of the mixture without specifying a cut-off. The following comment from BASF Wyandotte Corporation is representative of many of those received from chemical manufacturers (Ex. 19–167):

The proposal provides that mixtures containing at least one percent of a hazardous chemical would be considered hazardous unless the "mixture has been evaluated as a whole and found not to be hazardous". While we agree with this approach, we are concerned with the language in the preamble which indicates that testing must be performed on a mixture before its hazard can be evaluated. We believe it is often possible to evaluate the acute hazards of a mixture without testing. Such evaluation would be based on information in the scientific literature, knowledge of the chemical interactions, and testing results of similar products. We recommend reasonable scientific judgment be permitted to evaluate the hazards of mixtures. Where a mixture is found to be hazardous, only those components that contribute substantially to the hazard(s) should be required to be identified.

For examples of similar comments, see Exs. 19 (8, 27, 44, 48, 54, 63, 79, 91, 140, 145, 162, 170, 185, 204, 206, 210, 215), 181, 182.

Some of the comments relating to testing appear to have been based on a misinterpretation of the hazard evaluation provision in the proposal, especially as it pertains to mixtures. As described above, the manufacturer would not have been required to perform tests on the mixture. Objective scientific data related to the mixture as a whole could be used to determine its hazards. Given that objective scientific data are generally unavailable, OSHA anticipated that most mixtures would be considered to have the same hazards as their constituents and allowed for this in the March, 1982, proposal.

In reviewing the comments related to the assessment of mixtures, OSHA has concluded that some delineation can appropriately be made between assessments for physical hazard potential, and those performed to determine health hazard potential. For example, in presenting its views on the issue, Merck & Co., Inc. stated that: "* * * a 1% mixture of a flammable, combustible, or reactive chemical in an inert diluent may hardly be "hazardous" given the properties of the components" (Ex. 19–52). The Nalco Chemical Company addressed the need to differentiate between health and physical hazards (Ex. 19–55):

We can understand the need for some type of cut off such as a "1% cut-off" for certain types of hazards. We do not agree that it should apply to all "hazardous" ingredients in a formulation. Specifically, we do not believe the "1% cut-off" should apply to hazardous ingredients such as when the ingredient is combustible, flammable, corrosive, explosive, an oxidizer or unstable. The "1% cut-off" should apply *only to health hazards* such as carcinogenicity, etc.

Similarly, the Pharmaceutical Manufacturers Association (Ex. 19–110) also addressed the difference between health and safety and safety hazards:

While the one percent standard may be appropriate for some types of materials such as a very highly toxic or carcinogenic material, it is not appropriate in most cases. An otherwise flammable substance, for instance, would become inert if diluted with water to a one percent mixture. While a manufacturer may know that a mixture is not hazardous, the regulation would require that it be labeled as hazardous unless tests were conducted to show otherwise.

OSHA has therefore concluded that a percentage cut-off for physical hazards is not necessary. The physical hazard potential of a chemical may be diminished or neutralized by the other

constituents of the mixture and this may be known to the employer as a result of experience in using the mixture or actual testing. For that reason, the final standard gives the chemical manufacturer, importer, or employer greater latitude to determine that a mixture does not pose the physical hazards of its ingredients.

Participants objecting to the one percent cut-off were not able to provide similar convincing evidence regarding the appropriateness of the approach for health hazards. In fact, some of the examples they did cite demonstrated a misunderstanding of the provision and chemicals covered. For example, Master Chemical Corporation stated that (Ex. 19–87):

> Chemical identity information is particularly useless when required for mixtures. Very often there is no correlation between the toxicity of the individual components in pure form and the overall blend of a mixture. Consider the simple example of hydrochloric acid and sodium hydroxide. Both of these chemicals are extremely corrosive, and if mishandled, are capable of doing serious, even fatal, injury to living organisms. However, when combined in appropriate concentrations the resulting mixture is sodium chloride (table salt) and water, both relatively innocuous substances that certainly have nowhere near the hazard potential of either ingredient individually.

In order for a hazardous chemical to be considered a mixture, the components have to retain their chemical identity after being combined. The example cited by Master Chemical involves a chemical reaction, where the final product is completely different chemically than the component parts. Therefore, it would not be regulated under the hazard communication standard as a mixture with unknown hazards requiring the listing of hazardous ingredients.

Other participants cited examples of chemicals in the workplace where the one percent cut-off may result in fairly innocuous mixtures being considered hazardous. The National Association of Manufacturers (Ex. 19–209) objected to the one percent cut-off and cited the following:

> Thus the NAM asserts that the one percent cutoff point, as contained in the Proposed Rule, is an ineffective trigger point. To support this assertion, we offer the following:
>
> The one percent cutoff, in itself, means little
>
> —Somewhere in the workplace, vinegar can likely be found. Vinegar contains 5% acetic acid.
>
> —At the plant first aid station, one can find hydrogen peroxide at 3%.
>
> —The list is long, far too long to be covered in detail but includes such mixtures as window cleaners, bleach, most fertilizers, household ammonia and even concentrated sodium chloride.
>
> Note:—Although we recognize that OSHA has exempted food and drugs, we offer these examples as illustrative of this situation.

As the NAM noted, OSHA was cognizant of mixtures that are food, drugs, or cosmetics brough into the workplace for the consumption of employees, and proposed to exempt them from coverage by the standard. Furthermore, the final standard includes additional exemptions for other types of consumer products which are labeled under the regulations of other Federal agencies. Therefore, we do not find that these examples support the contention that using the one percent cut-off for predicting the health hazards of chemicals in the workplace is not appropriate.

Conversely, the examples cited by participants that indicated that one percent may not be protective enough with respect to health hazards in some situations are persuasive. As quoted above, there are situations where components present in concentrations less than one percent may present hazards to exposed employees. Admittedly, the situation may also be reversed, where the health hazard of a component is diminished by the mixture. However, in the absence of objective data supporting this, the prudent approach to protecting employees from health hazards remains in identifying the hazards present in the mixture.

OSHA therefore rejects the suggestions of a number of participants that the chemical manufacturer or importer be permitted to list only those ingredients which "contribute substantially" to the health hazard of the mixture. Although this is appropriate, and is permitted, when the hazards of the mixture as a whole are known, it is not appropriate when the hazards of the mixture are not known. Limiting disclosure in the latter case to those chemicals which have been subjectively determined to "contribute substantially" to the essentially unknown hazards of the mixture does not provide adequate protection for employees. This approach would introduce an additional layer of judgment which will serve to decrease the amount of information which is included on the material safety data sheet. Given the state of uncertain scientific knowledge with regard to synergistic effects in particular, it better serves the purpose of hazard communication to simply disclose those constituents which are hazardous in and of themselves.

The positions of the various parties in the rulemaking, as discussed above, range from disclosure of all ingredients, whether hazardous or not, to disclosure of those which contribute substantially to the hazard of the mixture, based on the assessment of the employer as to the hazards of that mixture. The latter approach does not appear to meet the objective of ensuring that employers and employees will receive the most complete information possible under this standard. The approach suggested by others, disclosure of ingredients whether or not they are hazardous, is broader than necessary to provide protection to employees.

OSHA has made several changes to the proposed provisions in this final standard in an attempt to accommodate the various concerns of the rulemaking participants, while ensuring the protection of employees exposed to mixtures. First of all, a distinction has been made in the determination procedures required for physical hazards versus health hazards. For physical hazard, the chemical manufacturer may use whatever scientically valid data is available to judge whether or not the mixture will have the same hazards as its ingredients which potentially pose physical hazards. This should alleviate the concerns of some parties, particularly regarding the flammability or combustibility of mixtures where the flammable or combustible component is diluted to render its effect inert.

For health hazards, the one percent cut-off for mixtures where the health hazard potential of the whole mixture is not known will apply. Although this may result in what some might consider to be overprotection, OSHA concludes that it is necessary to ensure adequate protection in all cases. Chemicals identified as carcinogens under the hazard determination provisions of this standard will have to be listed when present in quantities greater then 0.1%. In addition, if the employer has reason to believe that an existing permissible exposure limit for a component present in quantities of less than one percent may be exceeded under normal conditions of use, or that such a component could present a serious health hazard in such quantities, that component will also be required to be listed. Because the cut-off for carcinogens has been lowered, and listing is required when a chemical manufacturer, importer, or employer knows that an ingredient poses a serious health hazard in concentrations of less than 1% the provision relating to lowering the cut-off in individual cases by rulemaking has been eliminated. The Assistant Secretary has the authority to issue separate rules for specific substances in any event.

The provisions regarding mixtures in the final standard can be found in a new paragraph (d) entitled "Hazard determination." Listing requirements for ingredients are in paragraph (g) on "Material safety data sheets."

2. *Definitions.* The proposed standard included a number of definitions for terms used in the provisions, and OSHA received many comments suggesting revisions to them, or requesting that additional definitions be provided.

Several commenters suggested that OSHA exempt "articles" from the scope of the standard (Exs. 19–47, 19–73, 19–76, 19–166, 19–209, and 19–220). The purpose of this exemption is to ensure that items which may contain hazardous chemicals, but in such a manner that employees won't be exposed to them, not be included in the hazard communication programs. Examples of such items would be nuts and bolts or tools. The exemption has been added to the final standard and a definition was added as well. It was further suggested that OSHA adopt the definition for "article" used by the Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA) (Ex. 19–73). OSHA fund that the definition used by EPA was appropriate for this standard in part, but that it was necessary to modify it for purposes of ensuring protection for employees. The EPA definition is essentially as follows: "article" means a manufactured item: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (iii) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article.

OSHA has adopted parts (i) and (ii) of EPA's definition, but has changed (iii) to read: "Which does not release, or otherwise result in exposure to, a hazardous chemical under normal conditions of use." This is more appropriate for OSHA's hazard communication standard because some items considered to be exempted articles under TSCA may result in employee exposures to hazardous chemicals during their use, and the hazards of those chemicals should be communicated to the employees. For example, the ACTWU (Ex. 111) described a situation involving fabrics in common use which are treated with permanent press resins which release formaldehyde when handled. Workers engaged in making clothing from such fabrics should be informed about the nature and identity of their formaldehyde exposures. The fabric would probably be an exempted article under EPA's definition, but normal use of it exposes employees to a hazardous chemical. Therefore, the definition has been modified to ensure that in this type of situation, hazard information is transmitted to employees and downstream employers.

Several commenters suggested that the definition for "chemical manufacturer" be modified to refer to an "employer" in SIC Codes 20 through 39 producing chemicals for use or distribution, rather than an "establishment" as proposed (Exs. 19–76, 19–160, 19–162, and 19–220). These commenters felt this should be done because the Occupational Safety and Health Act refers to employers, and this standard should be consistent. This change has been made, and a definition of "produce" has also been added to clarify the scope. "Produce" means to manufacture, process, formulate, or repackage.

OSHA proposed to require the rules of nomenclature of the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) to designate the "chemical name" of a substance. A number of commenters suggested that in some cases, a simpler name is generally used and will allow access to the scientific literature, which is the primary purpose of requiring the chemical name (Exs. 19–62, 19–85, 19–135, 19–145, 19–162, 19–185, and 19–194). For example, the National Paint and Coatings Association stated (Ex. 19–62):

> There are many other cases where a commonly recognized name is far more meaningful to employees, toxicologists, and industrial hygienists. Even a highly trained investigator would be dismayed by an MSDS showing 1,3,4,-metheno-2H-cyclo-buta(c,d) pentalen-2-one-a,3,3a,4,5,5,5a,6-decachlor-octahydro- but he would recognize readily its common name of Kepone.

The NPCA continued to explain that their suggested modification was to allow exceptions which would permit easier access to toxicity information, and not to allow indiscriminate use of common names in lieu of chemical names in all situations.

OSHA has modified the definition of "chemical name" in the final standard to allow for this limited exception in certain prescribed, circumstances, i.e. "a name which will clearly identify the chemical for the purpose of conducting a hazard evaluation."

In the proposed standard, OSHA included a definition for "combustible" which was consistent with the Agency's definitions in related safety standards. The definition included a breakdown of combustible liquids into classes designated by flashpoint ranges.

Some commenters suggested that OSHA's definition of "combustible" should be consistent with those of various other groups, such as NIOSH, the Department of Transportation, and the National Fire Protection Association (e.g. Exs. 19–23, 19–46, 19–69, and 19–73), or that OSHA should allow any commonly used definitions. Although it would be desirable for all organizations to have uniform definitions, since there is no universally agreed upon definition, at this point it appears to be most important to be internally consistent, i.e. that OSHA define "combustible" the same way wherever the term appears in the Agency's standards. Therefore, the flashpoint range used in the proposal remains the same in the final standard. However, in response to suggestions from other commenters that the class breakdown is unnecessary for purposes of this standard, we have simplified the definition by removing the classes and simply noting the lower and upper limits on the flashpoints considered to designate a liquid as being "combustible (e.g. Exs. 19–43, 19–49, 19–62, and 19–71).

There were also several suggestions that a "compressed gas" is a property hazard, rather than a safety and health hazard, and should thus be deleted from the final standard (Exs. 19–43, 19–141, 19–152, and 19–188). In addition, commenters stated that it should be deleted because the gas should be evaluated for its own hazardous properties, not because it is compressed (e.g. Ex. 19–220). OSHA does not agree with these suggestions for deletion, and has included "compressed gas" as a hazard to be covered by the standard. The gas should certainly be evaluated for its own hazards, but by compressing the gas into a cylinder, other hazards become possible due to leaks or ruptures of the containers. Employees should be informed of these types of hazards as well.

The majority of the comments received on the definition for "container" related to stationary process equipment. The proposed definition excluded pipes and piping systems from the labeling requirements, but would have required employers to label reaction vessels and other process equipment. This was objected to by many participants (e.g. Exs. 19 (54, 59, 60, 72, 84, 96, 115, 142, 156, 164, 188, 214, and A–6). For example, Celanese Corporation stated (Ex. 19–185):

> The proposed standard defines "container" to include reaction vessels. A labeling/posting requirement for reaction vessels,

particularly batch-type reactors, will result in a significant labor burden on employers without any real additional protection of the workers. Since the chemical and physical properties are constantly changing, any single label would be inaccurate in relaying any hazard information to the worker.

In the preamble to the proposed standard, OSHA recognized the potential difficulties of labeling such containers (47 FR 12104), and invited comments on appropriate alternatives, such as a process sheet providing the required information and available to employees in their work area. OSHA did receive information in response to this request (e.g. Exs. 136, 149, 164), and the labeling provisions of the final standard have been modified to allow such alternatives. This issue is discussed at greater length in the section of the preamble dealing with labels and other forms of warning. This modification should provide employees with the visual hazard reminder which is a necessary part of a comprehensive hazard communication program, but allows for feasibility problems which may be encountered by employers attempting to comply with the labeling requirements. The definition for "container" remains as proposed since the problems addressed by the commenters are not really definitional in character and have been substantially satisfied by allowing, but not requiring, alternatives to labeling. Those employers who choose not to use such alternatives will still be required to label stationary process equipment. Comments dealing with the labeling of pipes are also discussed in the portion of the preamble dealing with labeling issues.

Several commenters believe that the proposed definition of "designated representative" was too broad (Exs. 19–54, 19–126, 19–155, 19–160, and 19–196). For example, O M Scott & Sons stated (Ex. 19–126):

> We suggest that stricter qualifications be placed upon the designated representative. For example, the representative should have demonstrated expertise in industrial hygiene, toxicology, law, or other professionally related field, and must have a legitimate reason for representing the employee.

OSHA does not agree and has concluded that employees have the right to determine who will represent them and exercise their rights under this standard. The definition has not been modified in accordance with these recommendations to limit representation to professionally trained individuals.

A number of commenters, particularly employee organizations, believe that unions should automatically be considered designated representatives of employees, without the requirement for individual written authorizations (e.g. Exs. 58, 63, 80, 101, and 111). For example, a representative of the International Union of Electrical, Radio and Machine Workers testified (Ex. 58):

> * * *(T)he union needs *automatic* access to MSDS in order to develop a prevention oriented health and safety program. Decades of public health practice demonstrate that problems can be prevented, only when they can be anticipated before people get sick. Union access to MSDS can facilitate this goal. Also, few occupational health problems are limited to one person. If there's a problem generally a number of workers are affected. Full union access to all information allows for a more comprehensive analysis of hazardous situations and will result in greater health promotion and a higher degree of worker protection.

OSHA agrees that recognized or certified collective bargaining agents should be given access to the materials developed under this standard for employees without obtaining individual written authorizations, and the definition of "designated representative" has been modified accordingly. Union safety and health representatives will be able to use the material safety data sheets and other materials generated under this standard to train workers and otherwise contribute to reducing the occurrence of chemical source injuries and illnesses. This is consistent with OSHA's current policy regarding "designated representative" under the records access regulation (29 CFR 1910.20).

As discussed under the scope section of this preamble, OSHA has added requirements for a "distributor" to ensure that hazard information is made available to their customers purchasing hazardous chemicals. A definition of distributor has been added to the standard as well.

In the proposal, "employee" was defined as workers in covered workplaces where they may be exposed to hazardous chemicals under normal operating conditions or foreseeable emergencies. This was further clarified by stating certain job categories which would be expected to be covered, and those which would not generally meet the test of exposure under normal operating conditions or foreseeable emergencies. However, this clarification did not actually exclude any workers since the triggering factor was whether or not their job performance routinely involves potential exposure to hazardous chemicals. Thus a security guard routinely posted at the gate to the plant may not be potentially exposed during the course of his normal work, but a similar guard posted inside the plant may be. The latter employee would then come under the provisions of the standard. The purpose of indicating job categories was to clarify that, generally speaking, office workers or others in manufacturing who are not exposed are not covered by the standard. The definition of "employee" is essentially the same as the one used in the proposal.

A few comments were received which addressed the issue of exposure (Exs. 19–76, 19–118, and 19–147), being primarily concerned that employees who are not routinely exposed need not be included. OSHA has concluded that the issue of exposure as related to coverage is already adequately addressed in the proposed definition. To further clarify the matter, however, a definition has been added for "exposure" (described below).

Several comments were also received suggesting that the definition of "employee" be modified to indicate that only employees employed by the employer owning the facility should be included (Exs. 19–81, 19–52, 19–214, 19A–37, and 109). Since employers can only be directly responsible for the safety and health of their own employees, the definition has been clarified in the final standard to indicate that an employer need only inform his/her own employees. However, in response to further comments requesting coverage of contractor employees (Exs. 19–124; 31), a provision has been added to the hazard communication program requirements to ensure that manufacturing employers inform contractor employers of the nature and identities of any hazards their workers may encounter in the facility, and to suggest appropriate protective measures. OSHA cannot require employers to inform their contractor's employees of the hazards in their workplace. However, in order for the contractor to apprise his/her employees, information will have to be obtained from the employer. Therefore, this addition will ensure the contractor receives the necessary information.

A number of commenters suggested that OSHA add a definition for "exposure" or "exposed." A definition similar to that used in OSHA's *Access to Employee Exposure and Medical Records* regulation (29 CFR 1910.20) has been incorporated into the final standard in response to these requests. The definition is not exactly the same because this standard already includes exemptions and limitations on coverage that the "access" regulation seeks to limit solely through the exposure definition. Furthermore, the "access" regulation definition refers to "past"

exposure due to the records retention aspect of the standard. This standard only deals with current and future exposures, so the reference to the past has been omitted. In addition, the "access" regulation refers to toxic substances and harmful physical agent, whereas this hazard communication standard is directed to "hazardous chemicals."

Many of the comments on the definitions for "flammable" were the same as those already discussed for "combustible," i.e. that the definitions should be consistent with those of other organizations (e.g. Department of Transportation; National Fire Protection Association), and that the definition for "flammable liquid" need not be broken down into classes (e.g. Exs. 19–43, 19–47, 19–69, 19–76, 19–111, 19–135, and 19–185). As discussed previously regarding the definition for "combustible", OSHA has concluded that the definitions for "flammable" should remain consistent with those in other OSHA standards dealing with flammable substances. The classes have been eliminated from the flammable liquid definition, however, maintaining the lower and upper flashpoint values as proposed.

In the proposal, OSHA defined ammonia as a flammable gas, although it doesn't meet the definitional criteria provided. This decision was based on Agency experience, which indicated that ammonia is involved in fires and is flammable under some conditions. In response to requests during the hearing, OSHA submitted to the record documentation establishing that ammonia is a flammable gas (Ex. 151).

The definition of ammonia as a flammable gas was the one most frequently commented on during the rulemaking proceeding. The commenters generally objected to the classification of ammonia as flammable, and cited years of experience, primarily with refrigeration systems, without fires occurring (e.g. Exs. 19 (9, 13, 18, 21, 29, 34, 38, 66, 83, 95, 103, 128, 141, 179, and 215)). Although OSHA has concluded that ammonia may be flammable in some situations, the specific designation of it as such has been eliminated from the final standard since it does not meet the general definition for a flammable gas.

A number of comments were received which suggested that the definition for "hazardous chemical" was too broad, and should include some limitation on coverage according to the risk involved (Exs. 19–43, 19–62, 19–76, 19–92, 19–96, 19–166, 19–220, 19A–10 and 19A–18). The definition of "hazardous chemical" was intentionally broad in the proposal, to ensure that all potential hazards are considered when a chemical is being evaluated. The concept of risk based on the degree of exposure may be introduced by the employer when training employees, but should not be a factor used to limit the amount of information presented on a material safety data sheet. This is particularly important when the MSDS is being transmitted to downstream employers where exposure situations are different and unknown to the chemical manufacturer or importer preparing the MSDS. (A number of manufacturers commented on their inability to know downstream situations in objecting to providing certain categories of information on the material safety data sheets, e.g. Exs. 19–63, 19–91, 19–96, 19–98, 19–111, 19–124, 19–156, and 19–194).

Similar comments were received concerning the definition of "health hazard" (e.g. Exs. 19 (43, 49, 59, 63, 69, 77, 84, 110, 116, 176, 188, 205, and 220). For Example, the Synthetic Organic Chemical Manufacturers Association, Inc. suggested (Ex. 19–44):

> * * * OSHA should amend the definition of "health hazard" by adding criteria which better define the concept of a hazard, such as a requirement of likely exposure at levels sufficient to create a significant risk of material health impairment.

As stated above, OSHA does not agree that it is appropriate to include concepts of degree of exposure or risk into the definition for health hazard. The standard already limits hazard communication duties to those chemicals to which employees are exposed under normal conditions of use or in foreseeable emergencies. Furthermore, employers must train their employees regarding the risks involved in the particular exposure situation in their work areas. For purposes of defining what chemicals are a potential "health hazard," a broad approach must be followed to ensure employee protection. And since manufacturers or importers cannot know whether there will be a "significant risk" in downstream uses, thorough information on potential health hazards must be provided.

The definition for "health hazard" has been modified somewhat by including in it the target organ classification of hazards that was proposed in Appendix A. This should clarify the required scope of hazards to be evaluated. In addition, it has been clarified that health hazards to be included are those for which there is scientific (i.e. statistically significant) evidence based on at least one positive study conducted in accordance with established scientific principles.

A number of participants suggested that definitions for acute health hazards, which are generally well-defined, be adopted from the American National Standards Institute (ANSI) standard for precautionary labeling (e.g., Exs. 19–48, 19–57, 19–59, 19–84, 19–91, 19–126, 19–140, 19–147, 19–167, 19–205, 19–214, and 182). OSHA has concluded that adoption of these acute health hazard definitions will clarify the coverage of the final standard, and has incorporated the definitions used in the latest ANSI labeling standard (Ex. 182A). These definitions may be found in Appendix A, and cover "toxic," "highly toxic," "corrosive," "irritant," and "sensitizer."

In addition, OSHA has determined that a definition criteria for what constitutes a carcinogen for purposes of this standard is necessary since there may be differences of opinion concerning certain substances (Tr. 1057–1067; 3928). OSHA has concluded that a chemical is to be identified as one which poses a carcinogenic hazard when either the National Toxicology Program, the International Agency for Research on Cancer, or OSHA itself, publishes a finding that the available information indicates the chemical is a potential or confirmed carcinogen. Employers can determine whether a chemical meets these by consulting the publications of these organizations, or by looking it up in the NIOSH *Registry of Toxic Effects of Chemical Substances* (RTECS). RTECS entries indicate the findings of NTP, IARC, and OSHA.

A definition for "immediate use" has been added to the final standard at the request of several commenters (Exs. 19–196, 19–199, and 19–211). The definition clarifies that to qualify a container for the "immediate use" exemption from labeling, it must be under the control of the person who transferred materials into it, and used during the same work shift as it was transferred.

As importers have been added to the coverage of the standard, a definition for "importer" has been included as well. In addition, OSHA has responded to commenters requesting that "label," "manufacturing purchaser," "material safety data sheet," and "mixture" be defined (e.g., Exs. 19–46, 19–64, 19–91, and 19–177) by adding definitions for those terms.

OSHA uses the term "physical hazard" in the final standard, as contrasted with "health hazard" which is already defined, and has added a definition for that term as well.

In order to clarify the information permitted to be withheld as a trade secret under the final standard, OSHA has used and defined the term "specific

chemical identity." The term refers to the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information which reveals the precise chemical designation of the substance.

In the preamble to the proposal, OHSA stated that it considered the definition for "trade secret" to be that taken from the Restatement of Torts (47 FR 12105). In response to several requests. OSHA has specifically included a slightly modified version of that definition in the final standard (Exs. 19–76, 19–91, and 19–185).

Several commenters also suggested that use of the term "transport" in the definition of "use" may be in conflict with the regulations of the Department of Transportation. The intent of the term was to refer to transport within a facility, and the definition of "use" has been changed to read "transfer."

3. *Hazard determination and communication program—Hazard determination.* Once the chemical manufacturer or importer has assessed the hazards of the chemicals they produce, the specific communication provisions of the standard apply only to those chemicals found to be "hazardous." Thus the hazard evaluation and determination process is critical to the successful implementation of an effective hazard communication program.

The determination of what constitutes a hazardous chemical for purposes of this standard was the most difficult issue discussed in the rulemaking record. It is clear from OSHA's analysis of the record that there is a considerable range of opinion concerning the appropriate approach. It is also clear that the uncertainty and disagreement among the participants relates to the determination of health hazards, not physical hazards. The evaluative procedures for determination of the physical hazard potential of chemicals are fairly objective and straightforward, and these procedures did not generate much comment from rulemaking participants. Therefore, this discussion will relate solely to the question of what constitutes a health hazard under the provisions of the final hazard communication standard.

The term "health hazard" was defined very broadly in the proposal as a "chemical which, upon exposure, may result in the occurrence of acute or chronic health effects in employees." This definition was further expanded upon in Appendix A, which included a discussion of the difficulty of defining health hazards, and a categorization of health effects according to target organ. Included in the categorization were examples of both the signs and symptoms of overexposure and some specific substance which may affect those target organs. Under paragraph (c) of the proposed standard, "Hazard determination and communication program," the chemical manufacturer was to be held responsible for adequately ascertaining the scientifically well-established health effects of the chemical involved. Appendix B provided guidelines for this evaluation, in the form of available information sources. No set procedures were prescribed, and thus the evaluation was performance-oriented, with the performance criterion being the appropriate identification of the scientifically well-established data. A proper evaluation would result in generating the appropriate hazard information to complete the labels and material safety data sheets, and to transmit to employees in training sessions.

Prior to the publication of the proposal, OSHA had examined various methods of determining the hazard of a chemical. This included review of existing regulations of other Government agencies, examination of commonly used textbooks, discussions with health professionals, and study of various lists of hazardous chemicals. The Agency's conclusion was that the hazard evaluation procedure involves a large degree of professional judgment in every situation, and that, as one hearing participant stated, there is no "cookbook" approach to determining the hazardous properties of a substance (Tr. 2062). Reliance solely on the few commonly used criteria (such as those used in the ANSI standard on labeling) would tend to eliminate coverage of a significant number of acute effects, as well as the majority of chronic effects. On the other hand, a reliance on lists of substances could exclude too many hazardous chemicals from coverage. In addition, lists of chemicals do not provide hazard information, so an evaluation of hazardous effects still has to be performed once a list has been established as the scope of chemicals covered.

A number of comments were received which indicated that hazard communication should not be required unless there is a "significant risk" or "unreasonable risk" of the employee's experiencing an adverse health effect under normal conditions of use (see, e.g. Exs. 19 (43, 49, 62, 69, 77, 91, 111,119, 185), 182, L–15). Upon questioning during the public hearing, some advocates of this approach further elaborated on this position by stating that exposure above the permissible exposure limit would be an appropriate delineation to determine "significant risk" (Tr. 1255; 2481).

OSHA does not agree that such an approach should be included in the final standard. The purpose of hazard communication is to ensure the disclosure of information about the possible hazards of chemicals in the workplace before the worker is exposed to them, and thus is at risk of experiencing adverse health effects. The hazard potential does not change even though the risk of experiencing health effects does vary with the degree of exposure. Therefore, although, for example, the material safety date sheet for sulfuric acid should always indicate its potential to be corrosive, the employer can indicate in the training program what the degree of exposure actually is in a given work operation. The chemical manufacturer or importer, in making hazard determinations, should evaluate and communicate information concerning all the potential hazards associated with a chemical, whereas the employer may supplement this information by instructing employees on the specific nature and degree of hazard they are likely to encounter in their particular exposure situations.

The Agency determined that the most comprehensive approach would be to require evaluation of all chemicals, not some pre-selected list of substances, and to require reporting of all types of health effects, not the limited few which are precisely defined.

Some participants in the rulemaking endorsed the proposal's performance-oriented approach to hazard evaluation, and judged the state of scientific knowledge to be such that no more specific procedures would be warranted or appropriate (see Exs. 19 (48, 88, 111, 116, 143, 169, 214); 28; 165; 167). For example, Bausch and Lomb stated in their written submission (Ex. 19–143):

> The hazard determination process should remain performance oriented. Attempting to create a precise step-by-step hazard determination procedure is difficult and most likely would not be flexible enough to address the variety of situations as effectively and as inexpensively as the existing proposal. Creating a list of chemicals is equally undesirable because the list would require frequent updating and would always be subject to controversy as to why materials are included or not included on the list.

Similarly, in response to a question from OSHA regarding the procedures to follow in performing a hazard evaluation, Mr. Gary Hancock, a toxicologist with the Bethlehem Steel Corporation, gave the following response (Tr. 2062–3):

Well, with respect to specific guidelines or criteria for doing a hazard determination, as a toxicologist I don't feel that you can have—use a cookbook approach in performing that type of an exercise. I think that hazard determination is really not an exact scientific process. That there is really a lot of art there and because of that it really requires that professional judgment play an important role. Again, I don't believe that you can set up specific criteria or guidelines. Perhaps general guidance in the way of, of course, anybody would do a literature review, but how to use that data that you get from literature review and the data that you gather in your interactions with other health professionals, industrial hygienists, occupational physicians about the conditions of use, all of that plays a role in hazard determination process. It is not always the same. It depends upon the situation and the chemical, and, of course, a number of other factors that might play a role. So I don't think you can specify that type of thing.

Other participants criticized the performance orientation. They suggested that hazard evaluations would be inconsistent under the proposed approach, and thus employees would not have equivalent protection in all workplaces. As an alternative, they suggested that specific procedures be included in the final standard, or that lists of substances to be covered should be developed or adopted (see e.g. Exs. 19 (65, 74, 89, 109, 148, 166, 175, A–2, A–3, A–5, A–11); 31; 33; 36; 46; 58; 62; 63; 64; 122; 123; 125; 131; 168; 180). For example, the AFL–CIO stated in their written testimony (Ex. 36):

Perhaps even more deficient than the proposed standard's hazard definitions are its determination procedures. While the definitions are inadequate, specific requirements or even guidance outlining an adequate hazard determination are absent entirely. The absence of specific requirements or guidance will, in our view, result in a compliance and enforcement nightmare with neither manufacturers nor compliance officers having any idea of what procedures constitute compliance.

The final standard must contain guidance or requirements for what constitutes an adequate hazard determination drawing from current industry practice as reflected in the record of this rulemaking.

Some industry representatives suggested that either OSHA or an independent scientific panel should review toxicological data, particularly in the area of chronic health hazards, and establish a list of substances which should be labeled. For example, the Adhesive and Sealants Council wrote (Ex. 19–54):

Secondly, the determination of health hazards of specific chemical substances is a complicated task that could have a significant impact on smaller companies that lack sophisticated testing or references resources. In addition, ASC does not concur with the suggested use of reference sources cited in Appendix B as a tool for hazard determination. The user of such reference sources could easily misinterpret data unless specifically trained in toxicological matters, and some of the reference sources cite results of toxicity studies that may lack scientific validity. ASC would recommend instead that OSHA develop its own list of specific chemicals that require labeling for chronic hazards under the proposed Standard.

During the course of the public hearings, OSHA questioned many of the participants as to the methods they use to evaluate hazardous chemicals in the course of their positions as health professionals working for employers, employee organizations, government agencies, or public interest groups (see, e.g. Tr. 193, 309, 523, 546, 589, 909–11, 1279, 1324, 1369, 1458, 1652, 2062, 2090, 2209, 2245, 2416, 3662–3, 3717). The Agency intended to review these submissions concerning procedures currently employed by these groups to determine if some generally agreed upon procedures could be established. This attempt to solicit such information produced some general criteria which could be incorporated into the standard, but no specific procedures for evaluating hazard data were provided by any of the participants. For example, Dr. Myra Karstadt, who is Executive Director of the Environmental Cancer Information Center, was one of the critics of the performance approach to hazard evaluation under the proposed standard. In response to a request that she submit the criteria she uses to determine the hazards of substances, she responded (Ex. L–2):

The ECIC is *not* an organization subject to the Hazard Communication proposed rule. Therefore, the strictly enunciated procedures which should be applied to chemical manufacturers and processors and others similarly situated are not applicable to the ECIC. The procedures I use to answer questions are, therefore, of no direct consequence to the hearings and should not be taken in any way to justify application of the so-called "performance" criteria for toxicity determination set out in the Hazard Communication proposed rule * * *

* * * the criterion which is always uppermost in ECIC toxicity review is identification and use of the best data available to provide an objective and scientifically accurate response to the inquiry received by the ECIC. Procedures used may involve accessing computerized data bases (as, Medline), direct reference to review volumes or articles, conversations with scientists expert in the area in question, etc. ECIC maintains flexibility in the procedures used to assess toxicity, but very complete records are kept wherever that would seem appropriate, especially for controversial topics or for any matter where reference materials are not obvious and easily obtained by anyone with reasonable expertise in the field.

Mr. Michael Wright of the United Steelworkers of America contended that there is an invariable procedure to follow when evaluating hazards, but admitted that the procedures he follows himself vary with the chemical (Tr. 879–80):

I think there is an invariable procedure and the difference between the 15 minute cases and the six hour cases are how much we've looked at that chemical before. I don't have to go back to a literature search on methyl ethyl ketone either, because I've already done that enumerable times, and I can depend on my past work. It's a brand new chemical. Then, it does take longer and I do need to go through all the sources * * *

* * * I think it might be worth—kind of a cascade system. For example, if you're evaluating carcinogenicity and if the first thing I can consult is the NTP list, and it's on the list, that's enough for me to say it's a potential carcinogen. I don't at that point necessarily have to consult all of the other lists. But if I can find it on the NTP list, then I would go to the IARC list. I would go to a variety of other sources and ultimately I would go to MEDLARS and TOX lines, which I think are really the best sources for all of us, cause they're comprehensive.

Under the New York state right-to-know law, the state is involved in reviewing toxicity information to prepare material safety data sheets for distribution. OSHA asked Assemblyman Joseph Pillittere, who testified during the public hearing in Houston, to submit for the record the procedures used by the state to prepare these sheets. The information he submitted revealed that the staff reviews the professional literature (standard sources such as NIOSH documents, the Merck Index, etc.), and prepares the sheets, which are then subjected to several levels of expert review (Ex. 129). No specific procedures for evaluating the data are apparently used.

ICI Americas, Inc. responded to the question regarding specific procedures by describing what they have termed "active 'intelligence gathering' activities" (Ex. 150):

These 'intelligence gathering' activities include:

—Initiation of toxicity tests on new chemicals;

—Close collaboration with ICI Americas' UK parent company to secure relevant information known to the parent. (Our parent company maintains one of the largest industrial toxicology laboratories in the world.);

—Scrutiny of the trade and scientific literature, including relevant government publications e.g. those published by NIOSH, NTP, Section 8e notices submitted to EPA, etc.;

—Review of Material Safety Data Sheets obtained from chemical suppliers;

—Participation in consortia of chemical manufacturers funding testing programs on commodity chemicals of significance to ICI Americas;

—Funding of research in toxicology through membership of the Chemical Industry Institute of Toxicology.

When information is received from such activities on a chemical used by ICI Americas, a detailed review of the data is conducted to assess its validity and evaluate its significance. This review is conducted by professional toxicologists on ICI Americas' staff, in conjunction with medical, industrial hygiene and product safety personnel.

It can be concluded from each of these responses—which represent a scientific organization, a union, a state government, and a manufacturer—that hazard determinations inevitably require professional judgment to be used in evaluating what information is to be looked at and what conclusions to draw from it. At the same time, although the record does not provide examples of specific evaluation procedures used by participants, there are a number of sources of information which are routinely referred to by them to obtain hazard information, or to help them make an initial determination that a substance is hazardous.

Some of those sources were mentioned in the quotes above—i.e. computerized data bases, NIOSH documents, and standard text books. There are also repeated indications that reviewers customarily check to see if a chemical is an OSHA regulated substance or appears on the ACGIH TLV List (Tr. 877, 1105). For determination of carcinogenicity, the IARC Monographs and the NTP list were mentioned (Exs. 122, 180A, L–5; Tr. 877).

In regards to mandating computerized literature searches, OSHA has determined that this is not appropriate. When a search is performed, a list of article abstracts is generated. The person searching the literature still has to evaluate the data to determine what the hazards are—the search does not result in a list of hazards to be reported. As Dr. Parkinson of the United Steelworkers of America stated (Tr: 910–11):

> You have to look at the content and that's really the difficult area. We've mentioned Medlars and Toxline but, of course, they just give you the title of the paper and usually an abstract of what the paper says and in my experience, unfortunately, one really has to go back to the original paper to evaluate how the work was done.
>
> This is being (sic) one of the major problems with a lot of the bibliographies, for instance, that NIOSH has produced in the past that they haven't been weighted in any way be a professional evaluation of the original work. So that when I'm faced with that problem, I inevitably do pull out the original papers and have a look at them if I can get hold of them.

The professional judgment that is required to evaluate the hazards is also a necessary part of determining the extent of search required to adequately ascertain those hazards. As Mr. Wright described above (Tr. 879–80), a "cascade" system is employed. Chemicals with well-known hazards need not be as vigorously investigated as those which are more obscure, or which are being actively studied to determine their health effects. The evaluator is responsible for ensuring that the determination is accurate, but the means to achieve that are best left to professional judgment. The appropriateness of mandating the use of NIOSH documents is also questionable for similar reasons. The term "NIOSH documents" includes a wide variety of publications from criteria documents to health hazard evaluations. Though they may be useful in a hazard evaluation, determination of whether they should be used must be left to professional judgment.

In any event, the incorporation of lists of substances as a floor is quite different than mandatory sources to be searched. Lists such as the OSHA PEL list and the ACGIH list contain a number of well-recognized hazardous chemicals. "Computerized data bases" and "NIOSH documents" are bona fide information sources that must be consulted in many evaluative procedures, but mandating their use in all cases is not appropriate.

The most substantive recommended alternative to the hazard evaluation procedures included in the proposed standard were provided in a post-hearing submission from the AFL–CIO, United Steelworkers of America, International Chemical Workers Union, and the United Auto Workers (Ex. 180A). According to this union submission, adequate chemical identity and hazard information will only be provided if three conditions are met: (1) The requirement to disclose chemical identity must be independent of the manufacturer's hazard determination procedures; (2) the standard must include specific definitions for what constitutes a health hazard; and (3) the standard must require a thorough hazard determination by the manufacturer.

The terms of the first condition are met in large part through the "Access to Employee Exposure and Medical Records" regulation (29 CFR 1910.20), which requires employers to make records of chemical identity available to employees and designated representatives of employees. This disclosure obligation is independent of whether or not the employer believes the chemical to be hazardous, provided the chemical falls within the rule's definition of "toxic substance" which includes any chemical listed in NIOSH's *Registry to Toxic Effects of Chemical Substances* (RTECS), which includes over 40,000 chemicals. The purpose of this standard, however, is to provide information about chemicals which are in fact hazardous. The goal, therefore, is to assure that the standard will result in complete and accurate hazard determinations with respect to identifiable hazards, not just potential ones. The narrower scope of this standard is therefore appropriate.

For the second condition, the unions have suggested that definitions be added to Appendix A for determination of what constitutes a health hazard. They believe that these definitions should include the full range of health effects, and considerations of animal or other laboratory evidence. In addition, since determination of carcinogenicity appears to be one of the biggest areas of disagreement between interested parties, they suggested that findings of confirmed or suspected carcinogenicity by IARC be sufficient to warrant communication of these hazards under this standard. As explained above, OSHA has responded favorably to these comments by adding certain definitions for acute hazards and for carcinogens.

Under the third condition, the unions concede that "there may not be one 'cook-book' procedure for determining all hazards posed by a chemical." However, they maintain that there are certain standard references which many health professionals routinely consider and consult in order to evaluate the hazards of chemicals. They state: "According to industry witnesses and other witnesses, OSHA standards, ACGIH Threshold Limit Values, NIOSH publications, monographs of the International Agency for Research on Cancer, and computerized bibliographic data bases of the National Library of Medicine are routinely reviewed in the evaluation of chemical hazards (Tr. 177, 851, 1054, 1105, 3157, 3306, 3427)."

With respect to this third condition, OSHA agrees that although there may not be established hazard evaluation procedures that are appropriate for determining the hazards of every chemical, some minimal criteria should be established so that certain chemicals will be regarded uniformly as hazards by all evaluators. NIOSH also addressed

the need for some minimal criteria in their written testimony (Ex. 31):

> * * * This may require the mandatory use of certain documents such as the NTP Annual Report on Carcinogens, ACGIH TLV's, NIOSH documents, OSHA regulations, and their respective updates in making such a determination. NIOSH believes that this type of approach is essential to producing an effective rule and that this consistent approach is preferable in the long term to the proposed rule.

NIOSH reiterated this recommendation in their post-hearing submission (Ex. L-5). They stated that "certain documents by themselves represent a scientific consensus as to a particular chemical's carcinogenicity, mutagenicity or teratogenicity."

In the final standard, OSHA has atempted to resolve the differences of opinion regarding the performance approach to hazard evaluation, and to define some criteria that will establish a minimum number of substances to be covered.

First, we have added paragraph (d) to the final standard, entitled "Hazard determination." In this paragraph we have clarified the responsibility of the manufacturer or importer to thoroughly evaluate the hazards. The performance approach was never intended to permit them to perform an inadequate hazard evaluation, but this new paragraph affirmatively states the duty.

In addition, we have established a "floor"—a minimum number of chemicals required to be covered. In any situation, the manufacturer or importer is required to treat chemicals regulated by OSHA or listed by the ACGIH on their TLV list as being hazardous for purposes of this standard. In addition, any chemical which is listed by the NTP or IARC as a suspected or confirmed carcinogen is also to be treated as a potential carcinogen under this standard.

Third, as previously stated, we have also added specific definitions on acute health hazards to Appendix A, which responds to the second union condition noted above. These definitions are taken from the latest draft of the revised ANSI standard for precautionary labeling (Ex. 182A).

In Appendix B, we have clarified the principal criteria to be applied in complying with the hazard determination requirement. First of all, the employer is to evaluate animal data as well as human data. Secondly, if a positive study conducted according to established scientific principles, and resulting in statistically significant findings of an adverse health effect is available, manufacturers or importers must report that effect whether they agree with it or not. They need not state the finding as a conclusion they agree with, but must report it nevertheless. They are also free to report any negative data which they believe is relevant to determining the hazard of the chemical. OSHA believes that this approach will ensure that employees and downstream employers are provided sufficient information to assess the potential hazards of working with the chemical.

These additional provisions provide minimum standards for health hazard evaluations, and will therefore better ensure their validity. Yet professional judgment is allowed and encouraged as the primary tool for evaluation.

Hazard Communication Program. Under the proposed standard, each employer would have been required to develop and implement a hazard communication program. The program was to include the procedures the employer would use to determine which chemicals are hazardous; a list of those chemicals identified as hazardous; and the methods the employer would use to comply with the requirement of the proposal with regards to labels, material safety data sheets, information and training, and preparing employees to safely perform non-routine tasks (e.g. emergency pipe repairs).

OSHA designed the hazard communication program to be a comprehensive approach to apprising employees of the hazards they are exposed to, as well as providing them with information concerning the protective measures to be used to reduce these hazards. In a conference report on chemical hazard warnings published by the Conservation Foundation, the purpose of a hazard communication program was explained as follows (Ex. 18-2):

> A workplace hazard communication program should inform employees about the nature of all the hazards to which they may be exposed, and also persuade employees to take the actions necessary to protect themselves against risk. While workers need to be responsibly informed about the hazards to which they may be exposed, they should neither be overwarned or underwarned. For any hazards identified, they should be offered remedies for protective action. The nature of hazards and information on the appropriate hazard control procedures should be conveyed through labels and other components of workplace labeling systems.

In general, participants in the rulemaking endorsed the elements of the hazard communication program. For example, PPG Industries, Inc. stated (Ex. 19-85):

> PPG is in general agreement with the elements of a hazard communication program as outlined in this section. We believe this section effectively places the responsibility for definition of individual work place hazard information requirements with the employer.

Similarly, the Boeing Company also endorsed the performance goals listed for the hazard communication program (Ex 19-109):

> We applaud OSHA's proposal to use a performance approach with respect to the hazards communication program. There is such widespread diversity among manufacturing industries that the only feasible way to accommodate training, labeling, and information availability is to leave the details to those who can best address these differences: The chemical users themselves. OSHA's performance goals (c)(2)-(4) provide sufficient and appropriate control over this aspect of hazard communications.

Although the proposed standard did not require that the hazard communication program be written, OSHA did raise that alternative in the preamble as an issue for comment. As the Agency stated at that time, a written plan would provide a structure upon which to evaluate programs. Employers would be able to establish in the plans the criteria they used in developing their programs, as well as the means used to meet those criteria. The written program would also serve as a useful reference for employees. Having the program in writing would make it easier to determine if the intent of the standard was being fulfilled.

It was anticipated by OSHA that even in the absence of specific requirements for written plans, prudent employers would prepare them. The plan would not have to be detailed or lengthy, but preparation of it would ensure that all of the elements were adequately addressed.

A number of participants stated that written plans should not be explicitly required (Exs. 19-63, 19-71, 19-72, 19-88, 19-91, 19-110, 19-158, 19-185, 19-188, 19-209, 19-214, Tr. 1313). For example, a representative from the Graphic Arts Technical Foundation testified (Tr. 1313):

> Having a written program provides no real function, in our opinion, except to demonstrate its availability. The key to a hazard communication program is its implementation and continued use in developing employee awareness through training. To the extent that the training is structured well and periodically evaluated for effectiveness, a written program does not add additional benefits.

Conversely, many employer and employee representatives felt that a written plan should be an integral part of a performance-based hazard communication program (Exs. 19-46, 19-51, 19-79, 19-89, 19-96, 19-98, 19-111, 19-

116, 19–124, 19–143, 19–170, 19–196, 19–204, 19–220L, 63, 106, 107, 122, 123, 125, 157, 164, 167, and 180).

For example, the American Petroleum Institute stated in their written submission (Ex. 19–111):

> Further, API has consistently supported the concept that each employer should have a written program to detail how workplace hazards are indentified, evaluated, and communicated to employees. In addition to using a written program to enable a company to internally evaluate the effectiveness of its hazard communication program, the requirement for a written program will help assure better compliance with the regulation.

Similarly, Kaiser Aluminum and Chemical Corporation endorsed a written program approach as well (Ex. 19–196):

> A written hazard communication program is essential:
>
> (1) To establish and document accountability,
>
> (2) To serve as a useful reference for employees, and
>
> (3) To delineate a benchmark for internal auditing.

A joint union post-hearing submission also addressed the need for documenting the hazard communication program in writing (Ex. 180A):

> Under the proposed standard, the employer's hazard communication program must include the procedures the employer will use to determine hazards of chemicals which he produces. But there is no requirement that the employer's hazard determination procedures be reduced to writing as part of the hazard communication program. Thus, in reality, it is a meaningless requirement.
>
> The hazard determination procedures utilized by the employer are central to the OSHA proposal. In the absence of a determination that a chemical is hazardous, no information need be provided.
>
> Since the proposal does not envision uniform hazard determination requirements, employers are free to devise their own procedures which are sure to differ in form and outcome (Tr. 12, 579, 682, 1063, 1066, 1260, 3027). The only means to evaluate the validity of these procedures is to require they be reduced to writing and made available to employees, designated representatives and OSHA (Exs. 36, 101).

Given the considerable support for requiring that the hazard communication program be written, and the fact that having such a written program will be beneficial to the successful implementation of the final standard for the reasons given in the above statements, OSHA has determined that written programs will be required. This should not measurably increase the compliance burden of employers since written materials would have been prepared voluntarily by most of them anyway.

One provision of the hazard communication program under the proposed standard required a list of hazardous chemicals in the workplace. The list was in essence an index or inventory of hazardous chemicals in the workplace for which material safety data sheets should be available, and containers of which should be labeled. The list was to serve as a check point for the employer and the employee to ensure that all of the hazardous chemicals in the workplace had the appropriate information available. The list could be compiled by the identity used on the container labels—ingredients did not have to be specifically listed, as long as the associated material safety data sheet provided the specific chemical identities. As stated in the preamble to the proposal, OSHA's intention was that the list be maintained in a current fashion, to indicate chemicals currently present in the workplace, but that outdated lists need not be kept.

A number of comments were received concerning the need to generate a list, as well as addressing the maintenance of and access to such lists.

Several participants suggested that lists should be permitted to be assembled for work areas, rather than for the entire work place (Exs. 19–43, 19–44, 19–111, 19–124, 19–145, 60, 125). The combined work area lists would thus comprise the master list of workplace chemicals. Given that some workplaces are very large, and employees in a particular work area would be better served by having a list specific to that area, the final standard has been modified to permit this approach.

Many participants objected to generating and maintaining a list of hazardous chemicals, indicating that the material safety data sheets themselves will suffice as an indication of which substances in the workplace are hazardous (Exs. 19 (44, 48, 54, 57, 59, 62, 69, 71, 76, and others)). For example, Monsanto Company stated (Ex. 19–147):

> Monsanto feels that lists of chemical substances in the workplace are unnecessary since the product identification and hazard information are all included on the Material Safety Data Sheet and available to the employee. Lists are difficult to maintain up-to-date and give casual observers the wrong impression that listing of substances is equated to exposure, which of course, it is not. Lists can be made by anyone who wishes to make them from the MSDSs available.

It is difficult to understand how employers could assure themselves that each hazardous chemical in a workplace had been identified, and appropriate hazard information prepared, without generating and maintaining a list. Furthermore, for the employees' benefit, there should be a list available so if a material is present in their work area, and is not accompanied by a material safety data sheet, they can check the list to assure themselves that the chemical is not considered hazardous and thus the absence of an MSDS is appropriate. As indicated in the proposal, the list should be useful to the employer in other aspects of establishing occupational health programs as well. For example, plant industrial hygienists could use it to develop priority schemes for sampling strategies or physicians could use it to highlight which chemicals merit closer examination. Therefore, in the final standard OSHA has maintained the requirement that a list be included in the hazard communication program.

A number of participants suggested that it should be maintained for some time period, or specifically in accordance with § 1910,20 (e.g. Exs. 19–89, 19–109, 19–199, 19–211, 31, 36, 63, 101, 122, 125). However, under the provisions of the records access rule, a chemical inventory is treated as an exposure record only in the absence of material safety data sheets. Under § 1910.20, neither MSDSs nor chemical inventories have to be kept for a specified period, provided *some* record of identity and where and when used is kept for 30 years. Thus, the employer has the option of keeping either the MSDS, or the inventory, or some other record of chemical identity for the 30 year period specified in the records access rule. For purposes of this standards, however, outdated lists and MSDSs need not be maintained. In any event, the list will be a useful tool and remains a requirement in the final standard.

4. *Labels and other forms of warning.* In the proposed standard, the employer would have been required to label every container in the workplace with the "identity" of the hazardous chemicals contained therein and "hazard warnings." The term "container" did not include pipes or piping systems. Containers leaving the workplace would also have to have been labeled under the proposed scheme with the identity and hazard warnings, as well as the name, address and telephone number of the manufacturer.

Two exemptions were provided in the proposal to the in-plant container labeling requirement. Where stationary containers in a work are had similar contents and hazards, the employer could choose to post signs or placards with the appropriate information, rather than individually labeling each container. Furthermore, the proposal

exempted a container holding ten gallons or less if an employee using it did so immediately, and transferred the material from a labeled container to the container being used, and thus was aware of the identity of the contents.

Under the proposal, the label served as an immediate warning of hazards in the workplace, a visual reminder of information presented to employees in training programs and on material safety data sheets, the other two required components of a comprehensive hazard communication program. This approach to the use of labels was discussed in a conference report issued by the Conservation Foundation (Ex. 18–2):

> The purpose of labels on hazardous chemicals, or on products containing them, is to warn about potential danger of significant risk. Labels for hazardous materials should be printed on or attached to a container so that they will remain legible and affixed to the container at least as long as the product remains within. They must convey critically important information in a limited space, and frequently in a limited amount of time and degree of concentration from the reader.

Under the proposed provisions, the labels were not intended to be either the sole, or the most complete source of information regarding the nature or identity of hazardous chemicals in the workplace. The identity on the label could be any term the employer wished to use, as long as it also appeared on the material safety data sheet for the substance along with the precise chemical name(s). Under this plan, the employer could thus use common terms, familiar to employees, while still providing them with more extensive information, including specific chemical identities, on the material safety data sheet.

Furthermore, the provisions were written in broad, performance-oriented language so that many of the existing labeling systems could continue to be used. This did not mean that labels of any type could continue to be used in all cases—the performance-orientation meant that those labels which met the minimal information requirements established, regardless of the format it was presented in, could continue to be used. Thus, for example, labels prepared in accordance with the National Paint and Coatings Association's Hazardous Materials Information System would generally be in compliance, as would those labels prepared in accordance with the giudelines in the American National Standards Institute voluntary consensus standard on labeling. Use of these systems would not mean that employers would not be held accountable for providing the information required. It simply meant that they would not have to alter the format of their information presentation.

Some participants in the rulemaking believe that a standardized labeling format should be promulgated by OSHA (e.g., Exs. 19 (6, 89, 148, 150); 31, 46, 66, 118, 123, 125, 134). For example, the National Institute for Occupational Safety and Health stated (Ex. 19–89:);

> NIOSH reaffirms its position on labeling as contained in the NIOSA Criteria Document "An Identification System for Occupationally Hazardous Materials." NIOSA is concerned with the potential lack of uniformity in design of and information contained on labels generated by various industries. Information transfer is inhibited if a worker is presented with multiple formats containing a wide variety of information on chemical hazards. It would be of considerable benefit to all who must work under this Rule if OSHA would specify a fixed format for all container labels.

However, other participants supported the performance-oriented approach since some labeling programs may be more effective in one industrial setting than another. The Western Electric Company expressed this view as follows (Ex. 19–90):

> We support the performance oriented requirements for labeling as outlined in the March 19 proposal. It is our opinion that the information on a label should be kept as simple as possible, using a readily identifiable system such as the NFPA diamond with numerical ratings in association with an aggressive training program. Such a system provides hazard identification to which an employee can easily relate. While this system has proven to be highly effective in our workplace, it should not be implied that it is satisfactory for all. Employers need the flexibility of implementing labeling programs best suited for their particular situations.

Since there is no information in the record to indicate that one type of labeling system is inherently more effective than another, and since the labeling provisions of the standard are supplemented by a training program where the employer will have to explain to employees the labeling aspects of the hazard communication program in their workplace, OSHA does not find that the record warrants disruption of current labeling practices to implement a standardized system. A number of participants in the rulemaking generally endorsed the proposed requirements as being appropriate (e.g. Exs. 19 (51, 71, 83, 90, 91, 109, 205, 220), 102, 106, and 114).

A number of suggestions were received concerning the information to be presented on the label. These specific recommendations ranged from requiring the number of the chemical as listed in the NIOSH Registry of Toxic Effects of Chemical Substances (RTECS) (Ex. 19–148), to indicating the location of the material safety data sheet (Ex. 19–204). Several other participants, however, commented that including too much information on a label can render it an ineffective means of transmitting hazard data. The American Petroleum Institute's panel during the public hearings included a behavioral scientist, Dr. Daniel Felker, who addressed this issue of information overload. (Tr. 1759–60):

> There is a considerable body of literature from the psychological, psychoanalytical research that says that comprehension is affected by the amount of information that is contained in any message.
>
> If you are interested in carrots, knowing about apples does not help you retain information about carrots. I mean, that's simplistic, but there is a thing of what we call cognitive overload.
>
> A human being, a human learner can attend so much stimuli at any given time. That varies by human being. By overloading the amount of stimuli or the number of messages will detract from the comprehension of any particular piece.
>
> So, if you're worried about making sure you don't pick up some substance, and that's your message, you are detracting from that by giving him, oh, many, many other kinds of information that are only peripheral to that.

The Conservation Foundation also addressed the problem of presenting too much information on a label (Ex. 18–2):

> Labels cannot practically attempt to warn in detail against all conceivable problems, even though case liability law may seem to suggest otherwise. The reasonably foreseeable major or frequent risks of use or abuse should be emphasized, with priority given to the more severe risks. The need for limiting the scope of label messages is most evident when labels must be small in size (e.g., on small containers). Even on larger containers, however, too many messages can detract from the more significant hazards or altogether discourage attention from the warning statement.

Given OSHA's stated purpose for the labels within the comprehensive hazard communication program, i.e. serving as an immediate warning and as a reminder of the more detailed information provided in other forums, the information required under the proposal is sufficient, and remains the same under the final standard. The identity on the label is keyed to the material safety data sheet for the chemical, which will contain more extensive information. The training program will explain to employees both the labeling system and the information on a material safety data sheet, so the employee will be provided with extensive information on each chemical through the integrated elements of the comprehensive hazard communication program.

In some cases, the suggestions for information to be included on the label related to the question of whether the label or the material safety data sheet should be the focus for detailed information in the hazard communication program. Dr. Daniel Teitelbaum, a consultant with experience in preparing hazard communication vehicles for various companies, addressed this issue of using the label as a detailed source of information. (Tr. 166):

> I think that in general if one looks at the pesticide labels, one finds that there is a vast amount of information which absolutely nobody understands and I'm not sure that putting the content on a pesticide label has been very helpful and I would have some reservations as to whether you needed to list the ingredients on the label.
>
> I would think that listing the ingredients on the Material Safety Data Sheet Keyed to the label is probably equally efficient and perhaps as effective.

Other participants also addressed the lack of a demonstrated need for identities to appear on the label, rather than on the material safety data sheet (American Iron and Steel Institute, Tr. 2041–42):

> One of the problems we have with putting chemical names on labels is that in most cases the chemical name, to me, a layman, has no bearing upon what the dangers, the inherent hazards of the chemical are. I really couldn't tell by looking at that chemical name what I'm working with. Whether it is as non-toxic as water, or whether it is as toxic as some very, very rare chemicals * * *
>
> I think that has been proven time and time again by these studies. The chemical name, if it is a very common name, such as benzene, is approached and reviewed by the person's eye. He goes back to that name.
>
> If it is, on the other hand, a very complicated long chemical name, he never resorts to it.

Several participants similarly indicated that no identification should be required on the label, but that it should simply contain hazard warnings (Ex. 19–57, 19–61, and 19–94). The rationale for this suggestion was that many labels in use in plants currently do not include identities and that what workers really need to protect themselves are warnings, not identities. These views contrast sharply with those of some participants, especially employee representatives, who criticized the lack of a requirement to list the chemical identities of all ingredients on the container label. Despite the fact that this information was required to be provided on the MSDS, unless the specific chemical identity was a trade secret, these participants argued that it needed to be provided on the label as well (e.g. Exs. 36, 58, 60, 62, 63, 64, 74, 77, 80, 103, 107).

The primary rationale for the argument was that material safety data sheets are often not available to the employer currently, and when they are available, workers do not always have access to them. As stated by the AFL–CIO, et. al. in their post-hearing submission (Ex. 180A):

> Even if material safety data sheets are provided by the manufacturer, the standard's theoretical right of worker access to safety data sheets and specific chemical identity contained therein, is in practice non-existent. Unfortunately, fear of employer retaliation will prevent many workers from requesting safety data sheets (Tr. 3082, 3109, 3323, 3836). This problem is further compounded by the proposed standard's requirement that workers identify themselves to the employer to gain access through their union representatives. Thus, in reality, the information printed on the container label is the only information available to many workers. Therefore, identification of hazardous ingredients by chemical name must be required on the label.

It should be noted that Section 11(c) of the Act specifically prohibits employers from discriminating against or discharging employees for exercising their rights.

OSHA agrees that employees should be provided with thorough information on each hazardous chemical in their work area, including specific chemical names but, as will be described in more detail in the following section of this preamble, OSHA has chosen the material safety data sheet as the most appropriate means of transmitting these specific details on the identities and hazards of the hazardous chemicals in the workplace. Labels are physically attached to containers, and in order for employees to obtain a copy, they would have to remove it from the container, or copy down the information. The material safety data sheets, on the other hand, will be located in an accessible place in the work area, where the employee can read them when necessary, or copy them for their own use. Furthermore, employee representatives will also have automatic access to this information under the final standard.

OSHA does not believe that it is fair to predict employer compliance with the material safety data sheet requirements based on what may have been the practice in the absence of regulation. The fact that sheets are often not available today is merely a reiteration of the need for a standard to require development and distribution of material safety data sheets for all hazardous chemicals, as OSHA is doing in this final standard for hazard communication.

Since this standard will require employers to ensure that material safety data sheets are readily accessible to employees, and the Access to Employee Exposure and Medical Records regulation (29 CFR Part 1910.20), guarantees them the right to examine and copy them as well, it is unreasonable to assume that in practice access to chemical identity information will be non-existent. In fact, some employers already provide access to material safety data sheets voluntarily (e.g. Tr. 745–46; 2501; 3001). Further under this final standard, employers will have to apprise employees of the existence and contents of MSDSs. In addition, the final standard allows automatic access by collective bargaining agents, so in any event, union representatives will be able to obtain material safety data sheets without any individual granting them written designation. Therefore, OSHA does not find the argument concerning chemical identity on labels to be supported by the evidence in the record, and has not changed the provision which allows common name designations to be used. Employees are granted access to the information on the material safety data sheet, and no participants in the proceeding have supplied convincing evidence that providing the information in some source other than on the label is less effective in communicating hazards.

The identity of a substance alone does not cause workers to modify their behavior, and thus achieve the goal of hazard communication. Additional data in the form of hazard warnings are what must be transmitted and received before an employee can act on the information. For example, Mr. Michael Wright of the United Steelworkers of America testified regarding a worker who died from being overexposed to methyl chloroform (Tr. 782–3), the container of which was labeled only with the trade name of the chemical, with no additional hazard information. When questioned regarding whether the worker would have been adequately protected if the label had also include hazard warnings, Mr. Wright stated (Tr. 872–3):

> I think in that case, had that warning been on the label and had there been an adequate training program, that he would have been protected.
>
> Our need for chemical identity is to check the adequacy of the warning and to insure that we have the most up-to-date information.

In their post-hearing submission, the American Iron and Steel Institute further

addressed the arguments in the public record dealing with the need to put chemical identities on container labels as follows (Ex. 178):

> * * * (T)he proposed performance-type Hazard Communication Standard does not preclude employees from obtaining chemical composition information if so desired; it simply does not require each and every chemical contained in the product to be included on the warning label or placard. Such data would still be available to workers through Material Safety Data Sheets (MSDSs) for non-proprietary products. We are aware that critics of the performance approach have pointed out that MSDSs are sometimes incorrect and/or incomplete. However, we do not accept this as a valid argument that complete chemical identification should be required, since labels have the same potential for possessing such flaws as do MSDSs. In other words, there is nothing about labels or placards which makes them an inherently better source of chemical composition data. To the contrary, even some proponents of a specification standard feel that the MSDS may be a better source of such information.

In particular, the AISI was referring to a union industrial hygienist, Mr. Michael Wright of the United Steelworkers, who testified (Tr. 907–8):

> As long as several other provisions are complied with, for example, as long as the union could have access to the MSDS without having to go through the process of getting a signed form from the worker giving us that access. If we've got someplace in the workplace we can go to get that information rapidly and quickly, I think it's less important that it be on the label.
>
> There are cases of its being on the label, I think, could create some problems if that was the only place. For example, plenty of plants I've been in, the label is very quickly obscured after the vat's open and people dip out of it a few times, whatever is in it, has come down over the label and you can't read the label anymore.
>
> That, I think happens fairly frequently. Things which are broken up into smaller and smaller containers and used in other places, the label could become very large for small containers and in those cases an MSDS is sufficient for us as long as there's maybe a code name on the container so we know which MSDS is appropriate.
>
> Now, again, two things are required for that. One is the union rep has to be able to go and get the MSDS without needing a signed consent. Second, the MSDS has to be readily available right in the workplace on every shift, can't be in a central office somewhere, in a central computer bank. It's got to be right there where you can go and get it.

Under the provisions of the final standard, Mr. Wright's conditions for accepting the MSDS as the primary source of chemical composition data have been satisfied. Unions are to have direct access without requiring written consent, and the MSDSs are to be readily accessible to employees. In addition, an identifier is required on the container to provide access to the appropriate data sheet. OSHA does not consider a label without an identity to be sufficient for purposes of this standard. The identity allows the employee to link the material in a container in the workplace to the appropriate material safety data sheet which contains additional information on the substance involved. Without that link, the material safety data sheet will not be effective in transmitting the information.

In sum, the final standard requires an integrated program which will provide employees with both identity information and hazard warnings, as well as an explanation of what protective action is warranted in the employee's exposure situation. All of these elements combined will provide employees with the complete information they need to protect themselves. Therefore, the provisions of the final standard answer the concerns expressed and are an acceptable alternative to chemical names on a label.

Several other issues concerning the proposed labeling requirements were also addressed. For instance, a number of interested parties also objected to inclusion of a telephone number on labels on containers leaving the workplace (e.g. Exs. 19–8, 19–54, 19–76, 19–91, 19–115, 19–67, 19–207). According to these commenters, labels on outgoing containers do not usually have telephone numbers on them now, such numbers may change frequently, and in any case, since the name and address appear on the label, the telephone number may be obtained from telephone information. Furthermore, since the telephone number is required on the material safety data sheet, this is considered to be sufficient. Although telephone numbers on labels could be useful information where available, the specific requirement to include them has been deleted from the final standard to accommodate these concerns.

The use of the term "identity" in the proposal was confusing to some of the commenters, who interpreted the requirements as requiring a listing of ingredients on the container because the term chemical was also indicated in the plural form, chemical(s). (See Exs. 19–14, 19–47, 19–79, 19–94, 19–115, 19–141, 19–144, 19–169 and 19–170). The term was expressed in the optional plural form because the employer may choose to list more than one name on the container. For example, if the container has a mixture of carbon tetrachloride and ethylene dibromide in it, the employer may find it appropriate to list those two names on the label. However, if this mixture is known by the common name "80/20," it may be as appropriate to use that common designation in the workplace. Employers are referred to the definition of "identity" for further explanation. Essentially, they may use whatever term they choose, including code numbers, common names, etc., as long as that designation permits access to the associated MSDS with the proper chemical designations of the ingredients.

Several commenters also suggested that the name and address on the label should be for a "responsible party" rather than the manufacturer in every case (Exs. 19–8, 19–54, 19–57, 19–84, 19–91, 19–158, and 19–162). In some situations, a distributor or repackager may be a more appropriate contact for additional information. OSHA has accordingly modified the final standard to permit the designation of a "responsible party" in lieu of the manufacturer, where appropriate.

A number of comments were also received on the ten gallon, immediate use exemption. The majority of those commenting felt that the exemption should be extended to any portable containers intended for the immediate use of the employee (Exs. 19–62, 19–88, 19–94, 19–111 19–115, 19–121, 19–131, 19–145, 19–146, 19–162, 19–185, 19–206, 61, L–16). For example, American Hoechst Corporation addressed the issue as follows (Ex. 19–88):

> The ten-gallon exception from the labelling requirement in subpart (d)(5) is also too restrictive. In continuous, as well as batch processes, fifty-five gallon drums or large mobile containers are used to transfer material within a plant. Employees are thoroughly trained in the handling of such materials and there is no need to label such containers. Any "need" for such labelling should be left to the discretion of the manufacturer.

In the final standard, OSHA has extended the ten gallon, immediate use exemption to any portable container which is intended for the immediate use of the employee, since the size of the container should not be the determining factor as to whether a label is necessary. The key factor is whether its contents are known to the employees exposed to them. It should be emphasized, however, that this labeling exemption is narrowly circumscribed. The final standard includes a definition for immediate use which indicates that it means the hazardous chemical will be under the control of and used only by the person who performed the transfer and only within the work shift in which it is obtained.

A number of participants also indicated that containers already

labeled in accordance with other Federal regulations should be exempted specifically from this standard. OSHA has addressed the overlap with other Federal regulations in the scope section of the standard and provides there for a labeling exemption for certain substances that are already subject to the labeling requirements of other Federal agencies. The only specific exemption which appears in the final standard under the labeling section states that labels applied to comply with the final OSHA standard shall not conflict with any labels applied in compliance with the regulations of the Department of Transportation. The rationales for these provisions are addressed in the discussion of the record under the scope and application portion of the preamble.

The most frequently addressed issue regarding labeling concerned the extent of in-plant labeling of process equipment. Numerous comments were received which indicated that labeling of reactor vessels and other stationary process equipment was neither necessary nor feasible. Some cited the situation involving batch processes where the chemicals in the process change frequently, and thus the employer could not reasonably be expected to update in-plant labeling with similar frequency (See e.g., Exs. 19 (43, 44, 46, 48, 52, 55, 58, 59, 60, 61, 62, 64, 67, 71, 73, 76, 111, 126, 158, 176, 196, 214): 61; 109; 136; 149; 164; 182).

In the preamble to the proposed standard, OSHA addressed this situation and solicited comments on the use of batch process sheets or similar documents as viable alternatives to labeling of equipment with in the workplace. This suggestion garnered considerable support from rulemaking participants. For example, Merck & Co., Inc. commented as follows (Ex.19–52):

> As noted in the background summary portion of the proposal, batch process operations would make labeling, tagging, or marking of process vessels impractical due to the frequent change in vessels contents. The posting of process sheets *in the process area*, which indicates the chemicals in the vessels during the process cycle and appropriate hazard warnings, appears to be a more practical allowance. Many of our chemical operations are batch processed. We have found this means of instruction and communication is very effective for our employees. A representative section from a process sheet shows a warning brief used before the operator is to handle the material:
>
> Soda caustic 25% (1–83462)
>
> Warning! Causes chemical burns. Do not get in eyes, or skin, or on clothing. Wear goggles and nitrometer mask, rubber gloves, and rubber apron when handling exposed liquid. In case of contact, flush affected area thoroughly with copious quantities of water for 15 minutes, then seek medical attention.
>
> Wear Goggles and Nitrometer Mask, Rubber Gloves and Rubber Apron. Adjust pH of batch to 7.5 to 7.7 with soda caustic 25%.
>
> Amount of soda caustic used ————.
> Final pH ——.
> Date ———— Time ————

Other participants in the rulemaking also submitted examples of their batch process sheets or similar forms (see, for example, Exs. 136 and 137).

Process instructions such as those quoted above from Merck & Co., Inc., provide the information necessary to ensure that the employee is informed. OSHA has determined in the final standard that such alternatives to in-plant container labeling should be permitted for all stationary containers, as long as they present the same information required to be on container labels, and are readily accessible to employees in the work area.

An additional issue raised concerning the labeling of in-plant processes involved labeling requirements for pipes and piping systems. The proposed standard specifically exempted these containers from labeling due to concerns regarding the feasibility and effectiveness of such requirements. Many of the facilities covered by this standard contain literally miles of pipes, and employees frequently do not even enter these areas except to perform maintenance or repair activities. Furthermore, in batch processes, the contents of the pipes change frequently (as was described in the discussion above dealing with other process equipment), and therefore accurate labeling of these pipes would involve frequent changing of labels as the batches change.

Industry representatives indicated that practicality determines whether labels are used on pipes and other stationary process equipment, or whether other systems will be used to communicate hazards (e.g., Ex. 19–91; Tr. 1004; 1099–1101; 1808; 2059–2060). For example, a representative of the Chemical Manufacturers Association testified (Tr. 1004):

> * * *A movable container certainly should be identified as it moves about the workplace, but a stationary piece of equipment need not always have to be so labeled.
>
> In many instances, there will be some form of identification on equipment relative to its contents, but in many other cases, there may be only a sign in the area, a symbol, a color code, or simply an operating procedure that outlines equipment contents and process flow covering chemical identifiers, hazards, protective measures, and the like.
>
> Some equipment contents vary from day-to-day, or hour-to-hour, and a reliance upon a sign or a label on something anywhere from one to a hundred feet up in the air would be risky at best, and impractical from an update, changeover point of view. Verbal communications are superior in this situation, coupled with operating procedures.

A representative of the American Iron and Steel Institute also expressed similar concerns (Tr. 2059–60):

> It becomes a practical impossibility in some cases to label something that's carrying molten metal. The label becomes ineffective in and of itself because to get close enough to the label to read it, you would be dead. You can't get that close * * * But to require us to label these things is almost nonsensical because it is so impractical. And if you require us to do it, we're going to have to go up to that label after each use and put back a new label, because the one will be destroyed.

The Chemical Manufacturers Association further elaborated on the determination of whether or not pipes should be labeled (Tr. 1101):

> It depends on the complexity of the operation, the number of pipes. It depends on whether there is a change of process ingredients, if you will, that flow through the pipe. It depends on whether they are designated systems. If we have say acrylonitrile running through a particular line, particular vessel, morning, noon and night, 365 days a year, I daresay you will see that prominently displayed.

A representative of the Teamsters Union also commented on the differences between fixed processes and those where the chemicals change frequently with respect to the appropriateness of labeling pipes (Tr. 2229–30):

> I think the timing of the change in the chemical composition of the vessel itself would probably be relevant to how feasible it would be to change the labeling to line up with the continuation of the process.
>
> If the chemical composition changed once an hour in a five-hour process in coming out with the final chemical, then, it doesn't seem unreasonable to me that since this is a fixed plant operation—it is not moving around—that you could come up with a system of changing the labeling as you went through the process. I am sure that there are other steps that have to take place to actually do the batch into the chemical that it is going the result in.
>
> Changing the label doesn't seem to be that onerous burden to reflect what is going on in the process. If the process is going to have five chemicals come through in 10 or 15 seconds in a process of coming to that end chemical, that presents a different issue and the utility of accurate labeling and changing labeling is going to be somewhat suspect.

Economics Laboratory, Inc., commented on the need to have flexible requirements to accommodate the needs of the various workplaces covered (Ex. 19–162):

As a general observation on the labeling requirements, we wish to state explicitly here the obvious fact that any employer has an abiding interest in the "sufficient" labeling of all containers, large and small, in the workplace. Worker protection and product integrity demand it. This standard would require hazard statements as well. This is most reasonable and practicable for dedicated containers and systems. Keeping such requirements simple and flexible, as we understand to be the intention of OSHA, will go far in promoting continued observation of any such standard.

It is clear that despite practical concerns with labeling, pipes may leak, rupture, or otherwise be involved in creating exposure situations, and thus employees need to be apprised of the hazards and any steps to take to protect themselves. In the proposed standard, employers would have been required to include in their hazard communication program the methods they would use to inform employees of the hazards of non-routine tasks, such as repair and maintenance of unlabeled pipes. For some employees, however, repair and maintenance of unlabeled pipes may be a routine task.

A number of participants in the rulemaking believe that labeling of pipes and piping systems should be included in the final standard (e.g., Exs. 19–112, 36, 60, 63, 64, 74, 108 and 131). For example, in their testimony in the public hearings, the AFL–CIO stated (Tr. 357):

* * *pipes and piping systems should be included in the definition of containers to assure the protection for many chemical workers at high risk from exposure to pipe ruptures, faulty valves, and maintenance activities.

In a joint-hearing submission prepared by four of the unions participating in the rulemaking, it was further stated (Ex. 180A):

Worker and union testimony indicates that many of the most serious exposures to chemical workers result from the rupture of unmarked pipes, faulty or blown valves and from maintenance operations on unmarked piping systems (Exs. 74, 160–2, Tr. 2563, 2579, 3603)* * *

It is difficult to comprehend, however, how labels could be read by employees when a pipe has ruptured, or a valve has blown. Under those conditions, it is likely that the label itself would be destroyed or obscured, and would have limited usefulness to the employee.

Although OSHA agrees that employees need to be informed of the potential hazards in dealing with pipes and piping systems, it is not necessary to require labels on all pipes and piping systems to accomplish it. Industry representatives indicated that a number of methods are used to ensure employees are apprised of the hazards in their work areas. For example, the Chemical Manufacturers Association representative cited above elaborated (Tr. 1005–6):

Personnel in each operation area, supervisor or chemical operator are familiar with the process equipment, piping and chemicals present. Most workplaces where hazardous substances are handled are off-limits to unauthorized personnel. If maintenance is required a line or a vessel must be opened. No work is done until the responsible operation person assures the maintenance personnel that the equipment is completely decontaminated and safe for access. Personal protective equipment is available and highlighted as necessary.

And the American Iron and Steel Institute representative indicated (Tr. 2059–60):

* * *We like to think of the use of other elements such as safe job procedures, placarding an area. The use of warning lights and sirens. The use of safety contacts to communicate to those workers the danger and the hazard with which they are faced.

The Dow Chemical Company indicated that all of their process equipment is labeled with a unique equipment number which may be cross-referenced to the appropriate material safety data sheet (Ex. 19–160). Vessels with a capacity greater than 5,000 gallons are also labeled with a National Fire Protection Association (NFPA) label. Dow further stated (Ex. 19–160):

Dow plant operations personnel are extensively trained to recognize the NFPA markings and to know the contents of all containers at various processing steps. We believe such training is more vital to safe operations than elaborate process equipment labels.

Economics Laboratory, Inc. commented on the fact that labels are sometimes not the most useful alternative for communicating hazards, since the equipment on which they are placed is located some distance from where employees are actually working (Ex. 19–162):

* * * There will be a desk or work station nearby where the mix sheet is kept as the formulation is assembled. We now use that sheet for hazard and equipment information, precisely because it is right where the workers need it when they need it. Even where mixers are used for several different products in a day, the mix sheet necessarily provides the correct identification.

Other testimony similarly indicates that in some cases, labeling will be done, but the requirement for communicating hazards in pipes should be adaptable to the many diverse plant situations (Mr. T. Evans, Monsanto, Tr. 1099–1100):

* * * [W]e have many plants that are, I won't say totally, but they are predominantly identified. We have some that have piping structures, such as the example I held up today, that would be an absolute nightmare and we would probably cause more trouble having people climb ladders and hang signs and identification on something like that than we feel is necessary.

In the final standard, OSHA is requiring employers to include in their written hazard communication programs the means they will use to apprise employees of the hazards of the chemicals in pipes and piping systems in the workplace, and the protective measures employees can use in the event of exposure situations. Employers will thus have the flexibility to use whatever means of communicating the hazards of the chemicals in the pipes and piping systems which they find to be most effective. Since MSDSs will be available in the work area in the event of an emergency, and employees will be trained as to the hazards and actions they are to take, this should provide the necessary protection.

Some of the participants in the rulemaking stated that OSHA does not have the authority to require manufacturers to label containers leaving the workplace (Exs. 19(47, 48, 54, 68, 72, 76, 91, 111, 116, 120, 147, 158); 109; 177). As was discussed in the preamble to the proposed standard, OSHA concludes that it does have such authority, and a discussion of the legal rationale for this finding can be found in the Legal Authority section of this preamble.

5. *Material safety data sheets.* In the proposed standard, material safety data sheets served as the primary vehicle for transmitting detailed hazard information to both downstream employers and employees. This focal role has been maintained in the provisions of the final standard.

A material safety data sheet (MSDS) is essentially a technical bulletin, generally two to four pages in length, which contains information about a hazardous chemical, such as chemical composition, chemical and physical characteristics, health and safety hazards, and precautions for safe handling and use. (e.g. Ex. 19–124). Although their use and availability is fairly widespread in the chemical industry, this is currently primarily a voluntary action since MSDSs are only required under OSHA standards in the maritime industry (29 CFR Parts 1915, 1916 and 1917). Some state right-to-know laws also require the availability of MSDSs (Ex. 16), but most of the sheets have been generated as a good business practice, rather than as a response to legal requirements.

Properly completed MSDSs serve as excellent, concise sources of information regarding the hazard of a chemical. Many participants in the rulemaking endorsed using them as a primary component of the hazard communication program, and cited their own successful use of them as support. For example, Armco, Inc. stated in their pre-hearing comments (Ex. 19–146):

> The OSHA proposal utilizes MSDS's as the primary means for transmitting comprehensive hazard information, instead of labels. Our experience has shown that MSDS's are better than labels for training employees in the safe use of chemicals. We agree with OSHA that employees can more conveniently examine and copy MSDS information for their own use.

Similarly, the National Association of Printing Ink Manufacturers stated: "Since the label is limited in the amount and detail of hazard information which it can contain, the MSDS serves as the source document and reinforcement of the information presented on the label" (Ex. 19–194). The Rohm and Haas Company elaborated on the MSDS's role as a source document by noting that: "Labels, placards, operating instructions, transportation orders, and other hazard communication documents should be based on and consistent with the MSDS" (Ex. 19–115). OSHA agrees, and anticipates that the MSDS will be the first part of a comprehensive program to be implemented, since both labels and training programs will be derived from the information generated for the MSDS.

The Shell Oil Company has designed its own MSDS form, and has utilized it as a primary part of their ongoing hazard communication program. In addition, it has prepared a "User's Guide" which explains the form and its contents in detail, including a glossary of terms (Ex. 19–124). As a result of experience with its MSDS program, Shell stated (Ex. 19–124):

> We strongly support the position taken by OSHA in this proposed rule that the employee's most thorough source of information about hazardous chemicals in the work area must be the MSDS. For several years we have been preparing MSDS's on our products and on process streams in our manufacturing facilities. We have well-developed procedures in place to prepare MSDS's which we believe represent responsible practice and fully meet the basic objectives of the proposed rule.

Some participants noted during the rulemaking that MSDSs have historically been difficult to obtain, and may be incomplete or inaccurate when finally received (Exs. 36, 46, 47; Tr. 98, 1395). Workers cited cases where they attempted to obtain an MSDS for hazardous chemicals in their workplace, but were either unable to do so or had to wait a significant period of time for the necessary information. For example, Jim Bryant of the United Steelworkers of America testified as follows (Tr. 3833–34):

> Just recently, we became aware of the fact that the company does have a record of safety data information and we have a right to ask for it. I think three months ago we asked for the safety data sheet information and they said they would check with it and get back with us.
>
> In our last month's safety and health meeting with the company, I was shown two copies of safety data sheets in which it had their brand name and their coded number and their formula, which they told me was their formula. I asked them at that time if it would be possible for us to obtain copies of this and they told me that they did not want to release that information due to their formula.
>
> I asked if there was any kind of a trade secret or what the problem was and they said they just didn't want their formula to be widespread. At that time, I told them, well, if they wanted to, they could block out the formula, the percentages wasn't that important, but we would like to know what was involved, what different chemicals were involved in the formula. And, the answer given to me was that they would think about it and they would try to work with us on it.

The Department of Defense, as well as downstream employers, also cited difficulties in obtaining MSDSs for products they purchased (Tr. 1377–78; 3680–81).

The adequacy of the information of the sheets when received was also discussed. Angela Oh, of the Los Angeles Committee on Occupational Safety and Health, reported (Tr. 3127):

> * * * we have found in our experience of requesting MSDS's that those data sheets are often inadequate in terms of information about a substance. And, we're talking about very basic physical properties of chemicals that are just left blank. People reading the sheets presume that there's no problem if nothing is written in.

Other participants submitted examples of inadequate MSDSs to the record to illustrate this point (e.g., Exs. 36, 74, and 101).

OSHA recognized the inconsistent quality and availability of MSDSs when the proposal was published (47 FR 12104). The fact that some employers do not voluntarily provide MSDSs, or that when provided the sheets may not contain thorough information, does not detract from the utility of an MSDS in a hazard communication program when it contains the necessary information and is readily available to employees and downstream employers. The provisions of this final standard are thus necessary to establish a requirement for MSDSs, and to ensure that all of industry matches the information transmittal practices set voluntarily by responsible employers. No participants in the rulemaking maintained that properly completed MSDSs are not useful sources of information.

The proposed standard placed the primary responsibility for preparing an MSDS on the manufacturer of the hazardous chemical. The rationale for this approach is that the manufacturer is most likely to have the best access to information about the product, and thus should be responsible for disseminating this information to users of the material. The downstream employers are free to undertake an independent evaluation of the chemical in question, but if they do so, would then assume responsibility for the adequacy and accuracy of the information they use.

This approach of placing the primary responsibility on the chemical manufacturer was supported by many participants. The American Iron and Steel Institute expressed the consensus of many manufacturers who use hazardous chemicals in their processes as follows (Ex. 19–207):

> The current proposal's provisions that chemical manufacturers be responsible for providing MSDS's to purchasers of hazardous chemicals is a greatly needed and indispensable addition. It makes much more sense in terms of total cost, time, and manpower to have the manufacturer prepare and supply MSDS's on its product for its customers rather than to have each purchaser develop its own. Manufacturers having the background chemical data at hand, are in a much better position than downstream employers to provide knowledge about the hazards and other pertinent information on their products. Conversely, users are in a better position for relaying and communicating this information to their affected employees through training and education.

The contention that the chemical manufacturers have the best access to information, and should bear the primary responsibility for preparing MSDSs, was not substantively challenged in the record. In fact, the Chemical Manufacturers Association stated: "* * * we recognize the desirability of having manufacturers provide MSDS's to their customers; indeed most chemical manufacturers currently do so" (Ex. 19–91). Similarly, the American Petroleum Institute noted that: "It is the responsibility of the chemical *manufacturer* to prepare a material safety data sheet for his product, and to make it available upon request to employer/user and as an employer to inform his employees of the hazards" (Ex. 19–111).

Another chemical producer who supported the assignment of responsibility to the manufacturer we Vulcan Chemicals. "As a chemical producer, we have developed and distributed material safety data sheets for our products and we concur that it is desirable for us to obtain MSDS's for the hazardous chemicals we purchase. However, we do not agree that each employer should *develop* an MSDS for hazardous chemicals purchased for use. The development of an MSDS should be the responsibility of the manufacturers of hazardous chemicals or products which contain hazardous chemicals" (Ex. 19–165).

While chemical manufacturers did not generally take issue with assuming responsibility for preparing the sheets, they did raise two objections to the requirements as proposed. First of all, they were concerned that the chemical manufacturer would be held responsible for providing information on the MSDS that only the downstream employer could know based on the specific use of the product, and secondly, many believed the MSDS should only be provided when requested, rather than being furnished automatically as proposed.

The first objection, concerning the provision of specific information in certain MSDS categories, resulted from a misinterpretation of, or a lack of clarity in, the proposed requirements. Employers such as Phillips Petroleum company believed that the proposal required them to know every downstream use of their products, and provide specific information on the MSDS related to that use. Phillips stated (Ex. 19–177a):

> Material safety data sheets are the most effective means of communicating technical and related data to employers who are chemical users. However, the data must be limited to general technical information concerning the chemicals or mixture and not attempt to be an assessment of specific hazards under every possible condition in a downstream workplace. Individual hazard communication programs must be tailored by each user employer.

OSHA agrees that the chemical manufacturer can only provide general information regarding certain items required to be on the MSDS. Nevertheless, this does not mean that the chemical manufacturer should not consider these categories, and provide as much information as the manufacturer has. Similarly, if the downstream employer has additional specific information that is applicable to a given category, the standard does not preclude addition of these data to the sheet to make it specific to that workplace. In any event, workplace-specific information must be incorporated into the training program required by the final standard.

A number of participants suggested that the categories in question, such as engineering controls recommended and procedures for decontaminating equipment, be deleted from the MSDS requirements (e.g., Exs. 19 (46, 54, 59, 76, 91, 162, 194, A–19). OSHA does not agree, since where available this information would be a valuable addition to the hazard communication program. Only control measures which are generally known to the chemical manufacturer or importer are required to be listed. Employers are not required to engage in extensive research to develop recommendations where information is not generally known. In the final standard we have attempted to clarify the extent of the chemical manufacturers' duty, and have indicated the responsibility of the downstream employer to contribute information when extant and appropriate.

It should also be noted that just as a chemical manufacturer cannot make specific control measure recommendations for unknown downstream uses, it also cannot accurately predict the hazard presented by the chemical downstream. Therefore, the chemical manufacturer must provide thorough hazard information, which would be applicable to a full range of reasonably foreseeable exposure situations, rather than limiting the information on the basis of presumed use. The downstream employer will then be assured of having the information reasonably necessary to make informed choices for control measures.

With respect to the second issue, under the proposed standard the chemical manufacturer would have been responsible for ensuring that an MSDS is provided with the first shipment of a hazardous chemical to another employer within the manufacturing SIC Codes. A number of chemical manufacturers objected to this provision, preferring that their customers request an MSDS from them. (See, for example Exs. 19–43, 19–84, 19–111, and 19–119). Two issues were involved in their rationales. One is that OSHA has no authority for requiring automatic downstream transmittal of material safety data sheets. OSHA concludes that the Agency does have such authority, and the legal rationale for this decision is discussed in the Legal Authority section of this preamble. The second is that manufacturers can maintain better control over the transmittal of the MSDS when it is only sent on request. For example, the Dyes Environmental and Toxicology Organization, Inc. submitted the following representative statement (Ex. 19–205):

> Paragraph (e)(5) directs manufacturers to provide their customers with an appropriate MSDS with their initial shipment of a hazardous chemical and with the first shipment after an MSDS is updated. This requirement is inappropriate, even on the assumption that OSHA has authority over downstream shipments of hazardous chemicals. For example, a manufacturer often cannot determine whether a particular shipment to a customer is the first shipment of the chemical to that customer. An MSDS sent with a shipment could well be directed to the wrong location so that the customer's employee responsible for maintaining MSDSs might not receive it. A better, more cost-effective approach is to require the manufacturer to have an appropriate current MSDS for each hazardous chemical it sells. The customer should have to request an initial MSDS, since the customer can best determine when a shipment is the first shipment and to whom the MSDS should be delivered. Therefore the manufacturer can mail updated MSDSs to the proper address.

In the final standard, OSHA has maintained the duty of the chemical manufacturer to provide downstream employers with an MSDS automatically when they purchase a hazardous chemical. The necessity for maintaining automatic provision of the MSDS is amply supported by statements in the record concerning the difficulties encountered by downstream employers in obtaining the MSDSs, and in follow-up time required to ensure their receipt. One difficulty in requiring downstream employers to request information is that they may not be aware that the chemicals that they purchased are hazardous, and that a material safety data sheet is available and thus should be obtained. The American Feed Manufacturers Association testified to this point (Ex. 35):

> Thousands of feed manufacturers are very small firms and most of them use large numbers of ingredients. There is no practical way for the average feed manufacturer to determine if one of the many products which he uses in his business is hazardous if he is not so informed by the supplier of the product.
>
> A downstream manufacturer must be able to assume that no health hazard exists or that the current MSDS is the one in effect * * *

Although small firms have special problems in requesting and obtaining MSDSs, large firms using literally thousands of hazardous chemicals also have significant problems with the "on request" system of obtaining the necessary hazard information. For example, the Motor Vehicle Manufacturers Association presented statistical information in their testimony

which indicated the problems encountered by large companies in obtaining this information despite the significant marketplace pressure they may exert due to the quantities of chemicals they use (Ex. 102):

> MVMA members have experienced varying response to requests for MSDSs. One member company has compiled data on their experience in obtaining MSDSs. The first slide represents the time from the first request made to a supplier to receipt of a response either with or without an MSDS. It can be seen that this can vary from three days to seven months. A second request was usually made within six months.
>
> If multiple requests are made, the response time can extend up to two years, at which time no further requests are made or an alternate supplier has been found.
>
> The next slide indicates that percentage of suppliers responding to requests for information. These figures show that even after four or more requests, almost ten percent of the suppliers had not responded to requests for an MSDS.
>
> The next slide presents figures on chemicals in one member company's inventory. There are 10 to 20 thousand chemical products in inventory. Based on an analysis of 1800 chemicals, there is an average of 5.4 chemicals/product, with a range of from one to twenty-seven. Multiple requests for information or the employer's attempt to obtain information independently on this number of substances would be unduly burdensome. As a result, MVMA feels that the standard must require the inclusion of an MSDS with the first chemical shipment. Since the MSDS is the key element of this proposed standard, MVMA emphasizes the fact that the downstream employer who purchases chemical products cannot obtain as required in the proposal, and MSDS from the chemical manufacturer if the manufacturer chooses not to provide one. Where the required MSDS is not supplied, the purchasing employer can only make a request to the supplier.

OSHA's draft Regulatory Impact Analysis prepared for the proposed standard also demonstrated the cost-effectiveness of automatic transmittal versus an "on request" approach. Since downstream transmittal with the initial shipment is the most cost-effective means of ensuring that downstream employers receive the necessary information, OSHA has concluded that the evidence presented warrants maintaining the proposed provision requiring chemical manufacturers to send the MSDS at the time of the first shipment.

One clarification has been made to the requirement, however, to respond to that part of the arguments which deals with the possibility of sending the MSDS to the wrong person if it is attached to the shipment. The proposed standard's provision concerning downstream transmittal was not intended to imply that the MSDS had to be physically attached to the shipment to comply, as was interpreted by some commenters (e.g. Exs. 19 (8, 48, 54, 55, 117, 124, 147, 162, and 167). The chemical manufacturer may mail the MSDS to the downstream employer, and direct it to any appropriate recipient on the downstream employer's staff. However, it is also possible that attaching it to the shipment may be the preferred means of transmittal in some cases. Some testimony in the record indicates that in the near future, MSDSs may be transmitted to customers via computer link-ups (Tr. 2276; 2341). OSHA is specifying that the information be sent, but not the manner in which it is to be transmitted.

Much of the material in the record addressing material safety data sheets concerns the information to be included in the documents. As discussed above, a number of comments were received suggesting that the requirement for providing information on engineering controls and equipment decontamination procedures, etc., be deleted. (See, for example, Exs. 19–46, 19–59, 19–91, 19–111, and 19–169). Since OSHA maintains that this information, where available to the manufacturer, should be included on the sheets for the use of employees and downstream employers, we have chosen to modify these requirements by indicating that the information to be provided may be stated in general terms rather than to delete them altogether.

A number of commenters similarly suggested that the requirement to include medical conditions which may be aggravated by exposure be deleted. For example, Mobil Oil Corporation stated. (Ex. 19–59):

> While there are examples of underlying medical conditions which would warrant special consideration regarding exposure to a toxic substance, e.g., a worker with underlying kidney disease working with lead, the requirement as proposed in not realistic or achievable. Information regarding the effects of toxic exposure on underlying medical conditions is available only for a very small number of substances.
>
> The employer therefore would be placed in the position of listing theoretical possibilities for which minimal or no supportive data are available. Thus, judgments of whether there could be aggravating effects for every possible medical condition for the most part would be speculative even for the well trained occupational health professional. Requiring every employer to make such determinations is totally unwarranted.

OSHA proposed this requirement to elicit just such information as that cited by Mobil involving workers who have kidney conditions and are to be exposed to lead. This type of data needs to be included on a material safety data sheet when it is know. OSHA does not expect, or require, the MSDS preparer to engage in a speculative activity to predict every type of medical condition which may be aggravated by exposure to a hazardous chemical. However, the utility of the information when available cannot be denied. For example, the Refractories Institute also objected to including such information on the sheets. However, when questioned regarding the usefulness of knowing an employee who was to be exposed to silica had an existing respiratory condition, they testified (Tr. 4072):

> That's one example. We feel that workers exposed to silica should not smoke. I think this has been well established that it aggravates the effects of inhaling silica . . .

Thus, OSHA has maintained the requirement, although it has been clarified in the text of the standard that the information to be included is that which is generally recognized concerning the hazardous chemical in question.

In the proposed standard, the MSDS served as the primary source for information about the chemical identity of the hazardous chemical, and in the case of mixtures, required a listing of those ingredients which were found to be hazardous. The proposal also required CAS Numbers for the chemical or chemicals involved, as well as any applicable common names, including the identity used on the label.

Some commenters thought that the common names or label identity should suffice (Exs. 19–54, 19–71, 19–115, 19–158, and 19A–19). The purpose of providing the chemical identity of the chemical(s) is to provide access to the scientific literature. In most cases, what is considered to be a common name will not serve this purpose (e.g. Tr. 2225). However, as discussed previously under definitions, in some instances a name is commonly used for a chemical which is not a precise chemical identity, but is used in the literature. Thus, using the common name will permit access to the information in the scientific literature. The definition of "chemical name" has been modified to permit this type of designation as appropriate. Other than this clarification, the duty to provide both chemical and common names is maintained as a necessary feature to ensure that employees and downstream employers can make the link between the commonly used designations and the proper chemical identity used in the scientific literature.

A number of comments were also received concerning the requirement to

provide CAS Numbers for the hazardous chemical(s) (for example, Exs. 19–59, 19–76, 19–85 and 19–91). Some pointed out that CAS Numbers are not available for most mixtures. This is true, but the provision was proposed anticipating that CAS Numbers would be provided for the hazardous components of the mixture in question. In addition, some of these commenters suggested that having both the chemical name and the CAS Number on the MSDS is redundant, and that having one would be sufficient to serve the purpose. OSHA agrees with this point. Where available OSHA believes that the CAS Numbers do provide useful information. However, the requirement to list them has been deleted to accommodate the concerns expressed regarding duplicative information.

One other suggestion made by several participants was that it may be more appropriate to provide the name and address for the preparer of the MSDS, or responsible party, rather than the manufacturer (Exs. 19–84, 19–109, 19–144, 19–158). The rationale for this suggestion was that in some cases, if a user of the MSDS is looking for additional information, the original manufacturer may not be the proper contact point. We have modified the standard to allow a "responsible party" to be named on the sheet, by which we mean that the name and address should be for someone who can provide clarification of the information on the MSDS, or additional information if necessary, in lieu of the manufacturer.

One other suggestion made by an interested party was that information should be provided concerning available exposure limits in addition to the required OSHA permissible exposure limit (Ex. 19–71). We agree that such information would be useful, particularly the Threshold Limited Value (TLV) recommended by the American Conference of Governmental Industrial Hygienists (ACGIH), or any exposure limits recommended by the manufacturer, and have included such a requirement in the final standard.

Various other suggestions for information to be included were made by interested parties, such as requiring composition percentages and information needed to comply with other Federal laws (Ex. 19–109). Although these suggestions may provide useful information in some situations, OSHA has determined that they are not necessary to protect employee health. Employers are free to include such information if they wish.

The proposed standard required material safety data sheets to be updated within a reasonable period of time following the manufacturer's becoming aware of any new and significant information concerning the health hazard of a hazardous chemical. The proposal did not specify a particular time period for adding this information to the MSDS. OSHA anticipated that to comply with this standard manufacturers would maintain a current awareness of the hazard information related to the chemicals produced in their facilities.

A specific time period was not established because many manufacturers with batch processes change their products frequently, and may not produce a given product for another year. In that case, it would be reasonable not to prepare and send out updates of the MSDS until the product was being made and sold again. For manufacturers with continuous processes and a stable product inventory, a reasonable time might mean a much shorter period. A number of participants suggested that OSHA specify what is meant by "reasonable" and include a specific time-frame in the final standard (e.g., Exs. 19–40, 19–172, 19–193, 123, 125, 131, 180, L–6). The time periods recommended varied, but we have decided that three months is a reasonable requirement for adding new and significant information to the MSDS. If the product is not currently being produced in the workplace, the information must be added before the chemical is used again.

Another issue of concern to participants in the rulemaking involved blank spaces on material safety data sheets. The proposal required chemical manufacturers to mark the MSDS when no information was found for a given category. The chemical manufacturer would be free to use whatever marking seemed appropriate—not applicable, not available, etc. In order to allow existing, properly completed MSDSs to continue to be used, OSHA stated that until such sheets are updated and marked as required, they would be assumed to mean information was sought but not found. It would thus be the manufacturer's responsibility to ensure that this interpretation is accurate. In other words, the manufacturers with sheets that have not been properly researched before completion were not being exempted from providing complete information by allowing blank spaces for an interim period.

The intent of the proposal was to eventually eliminate the practice of having blank spaces on MSDSs. Downstream recipients cannot be assured that each category of information was properly considered by the manufacturer in completing the sheets if blank spaces are permitted. The Conservation Foundation in its report addressed the need to mark blank spaces as follows (Ex. 18–2):

> • • •(I)f an LD50 acute toxicological test result is not reported on an MSDS, the reader cannot know definitively whether the information is unavailable, omitted by error, or simply not disclosed. Similarly, the absence of information on carcinogenic or mutagenic testing might lead the reader to infer that test results are negative, when actually these results may not be available, or the manufacturer may have omitted the information either accidentally or deliberately. For certain important classes of information, whatever results are available should be presented; otherwise, the statement "not available" or "unknown" should be entered on the form.

Some respondents believe that permitting this practice will encourage some manufacturers to continue distributing inadequate MSDSs. For example, in a joint post-hearing comment submitted by the AFL–CIO, ICWU, UAW and USWA, it was stated (Ex. 180A):

> Specifically, under the proposed standard the agency indicates it would assume that blank spaces on a data sheet meant that a manufacturer had searched for the required information and that such information was not found. However, the record is replete width testimony showing safety data sheets are typically incomplete, failing to reflect known information (Tr. 102, 112, 187, 389, 567, 1052, 1357, 1902, 3090, 3163, 4014, 4099, 4153). Under the OSHA proposal, allowance of blank spaces would, in practice, permit continued use of these incomplete sheets.

Other participants objected to this particular provision because they believed it increased the liability of the receiving manufacturer to an unacceptable degree. The Adhesive Manufacturers Association indicated that (Ex. 19–156):

> The discussion relating to blank spaces on MSDSs concerns AMA. Blank spaces create the potential for unnecessary liability problems. If through some clerical or administrative error a space is left blank, someone could mistakenly assume that no hazard is associated with the particular listing. The use of some term such as "not applicable," "unknown" or "not relevant" would ensure better protection for the manufacturer, downstream receivers and workers.

Conversely, some employer representatives believed that interpreting the blank spaces as meaning information was sought but not found placed an undue burden of responsibility on the manufacturer distributing the sheet. For example, the National Paint and Coatings Association wrote (Ex. 19–62):

* * *Such an interpretation is unfair and unwarranted in the context of the purpose of the MSDS which is to honestly convey useful hazard information. In addition, it fails to recognize human frailty and the likelihood of an inadvertent omission due to clerical error. To presuppose that the mere presence of a blank space is per se evidence that information was sought and not found places an overwhelming burden of absolute perfection on the preparer. Certainly a chemical manufacturer is responsible for the completeness and accuracy of the MSDS and will strive to assure that any omissions or errors are readily corrected* * *

In the final standard, OSHA has merely required that when there is no relevant information for a given category, the chemical manufacturer or importer should mark it appropriately. This should serve the original intent which is to eliminate eventually the practice of having blank spaces on distributed MSDSs. Marking the MSDSs will give extra assurance to employees and downstream recipients that all available information has indeed been included on the sheets.

Several commenters endorsed the use of OSHA's current Material Safety Data Sheet, Form 20, as a standard format for MSDSs (Exs. 19–46, 19–82, 19–98, 19–135, 19–160 and 19A–37). OSHA has determined that in keeping with the performance nature of this standard, a specified format or form should not be required, as long as the necessary information is provided. A number of companies have developed their own formats which they find most useful for their own facilities (e.g. Ex. 19–124). Anyone wishing to use the Form 20 may continue to do so, as long as they ensure that all of the information required by this final standard is provided.

Some participants also suggested that employers be permitted to prepare a single MSDS for a group of related chemicals or mixtures when the hazards do not vary significantly (Exs. 19–57, 19–63, 19–124, 19–194, and 19–209). OSHA has adopted this suggestion in the final standard, and allows one MSDS to be used for similar complex mixtures in certain situations.

6. *Employee information and training.* The final component of the comprehensive hazard communication program proposed by OSHA is employee information and training. Under the provisions of the proposed standard, the employer would be required to provide employees with training about the nature of the hazards they work with, and protective measures to be taken, at the time of initial assignment, and whenever a new hazardous chemical is introduced into the workplace.

Training serves to explain and reinforce the information presented to employees through the written mediums of labels and material safety data sheets. Labels and material safety data sheets will only be successful when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposure, and thus the occurrence of adverse effects. Training is critical to effective hazard communication—it is the forum in which hazard information can best be presented in such a way as to result in workers taking protective action, and thus decreasing the possibility of occupationally-related chemical source illnesses and injuries.

Richard Fleming, in an article which appeared in the *Toxic Substances Journal* dealing with the employer's responsibility for informing workers, addressed the need for training as follows (Ex. 18–8):

In the highly developed and specialized modern workplace, there is usually very little of the new worker's prior experience in the more normal outside environment that sensitizes or trains him or her to perceive the hazards present. Furthermore, a number of these hazards may in fact be imperceptible to the ordinary senses, or even to common sense.

There is, then, no substitute for direct, specific information about the special and inevitable hazards confronted by a worker in a new work assignment. Nothing short of specific knowledge and experience in carrying out the job and the circumstances surrounding it can fully teach the safety needs of that job. It may take more than this, but it cannot take less. Thus, a new worker must rely on adequate and appropriate information and training from those who know the job best * * *.

The record contains considerable support for the concept of employee training programs, and endorses the need to include such requirements in the final standard (see, for example, Exs. 19–11, 19–48, 19–51, 19–119, 19–146, 19–207, L–1, 182, and 19A–18). Individual workers testifying as members of panels during the public hearings provided extensive support for the need and usefulness of training regarding workplace hazards. For example, the following testimony was presented by members of the United Steelworkers of America:

I think the education part of it has a lot to do with it because we had people that were using solvents and there was warning labels on it. The warning label said "Caution: Hazardous Substance. Do Not Get on Your Skin. Do Not Breathe Excess Amounts of it," and the people, they washed their hands with it and they breathed it and everything else until we told them what it was doing to them, how it was affecting their liver and was possibly a carcinogen.

Since then, our people don't wash their hands with it anymore and now they take the precautions—once they are provided with the proper information of what it actually could do to them, then they care.

(Foster, Tr. 973)

* * * Workers are human. They don't want to lose their hearing, or vision or ability to breathe or anything else and I think the big thing lies in education, proper education.

I think you folks ought to give it serious thought in promulgating any standard to put the burden and responsibility where it belongs, on the employer, to ensure that you have adequate training and education programs in relation to the hazards associated with any chemical.

* * * It really falls into the court of the local union in many cases to ensure that they advocate training and education programs. It shouldn't have to be, it should be mandated by law that all employers are responsible for that type of program.

(Brown, Tr. 973–74)

Employer representatives were also enthusiastic in their support of the need for training provisions in the final standard for hazard communication. The American Iron and Steel Institute stated that (Ex. 19–207):

Employee education and training is a critical link in the successful implementation of any hazard communication regulation; without it, such a rule would be ineffective. AISI believes that the education and training provisions included in the current proposal are vital to the implementation of a complete and effective Hazard Communication Standard * * *.

Similarly, the American Textile Manufacturers Institute also endorsed the need for training provisions (Ex. 19–60):

The most serious shortcoming of the earlier proposal lay in its failure to accept the importance of training. There was no way for the extensive specification detail to have overcome the training omission. Indeed, training must be at the center of any occupational program for dealing with hazards in the workplace. Every workplace has its own peculiar characteristics around which a training program must be designed and flexibility is needed depending upon their variety and degree of hazard. Thus can every worker be made to understand and be aware of the potential hazards he faces and learn to treat the chemicals he handles with the respect they are due.

The American Chemical Society, a professional organization, supported the inclusion of employee training as well (Ex. 19–206):

The American Chemical Society believes that the use of good work practices is a very effective way to reduce chemical exposure risks. The responsibility to insure such practices lies with both the employee and employer. Good work practices can be maintained best through employee training

and safety programs. Training programs should apprise employees of: (1) potential hazards to which they may be exposed; (2) methods of protection; (3) the employee's role in reducing potential exposure; and, (4) employee rights and responsibilities under the standard.

Union representatives supported the concept of employee training, but were concerned that the training would not be adequate for purposes of hazard communication. For example, in a post-hearing submission from the AFL–CIO, ICWU, UAW and USWA, it was stated (Ex. 180A):

> Without question, effective training on workplace chemicals is an important part of a comprehensive hazard communication program. Workers and unions support and welcome meaningful training (Tr. 2518, 2530, 2541, 2551, 3390). Indeed, training on workplace chemicals is a major part of union health and safety activities (Exs. 49, 58, 74, 80, 90, 101, 107, Tr. 2550, 3390). However, the record clearly shows that, despite employers' claims to the contrary, meaningful training programs conducted by chemical manufacturers and employers are rare. Training on workplace chemicals is absent entirely or conducted by Supervisors who themselves have little information, as part of meaningless safety talks, "tool-box" talks, or "tail-gate" talks (Tr. 745, 1899, 2554, 3107).

The unions further stated that since, in their opinions, training efforts by industry have been inadequate to date, OSHA should ensure that training provisions in the final standard not be used to supplant other requirements. In particular, they believe that the disclosure of chemical identities of substances in the workplace is the only assurance workers will have of obtaining complete information on the hazards.

As previously stated, OSHA considers training to be one of three vital components in a comprehensive hazard communication program. No one of these three components alone—labels, material safety data sheets, or training—can be demonstrated to be completely effective in communicating hazards. Therefore the final standard has not been designed to use the training requirements to supplant the other aspects of the hazard communication program. The purpose for having training provisions in the hazard communication standard is to establish minumum information requirements for these programs, and to help ensure that all employees will receive the information they need. As with the MSDS requirement, the fact that existing training programs are sometimes inadequate of non-existent simply demonstrates the need for having a comprehensive standard to require that such programs are implemented, and that they meet established criteria.

There is evidence in the record to support OSHA's contention that effective hazard communication, and particularly training, reduces the potential for chemical source illnesses and injuries. For example, the Ethyl Corporation established a pilot program to reduce lead exposures in employees, as measured by lead levels in their urine and blood (Ex. L–8). They instituted a comprehensive training program on the industrial hygiene aspects of lead exposures, and included means to motivate employees to use good work practices to reduce their exposures. Over the twelve months of the program, urine lead levels decreased by 40% and blood lead levels by 24%.

This reduction in exposure, as measured by biological monitoring, was attributed to the employee motivation techniques employed during the training program. The Ethyl Corporation is now expanding this program to other employees, and considers their training to be a cost-effective and proven method of reducing exposures.

Teamsters Local 2707 testified during the Los Angeles session of the public hearings that, following training they presented on hazardous chemicals to employees of World Airways, the illness and injury incidence rate decreased nearly 30 percent. Ms. Nancy Garcia Stated (Tr. 2826):

> The employer found a significant decrease in the number of injuries and illnesses, and I think that part of that has to do with an awareness on the part of the employees of the chemicals and of the nature of the hazards in the workplace.
>
> I think the more information you can give to people, the better informed they're going to be, the more responsible they're going to be, in both the employer and the employee.
>
> We expected some good results, but we didn't expect the 30 percent decrease.

Local 2707 provided further information regarding their training program, and the change in incidence rates, in a post-hearing submission (Ex. 153). From 1980 to 1981, the injury/illness incidence rate dropped from 26.7 to 20.65 for World Airways. Another employer who did not undertake such a training program with the union experienced an increase in their incidence rate during the same time period.

During the public hearings, OSHA asked members of a United Steelworkers worker panel to describe what types of training they thought would be appropriate and effective. They replied as follows:

> * * * we need some type of scare tactic to the workers to let them know right across the board the danger that's involved in the chemicals and as far as the training program is concerned, I think that the company should have these training programs on a regular basis and not one that is brought up simply because of an investigation or something of this nature.
>
> (Guilbeau, Tr. 2552)
>
> I'd say a formal training program, periodic retraining, you know, slide shows, what I would call perhaps based on a blood and gut film, you know, here is a picture of what it will do to you type thing of what the chemical will do to you, stuff like that, and information—what you call a training program, you know, more or less, scare the people or something like that so they'll never live with that stuff.
>
> (Phillips, Tr. 2552)
>
> Well, I'm in full agreement with the training. You can take any label you want to and no matter how good that label is, you know, people have a tendency to look over these labels like the one that is on these cigarettes right here. The Surgeon General has determined that * * *. There are millions of Americans that have overlooked that every year.
>
> You take them same Americans, take them out and show them a good blood and gut film, give them first hand experience on what it will do to a lung or a heart or whatever, you know, that will change their minds. Training is the only way and retraining.
>
> (Walters Tr. 2553)

These statements indicate that employees could assist their employers in designing training programs which will accomplish the desired effect of modifying worker behavior. Employee assessments of training and other hazard communication program elements can provide good feedback to the employer in terms of qualitatively assessing the effectiveness of the information transmittal. Some employers are already using such evaluative tools. For example, PPG Industries, Inc. included in their submission some comments received from workers concerning their program (Ex. 19–85). In addition, the Hazardous Materials Identification System (HMIS) devised by the National Paint and Coatings Association (NPCA) includes a quiz to give employees which can objectively ascertain whether the presented information has been understood (Ex. 18–5).

The proposed provisions were performance-oriented, listing the categories of information to be transmitted to employees, but not specifying how this was to be accomplished. A number of participants endorsed this flexible approach (see Exs. 19–64, 19–67, 19–91, 19–176, 19–210, 167), while others suggested that the requirements should be more specific (Ex. 19–89, Tr. 2270–71). OSHA has made minor modifications to the

requirements in response to specific comments, but in general, the training provisions are largely the same as those proposed. In particular, the final standard expressly requires employers to train employees regarding protective practices implemented in their workplace, and specifically states that employers must explain the labeling system used and how to obtain and use material safety data sheets.

Several participants suggested that training should be given when the hazard changes in the workplace, rather than each time a new chemical is introduced. Since in some facilities chemicals change frequently, retraining would be done almost constantly, even though the actual hazard of the operation does not change. (Exs. 19–45, 19–63, 19–67, Tr. 1316–17). Similarly, other commenters suggested that due to the large number of hazardous chemicals in some work areas, the employees should be trained on the hazards of the process or operation, rather than specific chemicals (Exs. 19–188, 19–201, 19A–18, 19A–19). This suggestion has been incorporated into the final standard. However, specific information still must be available to employees for each hazardous chemical on the material safety data sheets.

Other participants suggested that periodic retraining be provided (e.g., Exs. 19–114, 122, 131). Although OSHA would certainly encourage employers to provide retraining if they wish to, the greatest need for training is prior to initial assignment, and when the hazard changes, requiring the employee to be aware of new procedures or protective measures. Since the employees will always have visual reminders of hazards in the form of labels, and will have ready access to detailed sources of hazard information (the MSDSs), these should serve to reinforce the information provided in initial training and the sessions provided when the hazard changes.

7. *Trade secrets.* One of the most difficult policy questions raised by this standard involves the treatment of hazardous chemicals that are considered trade secrets by the chemical manufacturer or employer. The general policy of OSHA reflected in this rule is that the interests of employee safety and health are best served by full disclosure of chemical identity information. OSHA acknowledges, however, and the record in this proceeding fully supports, the critical need to protect trade secret information because the economic well-being of the employer and its employees may be dependent upon the protection of such information, and once lost, its value as a trade secret cannot be recaptured. For these reasons, OSHA has a special responsibility to strike a particularly fine and creative balance in order to accommodate both the health interest in limited trade secret disclosure and the economic interest in trade secret protection. As discussed below, we believe that the record has pointed the way toward achieving this twin goal while minimizing any potential conflict between the two competing interests. It does so by permitting OSHA to narrowly define the circumstances under which specific chemical identity must be disclosed and to authorize the use of confidentiality restrictions that are necessary to protect the value of the trade secret to its holder. Both aspects of the rule are essential to the establishment of a responsible trade secret disclosure policy.

As a legal matter, OSHA has consistently taken the position that the Act requires OSHA to balance and accommodate employee occupational safety and health with the protection of trade secrets (45 FR 35248–51; 47 FR 12107). OSHA's basic legal authority to carry out this mandate has been upheld in a District Court decision, *Louisiana Chemical Ass'n et al.* v. *Bingham, et al.*, 550 F. Supp. 1136 (W.D. La., 1982) the appeal of which is pending in the Fifth Circuit Court of Appeals (No. 83–4099).

Implementation of this legal authority in the context of particular rulemakings is largely a matter of policy discretion. There is no one scientifically correct way to balance the competing interests. OSHA first faced this regulatory dilemma when it issued its rule on access to employee exposure and medical records, 29 CFR 1910.20. The records access rule took the approach of requiring the disclosure of all chemical identities to employees and their designated representatives, as well as their levels of exposure and health status data regarding "toxic substances", regardless of any trade secret claims. However, it permitted the conditioning of access to such information on the signing of confidentiality agreements, as well as the withholding of any trade secret process or percentage of mixture information. At the same time, OSHA expressly stated that the confidentiality agreement requirement was not intended to authorize the employer to demand penalty bonds or agreement to liquidated or punitive damages provisions. 29 CFR 1910.20(f); 45 FR 35274–75.

Responding to concerns expressed by industry representatives that the records access provisions were not sufficiently protective of trade secrets, OSHA's approach to trade secret disclosure in the hazard communication proposal was modified in several respects. First, a distinction was drawn between "high chronic hazard" chemicals and other hazardous chemicals with respect to the employers' duty to disclose their specific chemical identities. Second, a distinction was made between treating physicians and others with a "need to know" with respect to their access to trade secrets. Third, OSHA expressed its neutrality with respect to the terms of confidentiality agreements by not including a prohibition on the use of "reasonable" penalty bonds, liquidated damages provisions, and the like. This latter proposal had previously been the subject of a proposed modification to the records access rule (46 FR 40492), but was subsequently merged into the overall reconsideration of the records access rule in recognition of the fact that the issue of confidentiality agreements cannot be viewed in isolation from related issues (47 FR 30429).

Thus the hazard communication proposal permitted an employer to withhold precise chemical identity from anybody other than a treating physician if the employer could "substantiate that it is a trade secret" and that the chemical was not a "carcinogen, mutagen, teratogen, or cause of significant irreversible damage" for which there is a "need to know" the precise chemical name. When withholding such identity information, the employer was required to identity the chemical by a generic chemical classification which would provide useful information to a health professional and to disclose all other information required on the data sheet. When trade secret information was to be disclosed, the employer could condition employee, designated representative, and downstream employer access to such information upon acceptance of a "reasonable confidentiality agreement" which could "provide for compensation or other legally appropriate relief."

A number of commenters expressed general agreement with the approach taken in the proposal, although not without reservations in some cases (Exs. 19–40, 19–62, 19–65, 19–69, 19–73, 19–79, 19–91, 19–116, 19–119, 19–135, 19–146, 19–188; Ex. 182; Tr. 1318, 2023). However, the trade secret issue remained an area of great controversy and wide disagreement. Several employers stated that the proposal was insufficiently protective of trade secret interests (Exs. 19–44, 19–63, 19–87, 19–115, 19–155, 19–

165, 19–168; Ex. 177, 179). This view stemmed primarily from a belief that protecting trade secrets is of paramount concern to a chemical manufacturer, and essential to maintaining a viable business. The Chemical Manufacturers Association, while generally supportive of the proposal's basic approach, stressed the importance of trade secrets to them:

> Protection of trade secrets is essential to the chemical manufacturing industry. In the industry, formulations and the techniques for making them are an essential part of a company's edge over its competitors.
>
> The research that is required for the development of new chemicals and mixtures will be undertaken only if the results of the research are protected from competitors to permit a return on the investment in research.
>
> (Ex. 19–91)

> Numerous chemical manufacturers, as well as other companies and trade groups within the coverage of this proposed standard, have testified to the importance of trade secret protection to them. While it is difficult to attach a reliable monetary figure to this protection, there can be little doubt that the protection of proprietary information is of paramount importance. Indeed, the very existence of the extensive legal protection afforded under the patent system and trade secret law attests to the importance of encouraging research by permitting those who develop a new product to obtain financial rewards from the sale of that product.
>
> (Ex. 182)

The need for greater protection of trade secrets was particularly expressed by some manufacturers in specialized lines of business:

> For [a chemical speciality] manufacturer, its trade secrets may constitute its most valuable assets. Such trade secrets usually cannot be protected by patents. Were the rule to require revelation of trade secrets to customers, confidentiality agreements would not preclude the customers from switching to other sources of the same products which bear no development costs, resulting in irreparable injury to the manufacturer, * * * [or] from reverse engineering the competitive product, also injuring the manufacturer * * *.
>
> By insisting on revelation of trade secrets, the proposed rule substitutes a requirement to provide information for a mandate to communicate hazards. Unless OSHA can adequately restrict its exclusion from trade secret protection to circumstances where identified persons have a need to know directly related to employee safety health, OSHA should not require that trade secrets be revealed to anyone except physicians (and then on a confidential basis).
>
> (SOCMA, Ex. 19–44)

> * * * formulas cannot be safeguarded once they are disclosed * * * Both [the flavor and fragrance] industries rely heavily on their abilities to maintain the secrecy of valuable product formulas that are painstakingly developed over long periods of time and at great expense. It is no exaggeration to say that these secret formulas are the primary assets of the industries * * *. Trade secret information should be disclosed [only] in those cases where there is a significant hazard to workers and the disclosure will significantly alleviate the hazard.
>
> (D. Thompson, Flavor and Extract Manufacturers Association, Fragrance Materials Association, Ex. 27–15)

> Basic chemicals are generally marketed under their chemical name. There is very little need for restriction or secrecy regarding the chemical identity of these products. In chemical mixture formulations, however, the ingredient information is the crucial trade secret, very often the only trade secret. In mixtures, it is the synergism, antagonism and overall blend of chemical and physical properties of specific chemical substances in specific ratios that give the mixture unique properties and allows it to function as desired. This specific formulation of a firm's product is the key to its competitiveness in the marketplace. Once the chemical ingredients have been ascertained, formulation is easily duplicated. For this reason, disclosure of the chemical ingredients destroys the secret or confidential nature of this specific product formulation * * *. Because without trade secret protection the chemical identity disclosure provision would unduly jeopardize trade secrets of a small chemical processor like Master Chemical, this protection must be provided for in any final rule.
>
> (Master Chemical Corporation, Ex. 19–87)

By contrast, unions and other employee advocates approach the trade secrets issue from an opposite perspective. In general, they argue that to achieve the occupational health goals of the standard, all chemical identities must be disclosed to employees and their designated representatives, subject only to the kinds of basic confidentiality agreements permitted by the records access rule when *bona fide* trade secrets are involved. (Exs. 19–172, 19–175; 122; 123; 168; and 180A; Tr. 305, 612, 1647, 1838, 1938, 2092, 2235, 2643, 2693, 2934, 3057, 3105, 3279, 3602, 3640, 3788, 3978, 4031, 4107). These representatives contend that the trade secret provisions would inadequately protect employee health interests because they maintain that specific chemical identity rather than hazard warning information is the essential ingredient of a hazard communication standard (AFL–CIO, et al., Ex. 180A):

> While the two are inextricably linked, chemical identity is the key—you cannot get chemical identity from a hazard warning, but the chemical identity will provide you with access to hazard information.

Viewed from this perspective, the proposal "improperly subordinates worker health interests to employer trade secret claims" because "for those chemicals deemed trade secrets, specific chemical identity may be withheld, subject to certain conditions, even though the employer has determined that the chemical is hazardous." (AFL-CIO et al., Ex. 180A, p. 55).

Downstream employers who purchase chemicals from chemical manufacturers and are dependent on them for chemical identity information generally expressed views similar to the unions' with respect to their own need for access to trade secret identity information:

> * * *a manufacturer should not be allowed to withhold the chemical identity of any chemical which "contributes substantially" to the hazards of a mixture and for which there is a need to know the specific chemical identity in order to provide a safe workplace. Downstream employers, for example, may need to know the specific chemical identity of an ingredient in order to monitor the level of airborne contaminants. This would be true even if the ingredient does not fit the description listed in subsection (g)(1) (ii) [for "high chronic hazards"].
>
> (American Paper Institute, Ex. 1973)

> We feel that the latitude provided chemical manufacturers in identifying most chemicals by the broad generic chemical classification will substantially hinder the efforts of safety and health professionals to determine the requirements for safe usage of specific products.
>
> It is commonly accepted that both the product constituents and the method of application are equally important to determining the potential hazard posed by a particular product. By withholding specific identification of chemicals in lieu of generic chemical classifications, the user's hazard evaluation process can be severely compromised. Some chemical manufacturers have contended that the use of generic classifications, in conjunction with their assessment of the potential hazards, would provide sufficient information for users to determine the requirement for safe usage. We feel that this argument falls short since chemical manufacturers cannot be familiar with the variety of ways in which their products may ultimately be used. * * * We feel the benefits to be derived in fully disclosing the constituents of a hazardous material far outweigh the risk (real or imagined) that may be incurred by chemical manufacturers as a result of disclosing this information.
>
> (Caterpillar Tractor Company, Ex. 19–201)

The proposed standard deals with the generally recognized need for trade secret protection in some depth, but the proposed standard does not address some circumstances which a downstream user of chemical products may encounter.

For example, Chemical Product A, containig xylene (TLV=100 ppm) as a component known to an employer and its employee, could be used in such a way as to produce a known employee exposure below the OSHA TLV. At the same time, Chemical

Product B which contains an unknown amount of trichloroethane (TLV = 350 ppm) because of trade secret status may be used by the employee in such a way as to produce a simultaneous exposure that exceeds the additive TLV limitations for mixtures imposed by existing OSHA regulation. Thus, the employee's health may not be adequately protected, and his employer could be subject to an OSHA citation.

We suggest that the proposed standard require that a chemical's identification be disclosed if such chemical may potentially produce synergistic or additive toxic effects with other chemicals and that the precise chemical name be disclosed in any case in which the chemical product contains a component regulated by name, by OSHA.

(West Point Pepperell, Ex. 19–150)

Similarly, both the National Paint and Coatings Association and the Motor Vehicle Manufacturers Association testified that precise chemical identity is essential to their efforts as downstream employers to evaluate the hazards of chemicals they purchase, and that they undertake considerable effect to obtain this information from their suppliers when it has initially been withheld on trade secret grounds. (Tr. 564, 675–81, 3684–86). Because of their need for this information, the MVMA expressed concern that the proposed trade secret provisions might result in an overuse of the trade secret exemptions permitting the withholding of chemical identity under certain conditions (Tr. 3682). In general, however, these employers report less difficulty than do the unions in obtaining trade secret information concerning chemical identities when needed for occupational health purposes (Tr. 598–605, 679–81).

These basic positions on the trade secret issue led to some specific criticisms of the proposal. Several commenters said that there is a need to define "trade secret" (Ex. 19–65, 19–91, 19–155, 19–164, 19A–11). The CMA (Ex. 19–91; Ex.182), Procter and Gamble (Ex. 19–116), and Michelin Tire (Ex. 19–155) each recommended that a definition be taken from the Restatement of Torts (s757), since it is widely accepted and has been adopted by the common and statutory law of many states. Under this definition, chemical identity could be considered trade secret if, essentially, it is not known or used by a competitor. OSHA has incorporated a slightly modified version of this definition into the final standard.

While the Restatement of Torts definition is generally recognized as an appropriate basis for a regulatory definition, a more difficult question is whether a chemical in commerce whose identity can be ascertained by well-known analytical techniques — "reverse engineered" — should be considered known to the competitors and therefore not a proper subject for a trade secret claim. Underlying this discussion is a wide disparity of opinions on the relative ease with which complex chemical mixtures can be "reverse engineered."

With modern analytical laboratory equipment, and a limited amount of time and funding, the constituents of most chemical products can be readily identified. This vulnerability of product constituents to identification, in our opinion, negates the validity of the standard's trade secrets provision.

(Caterpillar Tractor Company, Ex. 19–20)

The plain fact is that most chemical identities are not and cannot be trade secrets today because of the relative ease with which they can be discovered by independent means through gas chromatography and mass spectrometry. Although some natural food flavorings and chemical intermediates may attain trade secret status, the vast bulk of chemical identities simply are not a secret under the law. A heavy burden should be placed on those who claim trade secret status unless they can fit into one of these small categories.

(California Department of Industrial Relations, Ex. 22C–18)

Typically a trade secret is claimed in a case where a solvent manufacturer's supplier, for example, takes a—let's say an aliphatic hydrocarbon and adds a chlorinated hydrocarbon to raise the flash point, sells it as safety solvent, charges three times for the mixture what his costs were for the ingredient, says that's trade secret.

Now, you know, in all those cases the buyer or a competitor could easily obtain it and analyze it, if they cared to. So it's really not a trade secret from anyone except the workers forced to use it.

Mr. Michael Wright, United Steelworkers of America, Tr. 854)

In general industry presents a different picture of the relative ease of reverse engineering complex chemicals that are trade secret:

The makeup of a chemical product, which is the essential knowledge providing the competitive advantage to a manufacturer, is frequently not ascertainable by competitors through analytical processes. "Reverse engineering" is not always possible. Chemical reactions may mask the identity of an ingredient, and materials present only in small quantities may not show up in laboratory analyses. Procter & Gamble estimates, for example, that an analysis to determine in detail the ingredients of its BOLD–3 would cost as much as $300,000—and might still be unsuccessful. Thus, in the absence of an OSHA disclosure requirement, these trade secrets would not be available to competitors.

(Chemical Manufactures Association, Ex. 19–91)

It is the presence of traces of trade secret ingredients or unique combinations of ingredients, that make those fragrances successful. History shows that the formulas of leading perfumes have been maintained as trade secrets for decades.

(Mr. Wallace Dempsey, Fragrance Materials Association, Tr. 3417)

The popular belief that it is now a simple matter for a competitor to determine the exact chemical composition and percentages of various formulations by "reverse engineering" is incorrect. While reverse engineering is theoretically possible, its usefulness is extremely limited. The analytical procedures involved in reverse engineering are extremely complicated and expensive. The complexity of the procedures make it virtually impossible to obtain accurate, reliable, results. Moreover, the cost of the procedures make it economically prohibitive. The cost has been estimated to be between $50,000 and $1 million dollars or more per sample, with no guarantee that the exact composition will be determined. However, if the precise chemical components of a product are supplied, via labels or any other means, the percentage of any given chemical in the formulation is relatively easy to determine. As a result, once the precise chemicals are known, the product can be duplicated by any competitor who cares to spend $500 to $10,000 to determine the precise percentage of each chemical in the formulation.

(Master Chemical Corporation, Ex. 19–87)

OSHA has determined that the record does not provide adequate support for using "reverse engineering" capability to modify the trade secret definition. It is clear from the statements quoted above that there is no consensus regarding the ease or practicality of reverse engineering. Furthermore, as a practical matter, it is impossible for the Agency to develop criteria for when reverse engineering would be considered feasible and thus would negate a trade secret claim. Many products can be reverse engineered if sophisticated analytical techniques are applied, and yet cannot be if less advanced technology is used. The determination of what is "practical" in terms of reverse engineering capability rests with this degree of analysis, rather than with a definitive finding of "ability" to be reverse engineered or not. Furthermore, the definition of a trade secret says that the competitor or potential competitor does not know *or* use the information. Thus, even though a competitor could theoretically "reverse engineer" and discover the components of a product, if this information is not in fact used, it remains a *bona fide* trade secret.

The question of trade secret definition also relates directly to a second set of comments involving the proposed requirement that the employer be capable of substantiating that the withheld information is a trade secret.

The unions and some employers testified that excessive denial of information on unsubstantiated trade secret grounds has been a significant problem to date. The AFL–CIO summarized the situation as follows (Ex. 180A):

> The record demonstrates that employer and chemical manufacturer trade secret claims have routinely been overbroad (Tr. 896, 1491, 1492, 1495, 1524, 1539, 3275–6, 3279). Union requests are frequently met with an initial employer response that all or a large proportion of chemicals are trade secrets (Tr. 896, 1890, 1495, 3640). When subjected to further scrutiny, these claims are often found to be invalid (Tr. 853, 1891) * * *
>
> The unions are not alone in their experience of broad trade secret claims. The Motor Vehicle Manufacturers Association, Ford Motor Company, Caterpillar Tractor Corporation, and Department of Defense all report difficulties in securing chemical identity information in the face of trade secret claims (Exs. 46, 102, 113, App. 1, Tr. 604 * * *

Although the CMA has cautioned that past experience in the absence of a standard is not a proper guide to how many trade secret claims will be made and predicts that the number of trade secret claims will be few (Ex. 182), the concern has been expressed that the substantiation requirement of the proposal would not prevent unjustified claims (Exs. 19–51; 180A). For example, the AFL–CIO et al. stated (Ex. 180A):

> Substantiation of trade secret claims is required but there is no requirement to commit the substantiation to writing or make it available for review to employees, designated representatives or OSHA. Thus, manufacturers and employers will be allowed to continue overly broad, invalid trade secret claims with no justification.

Certain employers whose primary concern is the protection of trade secrets have also expressed the need for a mechanism to be created whereby OSHA could monitor trade secret claims and referee, in the first instance, disputes that arise over the validity of a claim (Exs. 19–155; 27–6, 27–10, and 27–27). The suitability of conventional OSHA enforcement mechanism for this purpose has been described by the Michelin Tire Company (Ex. 19–155):

> It is Michelin's position that disputes about trade secret claims under the labeling standard should be resolved through conventional OSHA enforcement mechanisms. If an employer conditions the release of trade secret information on the execution of a confidentiality agreement and the employee or designated representative objects to the employer's decision, the employee should file a complaint with OSHA alleging that the labeling standard has been violated. OSHA should then make a limited inspection or request for information to determine if a citation is warranted. If OSHA issues a citation, litigation under normal administrative enforcement procedures should resolve any disputes between the parties.

OSHA agrees that the statutory enforcement mechanism will be satisfactory to investigate and in many cases settle disputes of this nature. In order to clarify the enforcement proceedings to be followed, OSHA has incorporated the specific steps into the provisions of the final standard. To facilitate these proceedings, OSHA is requiring that requests for trade secret information be prepared in writing, with supporting documentation, and that any denials of such requests also be written and include appropriate evidence. Then if the matter is to be referred to OSHA to settle any dispute between the requesting party and the employer protecting a trade secret, the Agency will be able to base a decision upon a review of these written materials. Should the matter not be resolved to the satisfaction of all parties, it may result in a citation and referral to the Occupational Safety and Health Review Commission (OSHRC) for judicial review. The OSHRC Judge may decide the case based on an *in camera* review of the documents prepared by the parties. The matter will then be resolved through the normal OSHRC enforcement proceedings.

Many comments were received on other aspects of the proposed trade secret provisions. For instance, a number of commenters observed that the authorization to withhold the "precise chemical name" under certain conditions suggested that the CAS number would nevertheless have to be disclosed, thereby negating the protection afforded (Exs. 19–43, 19–46, 19–52, 19–85, 19–115, 19–140, 19–146, 19–155; Tr. 2997). Since this was not OSHA's intent, the final standard has been written to make clear that all specifically identifying information may be withheld if the chemical identity is being withheld as a trade secret.

A more fundamental set of questions involves the issue of which trade secrets, if any, should be required to be disclosed, under what circumstances disclosure should be required, and to whom this information is appropriately disclosed. Discussion of these questions was generally in the context of addressing the proposed requirement that only "high chronic hazard" chemicals needed to be disclosed to downstream employers, employees and designated representatives with a "need to know," but that in any event, all trade secret identity information must be disclosed to a treating physician.

The proposal equated "high chronic hazard" with any "corcinogen, mutagen, teratogen, or a cause of significant irreversible damage to human organs or body systems" for these purposes. Other than some general agreement with the proposal, there was little or no specific support for having regulatory consequences turn on a distinction between these chemicals and other hazardous chemicals. Numerous commenters criticized the lack of definitions for the critical terms as making the provision unduly vague (Exs. 19–44, 19–46, 19–63, 19–65, 19–76, 19–89, 19–109, 19–123, 19–155, 19–164, 19–196, 19–204, 19–219; Tr. 2185, 2200–1, 2324). Some commenters thought that the terms, unless narrowly defined, would result in the overcategorization of trade secrets as "high chronic hazards" (Exs. 19–44, 19–46). For example, SOCMA stated (Ex. 19–44):

> Furthermore, the proposed rule could be interpreted to exclude from trade secret protection virtually all substances or mixtures. Just as any substance could be a "hazard" under the proposed definition, so any hazard could be considered a "cause of significant irreversible damage to human organs or body systems", at a sufficiently large exposure level.

Other commenters expressed concern that these categories could be interpreted too narrowly, both because inherent scientific uncertainty may permit a holder of trade secrets to deny that virtually any chemical is a proven "carcinogen, mutagen, [or] teratogen" (Tr. 1938, 2185–6, 2200–3) and because a chemical could cause "significant" damage to humans that may nevertheless be revrsible (e.g., Kepone, DBCP) (Ex. 180A; Tr. 3641–2).

Lack of definition was not the only criticism directed at the proposed distinction between "high chronic hazards" and other hazardous chemicals. Arguments were also made that the proposed distinction was both overinclusive and underinclusive. Thus, a few commenters argued that "mutagens" should not be considered "high hazard" because "no link between mutagenicity and workplace safety has been demonstrated" (Exs. 19–91, 19–115, and 19–105). On the other hand, arguments were made by several employers that the categories of hazardous chemicals to be disclosed on a "need-to-know" basis should be expanded to include "suspect" carcinogens, mutagens, and teratogens (Ex. 19–90), OSHA regulated substances (Ex. 19–90, 19–150), chemicals that have established TLV's (Ex. 19–90), and chemicals that cause synergistic or additive effects when combined with

other chemicals (Ex. 19–150). In addition, the American Lung Association commented that chemicals which cause acute toxic effects should be included in any mandatory disclosure requirement regardless of trade secrets (Ex. 19–154). The Federal Advisory Council on Occupational Safety and Health suggested that the standard should require the disclosure of "all hazardous chemicals which are recognized hazards that are causing or likely to cause death or serious physical harm to an employee, or if those chemicals are known to be carcinogens, mutagens, teratogens, or sensitizers when in low concentrations." (Ex. 125). And the AFL–CIO and supporting unions recommended that the more inclusive term "reproductive toxin" be used instead of "teratogen"; that the "significant irreversible damage" category be replaced by all chemicals which cause "a material impairment to health"; and that the "need to know" qualification be dropped (Ex. 180A).

A more fundamental criticism was that a distinction based on degree or kind of hazard is not a rational basis for making a categorical determination that certain trade secrets must be disclosed and others need not. For example, The CMA stated (Ex. 182):

> The hearings have not, however, provided sufficient reason to maintain the proposed standard's special treatment of the so-called "high chronic hazards." It has not been established that trade secret information that might be revealed under this provision (subsection (g)(1)(ii)) would add to employee protection. Epidemiological studies based on this information remain a rarity. There has been little evidence that trade secret claims have posed a barrier to such studies that would otherwise have been undertaken, much less that the limited category of trade secrets under the proposed standard would interfere with studies of this type.
>
> Rather, the same principles that govern the release of trade secret information for other hazards should logically be applied to the chronic hazards. As the foregoing comments have demonstrated, the proposed standard reasonably reconciles disclosure interests and trade secret interests. There is no basis in the record for the special treatment of the "high chronic hazards"

This position was generally shared by a number of employer interests (Exs. 19–46, 19–79, 19–111, 19–123, 19–147, 19–164). By the same token, the recommendation of the AFL–CIO and supporting unions was sufficiently broad as to constitute a rejection, from the opposite perspective, of the proposed different treatment for "high chronic hazards" and other hazardous chemicals as well. Thus, the proposed approach with respect to "high chronic hazards" was not favored by either employer or employee interests.

Many of the same commenters who believed that no special status should be afforded to "high chronic hazards," however, agreed that the "need to know" concept is an appropriate basis for making regulatory decisions. At one level, this qualification on trade secret disclosure takes the form of saying that trade secret identities should not have to be routinely revealed on labels and data sheets, where virtually anyone regardless of need can see the information (Exs. 19–47, 19–123; Tr. 700–1). At a somewhat different level, support for the "need to know" concept was expressed in terms of saying that trade secret information should only have to be disclosed in response to a request for the information from somebody who has a legitimate health need for it (Ex. 19–91, 19–155, 19–185; Ex. 167; Tr. 763). For example, the CMA stated (Ex. 182):

> There is no real conflict between the interest of the employee and the employer's interest in preserving its trade secret unless the employee has a real need to know the identity of a chemical. The "need to know" standard is an appropriate means of balancing these interests.

The Celanese Corporation commented (Ex. 19–185):

> * * * this standard should only disallow trade secrecy protection where the employee needs to know to protect himself and where the downstream employer needs to know to protect his employees * * *.
>
> Celanese suggests that OSHA take a different approach to this problem. For chemical manufacturers: if there is a need for a downstream employer to monitor his employees' exposure to a chemical, there is a need to know the precise chemical identity.
>
> For employers: if there is a need for an employer to monitor exposure of his workers to a chemical (whether he does it or not), there is a need for the employee to know its identity.

While the unions expressed concern that the "need to know" phrase "could be used to bar effective access to critical information" (AFL–CIO et al., Ex. 180A), in general they agree that there is a balance to be struck between the needs of employers to protect legitimate trade secrets and the needs of employees to obtain information concerning legitimate health interests (Tr. 844, 903, 2215–16, 3291, 3652, 4122–23).

Based on the information provided by various parties concerning the uses for which chemical identity information is necessary (e.g., Exs. 19–51, 19–207; Tr. 1945–6), OSHA considers the following to be purposes which demonstrate a medical or occupational health need to know specific chemical identity under the provisions of the final standard:

1. To assess the hazards of the chemicals to which employees will be exposed.

2. To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels.

3. To conduct pre-assignment or periodic medical surveillance of exposed employees.

4. To provide medical treatment to exposed employees.

5. To select or assess appropriate personal protective equipment for exposed employees.

6. To design or assess engineering controls or other protective measures for exposed employees.

7. To conduct studies to determine the health effects of exposure.

With respect to the question of who should be given access to trade secret information, there was general agreement that a treating physician should have access to any trade secret chemical identity that is needed for medical diagnosis or treatment of an employee exposed to the chemicals (Exs. 19–44, 19–46, 19–87, 19–88, 19–155, 19–193; Ex. 182; Tr. 598).

> * * * whenever a physician requests specific ingredient information for our products this information is provided to the doctor without hesitation. Master Chemical has no objection to supplying whatever information a physician may deem necessary for the treatment of a patient. On occasion we have even provided samples of the raw materials that make up the product. Master Chemical feels secure with the professional ethics of physicians and the confidentiality of their files.
>
> (Master Chemical Corporation, Ex. 19–87)
>
> The desirability of requiring disclosure to treating physicians—under terms of confidentiality—is undisputed. The proposed standard clearly meets this employee interest by requiring this disclosure.
>
> (Chemical Manufacturers Association, Ex. 182)

To this, some employers would add the qualification that even a treating physician should be required to document the need for the trade secret identity (e.g., that general chemical classification and toxicological information will not suffice) and enter into a confidentiality agreement (Exs. 19–44, 19–63, 19–158, 19–193).

While nobody objected to trade secret disclosure to treating physicians under appropriate circumstances, many commenters criticized the proposal for not providing the same general access to other health professionals (Exs. 19–40, 19–51, 19–73, 19–89, 19–161, 19–207, 19–

211; Exs. 158, 180A; Tr. 442, 558, 763, 1945–46, 1960–61).

MVMA regards the primary objective of this standard as prevention of unsafe and unhealthful exposures. To meet this objective health professionals, other than the treating physicians, need to be aware of health problems which may be the result of occupational exposure to a substance or mixture designated as trade secret. Such health professionals would include those responsible for the industrial hygiene programs and environmental control programs (i.e., appropriate disposal). MVMA recommends that such health professionals be included in obtaining information on a confidential basis.

(Motor Vehicle Manufacturers Association, Ex. 19–51)

I think certainly on a need to know basis, any member of a health care team, whether it is the physician, industrial hygienist, the occupational health nurse, safety professional, certainly needs to have information available to them, but on a need to know basis.

(Mr. L. Keller, PPG Industries, Tr. 763)

With regard to preventive medicine, withholding chemical identity information interferes with the ability of a physician hired or retained by a user employer to devise a proper medical surveillance program. For example, if the manufacturer of a chemical has not performed an adequate hazard evaluation and fails to mention the hepatotoxic effects of a trade secret ingredient, how will the company doctor catch the mistake and know to include liver function tests in a medical surveillance program?

Or if biological monitoring is desired to assess chemical exposure or body burdens, how will the company doctor specify a test if he or she doesn't know what chemical or metabolite to test for?

Physicians who are consultants to labor unions also have a proper need to know chemical identity information. Labor unions use consulting physicians to review the adequacy of company designed medical surveillance programs and just as with the doctors retained by the user employers, labor union doctors must know the chemical identities of work materials to independently arrive at a proper medical surveillance program.

In selected cases, physicians for labor unions also review the medical records of members who have suffered serious illness suspected of being work-related. Although the unions' doctors act as consulting physicians and not treating physicians, the union doctors can have a valuable role in suggesting further clinical testing or laboratory analysis to help determine work-relatedness.

* * * I, myself, am called upon to review industrial hygiene programs of companies where we have members and if I don't know what chemicals the people are working with, I have no idea, for one, whether—the kinds of controls that are in place are adequate. Whether they should be doing more monitoring to look for exposure. And if the type of personal protective equipment being provided—which there normally is some provided—is adequate to do the job.

(Mr. M. Nicas, IUE, Tr. 1945–46; 1960)

The one thing that I was going to add as far as epidemiology that we face situations where outside researchers have been brought in by local unions to do studies and they haven't been able to get a lot of different kinds of information, but some of that has been chemical identity information, trade secret information that has made their studies much more difficult.

(Ms. J. Gordon, IUE, Tr. 1960–61)

* * * these health professionals (consulting physicians, epidemiologists, industrial hygienists, toxicologists, or other health professionals) need full chemical identity information to evaluate potential health problems from actual exposure and recommend and institute appropriate controls (Tr. 442, 558, 763, 1960, 3304). Without full access to chemical identity information worker health protection cannot be assured (Tr. 564, 810, 1483, 1513, 1940, 2037).

(AFL–CIO et al., Ex. 180A)

Since other health professionals (e.g., occupational nurses, industrial hygienists, toxicologists; etc.) may have a need to know certain proprietary information, we recommend that "any necessary health representatives" be added to "treating physician." In this way, pertinent data can be made accessible to all critical personnel involved in the occupational health care system, without unduly burdening physicians with the sole responsibility for information collection.

(American Iron and Steel Institute, Ex. 19–207)

The CMA panel presented the only direct refutation of the arguments in favor of broadening the access provided to "treating physician" to encompass other health professionals who need identity information to carry out their occupational health duties. They stated that the greater urgency involved in a medical emergency where chemical identity is crucial to a specific diagnosis or treatment warrants special exception for treating physicians; and that with other health professionals, it is often sufficient to provide them with chemical and toxicological information which does not reveal the specific trade secret identity. At the same time, they recognized that there may be some instances where specific trade secret identity should be provided to other health professionals subject to confidentiality agreements (Tr. 1204–11). For instance, Dr. Curtis Smith stated (Tr. 1207):

I'd like to add that certainly we are interested in working with the professionals in other companies to help them in protecting their employees, but that—if confidential information is involved, that does take some working out of confidential agreement or of providing the information without reaching the trade secret.

Moreover, some commenters expressed concern about providing access to "designated representatives" (other than treating physicians) in general without focusing on the "other health professional" issue. In addressing this question, the CMA panel drew a distinction between access by local union representatives who work inside a plant, and union representatives from outside the given workplace where the identity of a trade secret chemical is being sought (Tr. 1087–88, 1088–89):

Most union representatives are employees also * * * I am talking about the local union representative. The local union representative is an employee and as such he would have as much information as any other employee.

Where it was a company proprietary bit of information he would also have the same obligation to keep that confidential within the confines of the company. So, there is no bar against the union representative provided it is on a localized basis.

But the (international) unions represent many different clients, so that they have a multiplicity of relationships and in that regard represent the outside world. The other fact that has to be kept in mind and it is critical for a trade secret, is how many people know about it and under what conditions was it made available. The more people who know a trade secret, the less it is a trade secret.

In its post-hearing comments, the CMA suggested the following on the question of "treating physician" versus "designated representative" access in general (Ex. 182):

Two employee witnesses on behalf of the ACTWU testified that disclosure to a treating physician would fully satisfy their interest in chemical identity information. (Tr. 4111, 4013).

(Another) interest, in access to chemical identity to permit the union to perform its own evaluation of the material, has been asserted by some union witnesses (although the testimony of the employee witnesses just described suggests that this interest may be of more concern to union officials than to the workers). Provision of trade secret information to a union is a matter of concern to many companies, in part because the union may well represent employees from competitive companies, thereby adding to the risk of disclosure and the harm in case of disclosure.

It argued that the issue of union access to trade secrets is best left to NLRB jurisdiction. Similarly, Michelin Tire Co. recommended modifying the definition of "designated representative" to encompass only "physicians" (Ex. 19–155):

By limiting the "designated representative" concept to physicians, several goals will be accomplished. First, the employee will have complete personal access to the information

required by the standard regardless of any limitation on the concept of "designated representative." Second, the employee may designate a representative who can effectively respond to any medical problem arising from the hazard communication information. Third, the employer must disclose sensitive information only to individuals who are subject to ethical rules of conduct and disciplinary sanctions. While unauthorized disclosure of trade secrets and confidential information is still possible, it is unlikely when release is limited to licensed individuals acting in their professional capacities.

Neither of these comments, however, explain why other health professionals have a less legitimate need for identity information than do physicians, or why they are less trustworthy to protect trade secret information given to them in confidence to carry out their professional health duties.

Based on this record, OSHA has decided to provide access to trade secret chemical identity to health professionals providing occupational health services to employees, while permitting the chemical manufacturer, importer or employer to withhold such information from other "designated representatives" who are not health professionals. It is noteworthy that neither downstream employers nor unions who argued for broadened access to trade secrets made specific arguments that such access was necessary for non-health professionals within their organizations. Indeed, they indicated that it was their practice to restrict their own access to such information to their health professionals and, as necessary, exposed employees.

(Confidential information) is available only to the health and environmental professionals, all of them are aware of the confidential nature and how we treat it. It's maintained centrally at staff rather than out in the operations.

The only exceptions to that would be (if) one of the physicians at one of our operations, or medical, wanted to get that information for medical purposes * * * They would have access to that.

(Mr. L. Roslinski, Ford Motor Company, Tr. 599–60)

We will readily agree that the only people in the union who will have access to that kind of information (i.e. trade secret chemical identity) are several of us who are working on that case specifically and as far as the union is concerned are the ones who need to know and that's typically—For example: one of our industrial hygienists, perhaps Dr. Parkinson, perhaps one other person.

(Mr. Michael Wright, United Steelworkers of America, Tr. 903)

Except in a medical emergency, the standard permits access to trade secrets by health professionals to be conditioned on a written statement of need and the signing of a confidentiality agreement, conditions which most commenters believed to be essential to striking a proper balance between the legitimate need for trade secret protection and the legitimate health needs of employees. The standard, however, no longer draws a distinction between "high chronic hazards" chemicals and other hazardous chemicals for purposes of access, since the record did not support the distinction as providing a rational basis for balancing the competing interests. In addition, in response to a comment requesting clarification on the question of OSHA's own access to trade secrets under the standard (Ex. 19–155), the standard explicitly provides that OSHA shall be provided access to such information upon request, and further states that any trade secret claim "shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections implemented."

It should be noted that in providing for access by health professionals and in eliminating the proposed disclosure requirements for certain "high hazard" chemicals, direct employee access to the specific chemical identities of such substances has been eliminated from this standard. Under the proposed standard, employees or their designated representatives would have had access to such identities if there was a "need to know" the precise chemical identity. The reasons for eliminating the distinction for disclosure of identities between "low" and "high" hazard chemicals has already been described. In addition, OSHA has indicated in the discussion various purposes for obtaining such information that would constitute a "need to know." A review of these purposes reveals that by and large professional training would be required for any of these activities. Given the lack of control a chemical manufacturer or importer has over "downstream" employees, OSHA believes that providing access to trade secret chemical identities only to health professionals on a confidential basis will protect these employees adequately while providing protection for the *bona fide* trade secrets of employers. This is not to say that "downstream" employees are more likely to disclose trade secrets or violate confidentiality agreements than health professionals, but it is an unmistakable fact that the more people who have access to confidential information, the more difficult it is to preserve its secrecy or to locate the source of a leak if one occurs. In any event, employees will continue to have restricted access to the identities of all toxic substances known to their own employers an a non-confidential basis under the records access rule.

The final area of discussion involved the issue of confidentiality agreements. The focus of this discussion was on the question of whether the standard should explicity authorize or prohibit the practice of requiring penalty bonds or liquidated damages provisions in such agreements. As noted earlier, this question was the subject of a prior proposed modification of the records access rule, the docket of which has been incorporated into the record of this rulemaking (Ex. 27). A number of employers commented that OSHA should permit the use of such contractual devices to strengthen their remedy in the event of an unauthorized disclosure of trade secrets (Exs. 27–6, 27–7, 27–9, 27–10, 27–11, 27–12, 27–14, 27–18, 27–19, 27–20, 27–21, 27–23, 27–25, 27–26, 27–27, 27–37). Several employers, however, including some who supported the proposed change, stated that confidentiality agreements, with or without bonding or liquidated damages provisions, were ineffective in protecting their economic interest. The key to protection was to restrict access to trade secrets in the first place (Exs. 27–14, 27–15, 27–16, 27–24, 27–25, 27–29, 27–34). For instance, Daniel Thompson, representing trade associations in the flavor and fragrance industries, commented (Ex. 27–15):

Liquidated damage clauses or penalty bonds are totally inadequate for a number of reasons. To begin with, bonding is commercially unavailable and legally insufficient as a protection against unconsented disclosures. First, blanket bonds routinely exclude the types of actions which can cause the loss of the valuable secret, e.g. mishandling of the information or a dissemination which cannot be prosecuted as a fraud under state law. (*P. Gordis, Property & Casualty Insurance* (12th Ed. 1965). Second, a bonding firm is most unlikely to write bonds covering individual union members or ex-employees against passage of the secrets. Third, bonds would not repay the employer/innovator where the union can show unintentional dissemination in any fashion; the secret is lost but the bonding company would probably refuse to pay. (Note, "The Freedom of Nonfree Information", 32 Stanford L. Rev. 339 (1980) Liquidated damages, likewise are easier to permit than they are to collect; few designated representatives have sufficient assets to pay liquidated damages or to post penalty bonds. Under the standard, anyone may be made a designated repesentative with an unqualified right to records. For those designated representatives that do have assets, for example, labor organizations, difficult problems of proof may well have to be

overcome by the wronged employer before he could received any relief through a liquidated damages clause. Moreover, the availability of labor organization funds for this purpose is at least uncertain.

An accused designated representative could defend himself by stating that the employer's competitor independently discovered the trade secret without relying on records wrongfully obtained through the access standard. The burden of proof would be on the wronged employer.

If a labor union entered into a secrecy agreement with a liquidated damages clause and its employee admitted to wrongfully disclosing trade secret information, the union could defend itself by stating that its employee's act was *ultra vires*. The wronged employer would be left without remedy unless he could prove otherwise. These are but a few of the numerous practical and legal problems with the proposal.

Even if all of these problems could be overcome; the net result, a cash award to a wronged employer, could not begin to compensate for the financial loss caused by disclosure of (some of our more popular) trade secrets * * *

For their part, the unions universally object to any authorization of bonding or liquidated damages provisions (Ex. 19–161; Exs. 27–28, 27–36, 27–38, 27–39, 27–41, 27–42, 27–43, 27–44, 27–45; Tr. 900–1, 3145–46). For example, the AFL–CIO, et al. stated (Ex. 180A):

When employers do agree to disclose chemical identities deemed trade secrets, the proposal permits employers to condition employee, designated representative, and downstream user access upon acceptance of a restrictive confidentiality agreement. Bonding requirements and liquidated damages clauses may be permitted as conditions for access. However, there is no evidence in this rulemaking record showing union or employee abuse of trade secret information which would justify restrictive conditions (Tr. 92, 859, 3522). Rather there is substantial evidence demonstrating that conditioning the release of trade secret information on written agreements with bonds or liquidated damages clauses is infeasible. Bonding agencies are reluctant to guarantee against the disclosure of information whose value cannot be assessed (Ex. 27). And not one union or employee representative testified that they would sign a confidentiality agreement which contained a clause for liquidated damages as a condition for receiving trade secret information (Tr. 377, 568, 603, 680, 702, 856, 2474, 3686). Thus the proposed restrictions are, in practical terms, the equivalent of denying workers, their designated representatives and user employers access to chemical identity information.

These comments point out the legal and practical risks both parties face when trade secrets are divulged on a confidential basis. Breach of confidentiality serves no one's interest. Because this is so, it is important that the trade secret holder and the health professional seeking the information enter into explicit agreements which set forth the conditions under which the trade secret is being disclosed and will be maintained. It is also important that each party understand the consequences of failure to live up to the agreement. OSHA has concluded that confidentiality agreements serve a important function in striking the balance between trade secret protection and health need. Short of a total ban on disclosure, limiting access to health professionals who state their need for the information and sign confidentiality agreements assures as much as possible that the necessary information is being entrusted to a minimal number of responsible, identifiable and accountable individuals. Confidentiality agreements impress upon the recipients of this information their obligation to use this information for the stated health purposes and to protect the provider of the information from competitive harm. To this end, the standard explicitly states that the confidentiality agreement may "restrict the use of the information to the health purposes indicated in the written statement of need," and "prohibit disclosure of the information to anyone other than OSHA who has not entered into a similar agreement without the consent of the employer." Overall, these authorized restrictions should effectively deter inadvertent or unauthorized disclosure of trade secrets. As stated by Michelin Tire Company (Ex. 27–16):

Perhaps the most important feature of any effective confidentiality agreement is a provision prohibiting any redisclosure of the trade secret to any person or organization who has not executed a similar confidentiality agreement. Such a provision is absolutely essential and is totally consistent with the purposes of the access rule in that it: (1) Allows access to exposure records containing trade secrets to all necessary persons; (2) ensures that the employer knows exactly who has had access to its trade secrets at any given point in time and will thereby assist the employer in enforcing his confidentiality agreement if it is breached; (3) ensures that each person who has access to the trade secrets fully realizes his disclosure responsibilities and is thereby deterred from nondisclosure; and (4) greatly reduces the uncontrollable casual redisclosure and dissemination of trade secrets which presently renders the confidentiality agreement provisions of the (records) access standard impotent.

The reference to OSHA disclosure was included to ensure that the confidentiality agreement does not preclude the health professional from disclosing information to the Agency, particularly when the potential harm to employees is great and the holder of the information is not providing proper protection. The standard does require the health professional to inform the holder of the information that OSHA will be receiving it prior to such disclosure. OSHA is required to protect the confidentiality of such trade secrets under Section 15 of the OSH Act.

While the primary function of a confidentiality agreement is to establish the conditions of trade secret disclosure and therefore preclude inadvertent or unauthorized dissemination of the confidential information, it is also important to recognize that, from a legal standpoint, the agreement constitutes a contract that is enforceable in the courts. As such, it may be appropriate that it contain not only provisions relating to the primary duties of the parties, but also provisions relating to remedies in the event of a breach. It is basic contract law that a party wronged by a breach of contract is entitled to actual damages, and that where the injury that will be caused by breach is difficult to estimate, as is the case of trade secrets, a provision liquidating the damages to be paid will be literally enforced if the court is convinced that it is a genuine pre-estimate by the parties of the extent of likely injury. Where such a provision is agreed to, it provides the advantage of greater certainty to both parties. On the other hand, where the stipulated amount is so large as to be out of proportion to the interest to be protected, it will be treated as a penalty or forfeiture and not enforced. Corbin, *Corbin on Contracts,* Ch. 58 (1964).

Accordingly, OSHA has concluded that the authorized confidentiality agreement may include a provision for "appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages." This language is designed to permit the kinds of liquidated damages provisions that would be enforced by any court, but not to permit penalty or forfeiture provisions that are inappropriate to a contractual agreement. At the same time, OSHA has decided to explicitly prohibit requirements for the posting of a penalty bond. Unlike liquidated damages, which must approximate actual damages and are payable only in the event of a breach, a bond would require the advance posting of money, is not dependent on the occurrence of any breach, and could easily act as an absolute barrier to access. Access to trade secret identity information is intended to be mandatory provided certain basic conditions of need and confidentiality are met. It would defeat the occupational health purposes of the

standard if holders of the information were given the freedom to set the terms of access prohibitively high by requiring the posting of penalty bonds.

Finally, OSHA recognizes that, while a confidentiality agreement provides a contractual basis for seeking remedies in the event of a breach, there may well be other non-contractual remedies available in law or equity to the trade secret holder. Milgrim, *Trade Secrets*, §§ 4.01–4.03 (1982). For instance, injunctive relief may be appropriate under certain circumstances, or, depending on the terms of the contract and the intentions of the parties, a tort action may be available in addition to or as an alternative to a contract action. While the measure of damages in tort would not be materially different than that in contract in most cases, there may be differences in terms of such factors as statute of limitations or elements of proof. In addition, punitive damages may be available in tort for willful or malicious disclosure or misappropriation of trade secrets. They may also be available under certain statutes authorizing such damages. Milgrim, *Trade Secrets*, § 7.08 (1982). Thus, to clarify that the confidentiality agreement is not meant to limit the trade secret holder to only contractual remedies if other remedies are available under state law—indeed, a confidentiality agreement is permitted but not required—the standard explicitly states that "nothing in this standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law."

In this way, the standard assures that chemical identity information which is trade secret is made available to those who need it but is not disclosed to others who may be in a position to use it to the competitive disadvantage of the trade secret holder. Employee protection is thus assured while maintaining the confidentiality of *bona fide* trade secrets.

8. *Effective dates.* In the proposed standard, OSHA staggered the projected effective dates by facility size (i.e. number of employees); whether the hazardous chemical is a pure substance or a mixture; and whether the employer is a chemical manufacturer or user of hazardous chemicals. The purpose of the staggered dates was to allow downstream employers to take advantage of the flow of information generated by chemical manufacturers to comply with the standard. The underlying approach was that larger employers would have to be in compliance first, and thus smaller firms could obtain information from them in time to meet their own compliance dates. This scheme was designed to comply with the Regulatory Flexibility Act, which requires Federal agencies to assess the impact of regulations on small entities, and establish different compliance standards for them where it is feasible, legal and desirable to do so.

As was pointed out by a number of commenters, the proposed scheme did not accomplish this intended effect (see, e.g. Exs. 19–58, 19–62, and 19–219). The primary problem is that small manufacturers may supply larger manufacturers with hazardous chemicals, and in those situations, the larger manufacturers would have to be in compliance with the standard before their smaller supplier was required to give them the necessary information. Small manufacturers may not be benefitted by this scheme as intended, as the U.S. Small Business Administration explained in their written comments (Ex. 19–58):

> Although OSHA attempted to properly analyze the impact of the rule, the fact that supply channels are not a function of size was not thoroughly addressed * * *
>
> To the contrary, it is a common phenomenon for small manufacturers to supply substances and/or mixtures to larger manufacturers. We understand that small manufacturers believe a staggered phase-in would not be beneficial to them because either:
>
> a. Large manufacturers would demand hazard information from their small suppliers; or
>
> b. Small manufacturers would supply their larger customers hazard information before OSHA required as a result of other market pressures.

Various suggestions for alternative time frames were submitted to the record. The majority of those commenting suggested that the time frame be the same for all employers, regardless of the number of employees involved (e.g. Exs. 19–46, 19–65, 19–79, 19–110, 19–147, 19–177, 122, 123, 125, and 180A). As expressed by Phillips Petroleum, Inc. (Ex. 19–177a):

> * * * The number of employees at any workplace has no direct bearing on the number of chemicals in the workplace. The time element will depend upon the number of chemicals to assess and the availability of qualified personnel to collect data, classify hazards, prepare material safety data sheets and develop or adopt a training and information program. Most companies can comply in a shorter period of time. However, all companies should be able to comply within two years.

Other participants suggested different time periods, generally ranging from one to four years (see, for example, Exs. 19–46, 19–62, 19–76, 19–91, 19–111, 19–119, 19–124, and 19–167). No specific justification was presented for any of the time frames suggested.

In the final standard, OSHA has followed the suggestions of the majority of participants who commented and modified the schedule of effective dates. A time period of two years has been established for labels and material safety data sheets to be transmitted downstream, and two and one half years for all employers to be in full compliance with the standard. This will permit downstream employers who use hazardous chemicals to take advantage of information generated upstream to design and implement their internal hazard communication programs. It will also shorten the proposed time frame for full compliance by one year, and thus employees will receive the full protection of the standard at an earlier date than originally anticipated.

D. Legal Authority

Authority for issuance of this standard is found primarily in sections 6(b) and 8(g)(2) of the OSH Act, 29 U.S.C. 655(b) and 657(g)(2). Section 6(b)(5) governs the issuance of occupational safety and health standards dealing with toxic materials or harmful physical agents. Section 3(8) of the Act, 29 U.S.C. 652(8), defines an occupational safety and health standard as:

> (A) standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.

The Supreme Court has said that section 3(8) applies to all permanent standards promulgated under the Act and requires the Secretary, before issuing any standard, to determine that it is reasonably necessary and appropriate to remedy a significant risk of material health impairment. *Industrial Union Dep't* v. *American Petroleum Institute*, 448 U.S. 607 (1980).

The "significant risk" determination constitutes a finding that, absent the change in practices mandated by the standard, the workplaces in question would be "unsafe" in the sense that workers would be threatened with a significant risk of harm. *Id.* at p. 642. This finding is not unlike the threshold finding that a chemical is toxic or a physical agent is harmful. *Id.* at 643, fn. 48. This finding, however, does not require mathematical precision or anything approaching scientific certainty if the "best available evidence" does not warrant that degree of proof. *Id.* at *pp. 655.6;* 29 U.S.C.

655(b)(5). Rather, the Agency may necessarily base its findings largely on policy considerations and has considerable leeway with the kinds of assumptions it applies in interpreting the data supporting it. *Id.*

Moreover, under the authority of section 6(b), and specifically section 6(b)(7), OSHA may issue certain kinds of "backstop" requirements that are essentially "information-gathering" in function. These requirements may be imposed at levels of risk below what would be necessary for the setting of exposure limits because they serve the purpose of "keep[ing] a constant check on the validity of the assumptions made in developing the permissible exposure limit, giving it a sound evidentiary base for decreasing the limit if it was initially set too high." *Id.* at p. 658 (footnote omitted). By logical extension, the same kinds of requirements may be imposed even where there are no such limits set if there is substantial evidence to support them, since such information is necessary to see if levels should be set in the first instance.

Further elucidation on the characteristics of a section 6(b) standard has been provided by the United States Court of Appeals for the Fifth Circuit in *Louisiana Chemical Ass'n., et al.* v. *Bingham, et al.*, 657 F. 2d 777 (1981). In that case, the Fifth Circuit concluded that, as a jurisdictional matter, OSHA's records access rule, 29 U.S.C. 1910.20, must be treated as a section 8 regulation, and not a section 6 standard, mainly because the rule: (1) Does not require the employers to make the records in the first place but applies only to records which they already make; and (2) pertains to thousands of substances not even specified as "hazardous." *Id.* at p. 781. This conclusion was further supported by the Court's finding that the records access rule fits neatly within the language and history of section 8, with its emphasis on enforcement and detection of hazards via recordkeeping. *Id.* at p. 783.

The hazard communication standard stands in contrast on all three counts. First, it affirmatively requires the evaluation of chemical hazards and the development of material safety data sheets, labels, and education and training programs to transmit this information. Second, the core requirements concerning the establishment of hazard communication programs (i.e. data sheets, labels, and education and training) pertain only to "hazardous chemicals." The hazard determination procedures and supporting definitions are designed so that only chemicals for which there is scientific evidence of actual hazards are made the mandatory subject of hazard communication programs. Of course, in fashioning the hazard determination procedures, the Secretary was entitled to rely on conservative scientific assumptions and was not bound to limit the scope of the rule only to those chemicals for which sufficient evidence exists to set exposure limits, since the law and sound public policy recognize the basic distinction between disclosure requirements and more onerous, comprehensive "command and control" requirements. Thirdly, the standard fits neatly within the language and history of Section 6(b)(7) which pertinently states that:

> Any standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure * * *

The fact that it is being issued as a generic standard and is stated largely in performance language does not alter its essential character as a 6(b) standard.

Moreover, the practices mandated by the standard—hazard evaluations, written hazard communication programs, labels and other forms of warning, material safety data sheets, and education and training—are, at bottom, directed not merely at the identification of workplace chemicals, but more significantly at the correction of their hazards as well. This correction will occur largely as a result of employee compliance with instructions on how to protect themselves when exposed to hazardous chemicals that are an integral part of any hazard communication program, as well as by other hazard-reducing strategies adopted by employers (e.g., chemical substitution). And because, as is discussed at greater length elsewhere in this preamble, the record clearly indicates that inadequate communication about serious chemical hazards endangers workers and that the practices required by this standard are necessary or appropriate to the elimination or mitigation of these hazards, the Secretary is hereby able to make the threshold "significant risk" determination that is an essential attribute of all permanent standards.

The Secretary's authority to issue this proposed standard is further supported by the general rulemaking authority granted in section 8(g)(2) of the Act. This section empowers the Secretary "to prescribe such rules and regulations as he may deem necessary to carry out (his) responsibilities under the Act"—in this case as part of, or ancillary to, a section 6(b) standard. The Secretary's responsibilities under the Act are defined largely by its enumerated purposes, which include:

> —Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions (29 U.S.C. 651(b)(13));
>
> —Building upon advances already made through employee and employer initiative for providing safe and healthful working conditions (29 U.S.C. 651(b)(4));
>
> —Exploring ways to discover latent diseases, estabishing causal connections between diseases and work in environmental conditions * * * (29 U.S.C. 651(b)(6));
>
> —Encouraging joint labor-management efforts to reduce injuries and diseases arising out of employment (29 U.S.C. 651(b)(13);
>
> —Developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems (29 U.S.C. 651(b)(5)); and
>
> —Providing for training programs to increase the number and competence of personnel engaged in the field of occupational safety and health (29 U.S.C. 651(b)(8); 29 U.S.C. 670(c)).

Because the hazard communication standard is reasonably related to these statutory goals, and will also have the effect of enhancing the role that employers, employees and their designated representatives play in the OSHA process by making them better informed about workplace hazards, the Secretary finds that this standard is necessary to carry out his responsibilities under the Act. *Cf. Mourning* v. *Family Publications Service*, 411 U.S. 356 (1973); *Whirlpool Corp.* v. *Marshall*, 445 U.S. 1 (1980); *Louisiana Chemical Ass'n et al.* v. *Bingham, et al.*, 550 F. Supp. 1136 (W.D. La., 1982) (OSHA records access rule upheld as valid section 8(g)(2) regulation). In addition to its status as a section 6(b) standard, therefore, this rule also falls within the broader class of section 8 regulations.

In addition, Section 8(c)(1) of the Act, 29 U.S.C. 657(c)(1), authorizes the Secretary to issue regulations requiring employers to "make, keep and preserve, and make available to the Secretary * * * such records regarding his activities relating to this Act as the Secretary * * * (deems) necessary or appropriate for the enforcement of this Act or for developing information regarding the causes and prevention of occupational accidents and illnesses." Thus, specific statutory authority exists

for OSHA's own access to information under this standard.

Certain aspects of the standard merit further discussion regarding the legal basis for the approach taken in this standard. The standard directs its major obligations toward those employers who are in the best position to develop information concerning chemical hazards or who are the primary users of chemicals in industry. To this end, the standard applies directly only to employers in Division D (Manufacturing), SIC Major Groups 20–39. In issuing standards, the Secretary may, under priority-setting discretion given to him in Section 6(g), 29 U.S.C. 655(g), apply the standard only to certain segments of business, thus "(giving) due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, workplaces or work environments." The preamble discusses elsewhere why the Secretary's decision to direct the standard only towards employers in manufacturing is a rational one based on relevant policy considerations and the evidence in the record before him.

The system of hazard communication established by this standard is also designed to impose the duty of hazard evaluation primarily on the manufacturers who produce hazardous chemicals for distribution in commerce. It requires the disclosure of hazard-related information not only to their own employees involved in the manufacture of chemicals but also to the employers to whom the chemicals are shipped, so that this information will then be communicated to the employees of such employers. Chemical manufacturers are in the best position to develop and disseminate this information not only because they have greater scientific expertise with respect to the chemicals they produce, but also because they may be the only ones who know the identity of the chemicals in the first place. Likewise, an importer is in the best position to either develop the necessary information or obtain it from foreign chemical manufacturers who ship hazardous chemicals into the United States. A downstream employer cannot reasonably fulfill his obligations to establish an adequate hazard communication program unless the necessary hazard-related information originates with the chemical manufacturer or importer and is passed forward through the distribution system. Thus, requiring chemical manufacturers and importers to be responsible for hazard determinations and to provide their industrial customers with material safety data sheets and labeled containers is essential to carrying out the statutory mandate of prescribing "the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed * * *" 29 U.S.C. 655(b)(7). *Accord: American Petroleum Institute* v. *OSHA*, 581 F. 2d 493 (5th Cir. 1978) (benzene standard vacated on other grounds), aff'd other grounds *sub nom. Industrial Union De't., AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980):

> Placing the responsibility to warn downstream employees of concealed hazards on those upstream employers who create the hazards and know of the hazard is consistent with the remedial purpose of the Act and is within OSHA's broad authority to prescribe warning labels.

581 F. 2d at 411 U.S. 356 (1973); *cf., Mourning* v. *Family Publications Services, supra.*

This standard also provides for the degree of trade secret protection which the Agency considers to be consistent with its mandate to promote the health and safety of employees. As a matter of legal authority, OSHA has previously taken the position that its mandate requires it to balance and accommodate the interests in occupational safety and health with the protection of trade secrets, but that any unavoidable conflict should be decided in favor of the health interest. (See 45 FR 35248–51, Records Access Preamble.) This position has been based on: (1) Federal preemption doctrine, which says that state law (i.e., trade secret protection) may be preempted if it burden or conflicts with federal law; (2) the OSHA statute, whose limited trade secret section (Section 15; 29 U.S.C. 664) simply carves out an intragovernmental exception to the Trade Secrets Act, 18 U.S.C. 1905, and does not otherwise directly restrict OSHA's broad rulemaking authority in the are of providing access to toxic substance information; and (3) analogous judicial contexts, where the courts have adopted a balancing approach favorable to the health and safety interest.

In *Louisiana Chemical Ass'n.* v. *Bingham, supra,* the District Court upheld this approach as a valid exercise of legal authority—one which may, if adopted by rulemaking, be used to authorize the disclosure of trade secrets to non-government personnel under the Trade Secrets Act. *Cf Chrysler Corp.* v. *Brown*, 441 U.S. 281 (1979). The hazard communication standard strikes a somewhat different balance than the one originally taken in the records access rule in that it permits limiting trade secret disclosure, with appropriate confidentiality protection, only to health professionals providing occupational health services to employees. This new approach is based on a determination that health professionals acting in this capacity are, by profession, qualified to use the information (i.e., chemical identity information) in a manner which best serves the interests of occupational safety and health and may also be expected to scrupulously safeguard the confidentiality of that information, thereby minimizing the potential for competitive harm. Accordingly, it is consistent with the Supreme Court's decision in *Detroit Edison Co.* v. *NLRB*, 440 U.S. 301 (1979) in which the Court held that the National Labor Relations Board abused its remedial discretion when it did not limit union access to confidential test data to a psychologist acting as an intermediary on behalf of the union.

Finally, the fact that this rule is being issued as a § 6(b) occupational safety and health standard carries with it two significant consequences. First, judicial review of the standard lies exclusively in the United States courts of appeals. Section 6(f) of the Act, 29 U.S.C. 655(f); *Louisiana Chemical Ass'n.* v. *Bingham, supra*, 657 F. 2d 777.

Secondly, as a standard, it preempts competing state standards which do not meet certain procedural and substantive criteria. Section 18(a) of the Act, 29 U.S.C. 667(a), says that a state is not prevented from asserting jurisdiction over "any occupational safety and health issue with respect to which no standard is in effect under Section 6." Conversely, where OSHA has issued a standard under Section 6, § 18(b), 29 U.S.C. 667(b), requires a state desiring to issue standards relating to the same issue to submit a state plan to OSHA. Section 18(c), 29 U.S.C. 667(c) authorizes the Secretary to approve the submitted state plan only if the state plan provides for standards and a plan for their enforcement which are, *inter alia* "at least as effective in providing safe and healthful employment and places of employment as the standards promulgated under Section 6 which relate to the same issues."

While questions of effectiveness and commonality of issues must be resolved on an *ad hoc* basis, in general the Secretary intends to scrutinize carefully any state law or regulation submitted under an approved state plan which contains any hazard determination or communication requirements which are applicable to chemical manufacturers or other employers in SIC Codes 20–39. The

purpose of this review is to assure not only equal or greater effectiveness but also that any additional requirements contemplated by the state do not conflict with or adversely affect the effectiveness of OSHA's standard. Because the hazard communication standard is "applicable to products" in the sense that it permits the distribution and use of hazardous chemicals in commerce only if they are in labeled containers accompanied by material safety data sheets, and because there is a strong policy justification for uniform application throughout the distribution system of a national hazard communication standard, the Secretary intends to approve a state standard only if it is "required by compelling local conditions and do[es] not unduly burden interstate commerce." Section 18(c) of the Act; 29 U.S.C. 667(c). If the Secretary does not approve such a standard, the state submitting the plan shall be afforded due notice and the opportunity for a hearing. Section 18(d) of the Act; 29 U.S.C. 667(d).

III. Regulatory Impact Analysis, Regulatory Flexibility Analysis and Environmental Impact Analysis

The following is a summary of the regulatory impact and regulatory flexibility analyses prepared by OSHA for the final hazard communication standard. Copies of the full text of the document may be ordered from the National Technical Information Services, U.S. Department of Commerce, Springfield, Virginia, 22161, or may be examined and copied in OSHA's Docket Office, Room S6212, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210; (202) 523-7894.

Statement of the Problem

During the 1970's, increased attention focused on chemicals found in the workplace as an important source of hazardous exposures which cause or contribute to chronic diseases such as heart ailments, kidney damage, sterility, and cancer. Many chronic diseases are characterized by long latency periods of 20-30 years or longer. Often the exact relationship between the intensity of exposure and the risk of disease is not well understood. The problem is exacerbated by the likelihood of multiple exposures. The worker might be exposed to numerous chemicals at a point in time or over a long period of employment. In addition, the exact synergistic effects of these chemicals on health is likewise highly uncertain.

Other chemicals can cause acute damage such as burns, rashes, or even toxic reactions after an immediate high level dose. Still other chemicals contribute to serious accidents on the job such as fires and explosions.

Data indicate that there may be as many as 575,000 chemical products, with hundreds of new chemicals introduced annually. This growth in the number of industrial chemical products can result in a wide variety of effects on health and safety in the workplace.

A large number of workers are exposed to such risks on their job. The National Occupational Hazard Survey (NOHS) indicated that about 8.5 million workers were exposed to chemical hazards in manufacturing during 1972-74 (Ex. 16-7). Because the manufacturing labor force grew at a 0.7 percent annual rate during the interim years 1973-82, the number of exposed workers in manufacturing may now total about 9 million workers. The NOHS data also indicate that over 280 million exposures to chemical hazards occurred in the manufacturing sector during 1972-74. Using the same labor force growth rate and assuming a 3 percent annual growth in the average number of hazards to which each worker was exposed, chemical exposures in manufacturing may total 388 million in 1982.

Efficient use of resources in our society requires that all participants have complete and accurate knowledge of economic and technological data. Rarely, however, is this requirement fully satisfied. Decisionmakers are often ignorant of the attributes of the good or service. Hence, the participants may not be apprised of the longer term consequences of the exchange.

The economic justification for a regulatory action in the case of chemical hazards is contingent on the degree of market failure. If the problem is an intermittent one, which is quickly rectified by market incentives, then the economic justification for regulatory intervention may be insufficient. This is not, however, the case.

The testimony presented to the public record on the March 19, 1982, OSHA proposal indicates that the market failure problem is extensive (see, for example, Exs. 19-61, 19-109, 94, 103 C, 103 R, 122, 178, L-16, and Tr. 98-101, 1308-9, 1811, 2932). This conclusion was perhaps best summarized by the Boeing Company (Ex. 19-109):

> Marketplace pressure, as suggested in the preamble, is not an acceptable means by which to ensure that suppliers will pass on the hazard warning information (specifically, Material Safety Data Sheets (MSDS's)) to users. This suggestion will only reinforce the current voluntary system which already relies on pressure from "the market," or users pressuring the suppliers and manufacturers for information. It is a cumbersome and ineffective system which we hope will not be sanctioned by OSHA as an old idea under the guise of new terminology.

Many of the potential hazards associated with chemical products have not been communicated to workers, or in many cases, to employers. Because of the inadequacy of chemical information, the employer cannot or does not take into account the potential impact his or her decision concerning the use of the chemical product may have on others. Employees pay for the inadvertent or advertent errors in judgment by an employer through impaired health, injury, or death. Other members of society pay through a reduction in production and community welfare. The failure in the market for hazard information in turn causes a misallocation of resources in other markets. For example, the employee is unable to match his or her risk preferences with the risk characteristics of the job.

Furthermore, the current remedies may magnify the information problem. The tort liability system on the whole provides disincentives for employers to provide information on the relative hazards of chemical substances. Tort liability does represent one form of redress for employees with injuries and illnesses from exposure to chemicals, but Worker's Compensation laws generally bar employees from suing their own employers. A lawsuit against a chemical manufacturer or supplier would provide compensation for risk-averse employers and employees and would encourage upstream distributors of chemical products to include potential accident costs in their decision-making process. The absence of correct information concerning the hazard posed by the chemical substance or mixture, however, will influence the decision to initiate a lawsuit. If the probability of a successful outcome of a lawsuit is relatively low, then the individual will be inclined to take a conservative stance and not litigate. It has been demonstrated that when the population-at-risk is more risk-averse, conservative behavior decision is the norm. Hence, the employer's incentive to provide a more healthful and safer work environment arising from the probability of litigation is likely to be muted. A similar situation results when the transactions costs associated with a lawsuit are high. The potential effectiveness of legal remedies is limited by the fact that workers often cannot afford to forego potential payments while awaiting settlement, especially if the probability of winning the lawsuit is relatively low. They may not be able to

afford the costly legal fees associated with protracted litigation.

Likewise, the Worker's Compensation system with its dual tests of workplace connection and employer responsibility provides disincentives to the provision of accurate information. Available evidence from a Department of Labor (DOL) study indicates that many occupational diseases are not compensated through the Worker's Compensation system and hence are "externalized" to society (Ex. 16–38).

The objective of a regulatory action by OSHA must be to prevent injury and illness due to mishandling of hazardous chemicals by employers and employees. OSHA could propose to achieve this objective by a case-by-case regulation of industrial chemicals. The dynamic nature of the production of health and safety information for existing and future chemical products does not, however, provide the environment for effective, efficient case-by-case regulation. The testimony of a representative of the Ford Motor Company provides a statement of the problem (Tr. 593).

> It's a dynamic happening out there, both in the hazard and toxicity sense of chemicals being made or changed or switched * * * there may not be any eyebrows raised today, but, you know, we switch chemicals a year from now—pick five that you think might be, you know, a problem a year from now that aren't really raising any eyebrows now because the tox[icity] data isn't in or hasn't been found.

The nature of the market failure problem together with the large variety of potential hazards suggests the value of a different approach—one which would provide accurate, continuously updated information to employees and employers on the hazards of chemicals in their work environment. In turn, it is not unreasonable to asssume that if employers and employees are provided with meaningful risk information, they will take the appropriate protective action. One representative from Mobil Oil Corporation testified that (Ex. 164 B):

> There should be very noticeable behavior changes and actions on the part of managers and employees which can be directly attributed to a chemical handling information system. The first, will be increased discussion and concern about the whole area of exposure to chemicals. There will also be inquiries about materials which were not included. Protective equipment will become of greater concern on two accounts: Employees will wear it more willingly in most cases and supervisors will enforce its use with more confidence. Management and employees will both review current work methods to minimize exposure. Some marginally safe tasks may be completely eliminated, either by new manual methods of working or through engineering improvements. If management encourages it, many creative improvements which are safer and more cost effective may be expected. A chemical handling information system which includes concern for not only the hazards of materials but also the methods of handling is not just another safety program. A well designed approach which communicates well and invites employee participation is a strong tool for organization change. Although a great deal of effort is involved in developing the system, the benefits more than justify the cost.

Improved hazard recognition will encourage market-oriented responses such as increased precautions when handling hazardous chemicals and substitution of less hazardous products. These responses will translate into reduced injury and illness incidences from exposures to industrial chemicals. The benefits of such a regulatory action will not be confined to substances that are not currently regulated by OSHA as indicated by the following testimony (Tr. 97–8):

> For example, I recently had occasion to treat a gentleman who was an automobile body mechanic who had developed carcinoma of the larynx. A question was raised as to whether or not there was an association between the materials with which he worked and the occurrence of a cancinoma of the larynx. This was particularly relevant in this gentleman's case becasue he had never been a smoker. After careful investigation, we learned that many of the automobile putties which were used over the last 20 years contained large amounts of asbestos. This dust was very likely involved in this gentleman's carcinoma of the larynx. He had no awareness of the presence of asbestos in the material at any time because the product label never listed it as an ingredient of the putty. This lack of information is often the fault of the employer, but more often than not the downstream employer does not have the information to pass along to the employee. Neither the product label nor the Material Safety Data Sheets currently disseminated by many manufacturers contains adequate toxic substances information for the development of an individual or company-wide materials health and safety program. This failure of labeling and of Material Safety Data Sheets is at the root of the current failure in hazard communications. Even those manufacturers and employers who have complied with various voluntary and required labeling protocols usually stress only the immediate, acute hazards. They do not stress such long-term or potential problems such as chronic pulmonary disease, chronic renal disease, allergies, cancer, mutagenesis, or birth defects which may result from exposure to to certain materials.

Several state and local right-to-know laws have been prescribed to deal with this market failure problem. The coverage and requirements of these laws, however, are consistent only in their inconsistency. The consequent cost and ineffectiveness of this decentralized effort has been well-documented in the public record as the following statements indicate:

> Compliance with separate differing pieces of legislation is unduly burdensome and a waste of scarce safety and health resources. Unfortunately, it is the employee who ultimately suffers from these potential non-uniform and possibly even conflicting requirements because the employer will be required to allocate a disproportionate amount of resources to comply, in form, with the multitude of disparities in worker right-to-know rules or laws. (American Iron and Steel Institute, Tr. 2023).

> Our experience with differing labeling, material safety data sheet distribution, employee training and customer communications required by the several states and localities which have adopted right-to-know ordinances or statutes has been brief but educational. We have found that the varying requirements are an increased burden. Each such state or jurisdiction essentially requires special handling with respect to advice on compliance procedures for shipment and instructions to distributors and salesmen. Such special handling is inefficient and costly. We urge the Occupational Safety and Health Administration (OSHA) to carefully consider this cost impact on interstate commerce with respect to any changes to the hazard communication standard that may be proposed by a State. Therefore, DuPont believes an appropriate federal rule that establishes a standard is timely and necessary. The concerns of the chemical industry with variable and cost-ineffective state regulations will not be alleviated unless OSHA utilizes its preemption authority as provided in the Act. (DuPont, Ex. 19–57).

> As a multi-state employer, U.S. Steel is potentially facing the administrative and economic nightmare of complying with fifty different state statutes and several hundred local ordinances on hazard communication. This potential morass is exacerbated by the realization that each of these statutes differ in basic as well as particular requests. Thus, the fundamental reason for legislating a hazard communication program, i.e., worker safety and health, is lost in the shuffle of attempting to comply (in form) with the multitude of hazard communication regulations (U.S. Steel, Ex. 19–125).

Evolution of the OSHA Standard

January 16, 1981 Proposal

On January 16, 1981, OSHA published a Notice of Proposed Rulemaking to address this market failure problem (Ex. 10). This proposal was subsequently withdrawn to allow for careful review of its regulatory provisions in accordance with Executive Order 12291 on improving regulatory management. The January proposal included the following key features: (1) Coverage of all manufacturing industries and importers

and repackagers of chemical products and virtually all containers including pipes and support systems such as pumps and valves; (2) highly specific search and evaluation procedures required for hazard evaluation by all manufacturers; (3) detailed labeling of chemical products with no adjustments for trade secrets; (4) Material Safety Data Sheets (MSDSs) for hazardous chemicals to be filed in a central location if available; (5) certification that a particular chemical product does not pose a hazard where applicable; (6) extensive recordkeeping on hazard search and evaluation procedures to be kept for 3 years; and (7) a phased-in compliance period of approximately 2 years. These components are summarized in Table 3.

Serious concerns were raised regarding the excessive costs and paperwork burdens that would be imposed by the January proposal. The initial (startup) cost of the January proposal, as shown in Table 4 was estimated to be between $2.6 and $3 billion depending on the amount of testing conducted to meet the certification requirement. The total annual cost of the January proposal was expected to approach about $1.254 billion. The total present value cost at a 10-percent discount rate amounted to about $22.864 billion or more over a 40-year period. Even these cost figures were somewhat understated because they did not include the costs of labeling pipes outside the chemical and petroleum manufacturing industries. In particular, the required labeling of pipes and support systems would have proven very costly with an initial cost estimated at $1.727 billion or between 58 and 66 percent (depending on the testing assumption for certification) of the total initial cost of the January proposal.

A related issue involved the "specification" orientation of the January proposal with its highly detailed set of required compliance activities. Particular concern centered on the specific search and evaluation procedures established to determine the chemical hazards, including search and evaluation of all relevant scientific literature for certain chemicals, and documentation in cases where the chemical posed no hazard. In addition, the labeling requirements were extensive, calling for chemical names, common names, Chemical Abstract Service (CAS) numbers for all ingredients present in concentrations of 0.1 percent or greater, and hazard warnings which were specified in an appendix. These detailed requirements did not recognize the flexibility necessary to accommodate the diversity among substances, different manufacturing industries, workplaces, process types, and other characteristics relevant to controlling workplace risks. Such detailed labels were clearly not cost-effective, because they did not accommodate current industry labeling practices, thereby requiring extensive redesign and modification of most existing labels.

Another issue involved the absence of an exemption for trade secrets. The January proposal required the provision of all ingredient information, thus making no allowance for trade secrets, except for the allowance for deletion of unpublished information from the hazard evaluation file.

In addition, many provisions appeared to be redundant. For example, the information to be provided by an information sheet, if available, was essentially identical to the label.

Finally, OSHA had serious questions regarding the overall effectiveness of the January proposal in light of its focus on *identification* of chemicals rather than on *communication* of the chemical hazards to employees and employers. No education and training requirements were provided to instruct employers and employees on the hazards of chemical and on appropriate precautionary measures. And finally, the required certification of "no hazard" could have easily directed scarce testing resource away from substances with the greatest hazard potential because of employer concern over the financial liability ramifications. As a result, it is doubtful that reliance on extensive labeling would have accomplished the goal of informing workers of chemical hazards and reducing the risk of exposure in an effective manner.

March 19, 1982 Proposal

OSHA carefully reviewed the January 1981 proposal and alternatives in light of these concerns. The objective of the review was to improve the cost-effectiveness of the information approach to the control of chemical hazards in the workplace. In March 1982 OSHA published a revised proposal (Ex. 15).

The March proposal was oriented toward providing hazard information to workers and employers, was largely performance-oriented, substantially reduced the paperwork burden of employers, and eliminated unnecessary regulatory requirements. As a result, the costs of the current proposed hazard communication standard were substantially reduced over those estimated for the January proposal. The total initial cost of the January proposal was estimated at about $2.6 billion, or $185 per employee. It was noted that an assumption of more rigorous testing in response to the certifications of no hazard could raise this cost as high as $3 billion, or $215 per employee. OSHA estimated that the March proposal would reduce the initial cost by 80–90 percent, down to approximately $591.44 million, or $42 per employee as presented in Table 4 (Ex. 17). The annual cost of the March proposal was also substantially lower—$158.92 million, or only $11 per employee.[1] By contrast, the estimate of the January proposal was about $1.254 billion or more, or $89 per employee. Finally, the estimated total present value of the cost of the March 1982 proposal over a 40-year period using a 10-percent discount rate was $3.368 billion compared to $22.864 billion or more projected for the January 1981 proposal.

The March proposal did not require labels on pipes and support systems. This change alone eliminated almost 58–67 percent of the initial compliance cost contemplated in the January proposal. The exemption of pipes and support systems from labeling requirements would have lowered the annual costs by an even larger percentage, saving 70 percent of the annual cost of the January proposal. In part, these high costs stemmed from the expected need to relabel one-half of the pipes and support systems annually.

As part of the approach of effective hazard communication, the March 1982 proposal also included an education and training provision (but left the specific content and format up to the employer) to inform employees about hazards and protective clothing and equipment. The education and training provision also required employers to instruct employees on the precautionary measures to take when handling hazardous substances and appropriate responses should exposures occur. This provision would have resulted in some increase in costs over the January proposal. It was expected that the education and training would, however, significantly enhance the effectiveness of the program.

In contrast to the January proposal, the March proposal was largely "performance-oriented." As noted above, both the labeling and education and training requirements were performance-oriented to allow employers to take advantage of a wide

[1] The cost per employee represents an average for all establishments in the manufacturing sector. Cost per employee for each respective industry and for each establishment size category is presented in the Regulatory Impact Analysis.

variety of compliance approaches tailored to their particular industries and work environments. Similarly, the hazard evaluation procedures were made substantially more flexible relative to the January Proposal. The evaluation was to be based on scientifically well-established studies and thus limited to known hazards of a chemical. Also, a list of references and data sources was provided merely as a guide rather than as a required procedure for this evaluation. If a chemical was determined to pose no hazard, no certification or other compliance activities would have been required for the chemical.

The March 1982 proposal added some specific information requirements for the data sheets filed in a central location for hazardous chemicals. The MSDS information included chemical names, common names, and CAS numbers for ingredients present in specified concentrations; physical hazards and/or known acute and chronic health effects; routes of entry; precautions for safe handling and use; effective work practices and personal protective devices; emergency and first-aid procedures; and date of preparation. This information was viewed as the minimum necessary to ensure an effective hazard communication standard. The chemical identifier on the label provided a link between a simple hazard warning on the label and appropriate precautionary measures provided on the MSDS. Under the March OSHA proposal, the MSDS was the only source of detailed information on the known health and safety effects associated with specific chemicals and appropriate precautions and emergency procedures. For this reason, the chemical manufacturer was required to develop an MSDS if one was not currently available for hazardous chemicals and include it with first shipments. Viewed from another perspective, these small cost increases would be cost-effective in supplying hazard information when compared to the substantially higher costs of providing the detailed information on each and every container as required by the January proposal. The extra $18.19 million initial cost of the current MSDS provision compares quite favorably (and provides more information) to the additional $395.94 million cost for extensive label provided in the January proposal. Likewise, extensive labels would have added $281.07 million to the annual cost of the limited label requirement in the current proposal, while the MSDS provision in the March proposal resulted in only a $1.35 million increase.

The March proposal provided for a trade secret exemption either through use of generic names to mask ingredients or through confidentiality agreements with industrial customers. While there are no cost estimates on the effect of the proposed change, the positive impact on commerce was expected to be substantial.

Final OSHA Standard

Components

OSHA evaluated the expected cost-effectiveness of the January 1981 and March 1982 proposals as well as other approaches to hazard communication. The evaluation of the cost-effectiveness of a hazard communication program must be based on the results of the "package" as a whole, not merely a sum of the expected results of the separate ingredients. Thus, the following discussion relies on the March 1982 proposal as the baseline "package."

The March 1982 proposal covered employees in the manufacturing sector (SIC 20–39). During the course of the proceeding, OSHA reevaluated this scope. Evidence indicates that employees in the manufacturing sector are at higher risk of harmful exposure to chemicals relative to other sectors (Ex. 17). Alternatively, the standard could be applied selectively to different industries within the manufacturing sector. This selection of industries would, however, introduce significant incentives to shift chemical production and use to exempted industries, since multi-product firms and vertically integrated firms are not accurately captured within the conventional SIC system. OSHA has included in the final standard a requirement for distributors and importers to pass on the MSDS and maintain the container labels for shipments destined for an employer in manufacturing. OSHA has also included a requirement that employees in laboratories be apprised of the hazards of the chemical products used in their respective workplaces.

OSHA also received much comment on the advantages and disadvantages of a performance approach as opposed to a specification approach to a hazard communication standard (Exs. 19–43, 19–44, 19–46, 19–50, 19–54, 19–57, 19–62, 19–81, 19–88, 19–91, 19–96, 19–115, 19–116, 19–140, 19–146, 19–147, 19–160, 19–188, 19–201, 19–204, 19–209). The wide diversity of production processes and work environments within and across industries in the manufacturing sector, however, precludes the promulgation of a cost-effective specification standard. The rapidly changing nature of the industrial production processes and the production of hazard information would quickly render a specification standard obsolete. All participants when questioned about the hazard determination process indicated that a significant amount of professional subjective judgment must be included in any hazard evaluation. Therefore, a completely specified weighting procedure for the hazard evaluation would suggest certainty where certainty does not exist. OSHA has, however, included selected lists of chemicals that have been evaluated and found to be hazardous to serve as a floor for the coverage.

OSHA has also included a requirement for the employer to develop a compliance plan. The plan would merely document the hazard determination procedures and the methods use to inform employees of the potential hazards associated with non-routine tasks.

The label in the March 1982 proposal was to serve as the alert mechanism to supervisors and employees about the presence of chemical hazards in his or her immediate work area. The content of the label was limited to hazard warning(s), a chemical indentifier to serve as the link to the MSDS, and the name, address and telephone number of the chemical manufacturer. An alternative approach to this limited label would be an extensive label which would include the chemical and common names, CAS numbers, and hazard warnings for all ingredients or all ingredients present above some cutoff defined in terms of percent concentration. Several problems with the extensive labeling approach, however, preclude its adoption. First, the objective of the standard is to communicate to employees and supervisors the potential acute and chronic hazards associated with chemical products. Evidence on the expected cost-effectiveness of the extensive label approach in achieving this objective was not presented to the public record. The limited label approach in combination with a detailed MSDS as required by the March proposed standard is expected to be at least as effective and, in light of the potential for information overload with the extensive label, perhaps more effective than the extensive label alternative. In addition, the limited approach would involve a cost savings of 50 percent. Second, the requirement for an extensive label would ignore proven industry practices. Changes in these practices to comply with a

requirement for extensive labeling of containers would involve significant costs with no gains in terms of the effectiveness of the overall hazard communication program.

Several participants in the public hearing questioned the need for implant labeling of containers. Again, the role of the label is to serve as the alert mechanism. Evidence was not presented to the public record to support other means of communication in all cases. OSHA has, however, acknowledged that labeling of reactor vessels and the like may be cumbersome and ultimately counterproductive. The final standard would therefore allow the employer the option in these cases to label the container or to provide batch tickets, production sheets, etc. as long as the necessary information is conveyed. The cost savings for this change cannot be determined. It is espected to be significant, expecially for small entities.

The March 1982 proposal did not require the labeling of pipes and pipe support systems, although comment on this provision was requested in the public hearings. OSHA did include a direct requirement in the March proposal for employers to inform employees about the potential hazards associated with non-routine tasks as the cost-effective approach to this particular problem. Testimony presented during the public hearing did not refute the conclusion that labels on pipes and pipe support systems are not the most cost-effective means of communicating hazards and precautions to take.

Many participants requested an exemption from the labeling requirement if a container label was already required by another Federal agency. To avoid any unnecessary duplication of effort and confusion that may be created by multiple labels, OSHA has included in the final standard a labeling exemption for certain substances (e.g. pesticides) required to be labeled by another Federal agency. The reduction in the cost of compliance as a consequence of this change could not be determined. It is expected to be significant, however, especially for small entities.

In the document accompanying the March 1982 proposal, OSHA tentatively concluded that the expected cost of providing MSDSs with first shipment was less than the expected cost of providing them to industrial users in manufacturing "upon request." The expected cost savings stemmed from the avoidance of requests from industrial users. Testimony submitted by chemical producers suggested that the relative cost of the "upon request" approach was lower than the provision of MSDS's with first shipment (see, for example, Exs. 19–43, 19–46, 19–59, 19–72, 19–79, 19–84, 19–85, 19–91, 19–94, 19–111, 19–115, 19–116, 19–117, 19–119, 19–124, 19–141, 19–147, 19–152, 19–164, 19–169, 19–177, 19–181, 19–205, and 19–213). Two major problems arise with this testimony. First the cost estimates failed to include the cost of requesting MSDS's for user employers in the manufacturing sector. A more appropriate cost evaluation must include the full social cost of the alternatives, not merely the cost to a particular segment. As indicated by several industry representatives and by the OSHA cost estimates, the additional cost of multiple requests that would be required with the "upon request" approach is significant. Second, the cost savings that chemical producers would presumably enjoy with the "upon request" approach relative to provision with first shipment was due to the perceived avoidance of the need to maintain customer lists. These participants then indicated in further testimony that they do currently maintain lists in order to provide their customers with updated chemical information. This inconsistency was not resolved in the testimony submitted to the public record.

Education and training in the March 1982 proposal was included to ensure the effectiveness of the standard. The format of the education and training program was left to the discretion of the employer. OSHA argued that the performance approach was necessary to allow for the diversity of production environments that characterize the manufacturing sector. The need for education and training was endorsed in the public hearing as a critical component of an OSHA standard.

In sum, OSHA's final standard is designed to support an effective hazard communication system while minimizing its cost impact on employers. The labels are limited to the hazard warning and an identifier to provide a link to the MSDS's, thus improving the effectiveness of the label and lowering the costs of providing the labels. The MSDS complements the label by providing more detailed ingredient and hazard information; all of this would be available in a central file as opposed to on every container. The education and training requirement encourages the employer and employee to use the information provided by the MSDS, thereby increasing the hazard awareness of employees and supervisory personnel. The standard provisions are largely performance-oriented and unnecessary paperwork has been eliminated.

Summary Costs of the Standard

The initial cost of the final OSHA standard does not differ significantly from the cost of the March 1982 proposal. The initial cost as presented in Table 3 is $603.926 million or $43 per employee. The total annual cost is $158.87 million or $11 per employee. The present value of the cost is $3.374 billion using a 10 percent discount rate. A complete discussion of the methodology used in the cost evaluation is provided in Chapter IV of the Regulatory Impact and Regulatory Flexibility Analysis.

TABLE 3.—A COST COMPARISON OF THE JANUARY 1981 AND MARCH 1982 PROPOSALS AND THE FINAL STANDARD

Cost	January 1981 proposal	March 1982 proposal [1]	Final standard
Initial cost:			
Total (millions)	$2,600.000	$591.440	$603.926
Average per employee [2]	185.00	42.00	43.00
Total annual:			
Total (millions)	1,254.000	158.490	158.870
Average per employee [2]	89.00	11.00	11.00
Total present value (40-year period; millions) [3]	22,864.00	3,368.000	3,374.000

[1] The estimates of the cost of the March 1982 proposal have been revised as necessary to reflect the testimony in the public record.
[2] The cost per employee represents an average for all manufacturing establishments. Hence, it is not a reflection of the average cost for a particular industry or establishment.
[3] The discount rate is 10 percent. The growth rates vary for each compliance activity. These are outlined in Chapter III.

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

Summary of Benefits of the Standard

General Scope. The purpose of the hazard communication standard differs substantially from other OSHA regulations. Rather than directly control exposure levels in the workplace, it is designed to enhance employer and employee awareness of the safety and health hazards associated with chemical substances. In turn, this hazard recognition produces market-oriented responses by employers and employees that translate into lower incidences of chemically-related injury and illness on the job. The standard will also provide benefits from the avoidance of multiple and redundant searches for information on chemical ingredients and hazards that are incurred by industrial users. Finally, the promulgation of a uniform, Federal standard will reduce the cost of compliance with the increasing number of state and local right-to-know laws. This section highlights these expected benefits which are described in greater detail in Chapter III of the Regulatory Impact and Regulatory Flexibility Analysis.

Reduction in the Incidence of Chemical Source Injury and Illness. Most importantly, the standard will increase employee awareness of the potential health and safety risks associated with industrial chemicals. This should result in increased worker use of personal protective devices improved work practices, and other precautionary measures when handling hazardous substances. Improved hazard communication should also result in early job transfers and treatment of chronic disease and lowering of future health care costs.

Similarly the standard will provide employers with improved information on the health and safety hazards of various chemical products as part of their investment and production process decisions. This knowledge should result in more safety-enhancing investments—in new control technology process redesign and, perhaps most importantly, in product substitution. The latter is often preferable because it substantially eliminates the hazard without extensive control devices. Improved information among supervisory personnel of the necessary precautions should result in proper day-to-day handling of hazardous substances.

In addition to the health effects implications, there are other expected efficiency improvements as well. In a properly functioning labor market improved information should lead to better matches between the risk preferences of workers and true job risks (and to some extent relative risks to the firm), thus improving labor market allocation. Employers would also benefit from lower production costs as a result of gains in worker and equipment productivity, reduced worker absenteeism and turnover, and over the long run, lower Worker's Compensation costs.

Finally, society should benefit from a reduction in occupational injury and illness costs currently externalized by firms. These include transfer payments to disabled individuals and their families, such as Social Security disability benefits and public assistance; health care costs not paid by the individual or company such as Medicare and Medicaid; and higher administrative costs of related government programs.

One method of estimating the benefits from a reduction in the incidence of injury and illness due to chemical exposure is the human capital approach. This includes an evaluation of the: (1) Reductions in lost earnings and medical expenses for various categories of chemical source illnesses and injuries as well as (2) lowered turnover costs; and (3) property losses from chemical fires. The injury and illness categories include non lost workday and first-aid cases; lost workday cases, permanent disease disabilities; and cancers related to industrial chemical sources.

Under the methodology used in this study, the current number of cases associated with each category were estimated together with the projected reduction in these cases as a result of the proposed standard over a 40 year period (the period necessary for complete turnover of the current workforce). For example, the rate of chemical source lost workday injuries is expected to decrease by 1 percent per year for 20 years, while cancer cases decline only 2 percent beginning in the 10th year to account for the long latency periods associated with carcinogenesis. The expected reductions in each year were then multiplied by an appropriate average economic cost measure (e.g., average number of workdays lost per lost workday injury converted into monetary terms through average manufacturing wages or average medical expenses per lost workday injury). Finally all benefits were discounted to the present using a 10-percent discount rate to facilitate the necessary benefit comparisons.

It is not possible with available data to precisely measure even the earnings and medical losses resulting from workplace exposure to chemical subtances. In fact, some cost components cannot be measured at all—i.e., the suffering that invariably accompanies a disabling disease. Others can be measured only imperfectly. For example, while the current number of lost workday injuries due to chemical sources can be reliably estimated from Bureau of Labor Statistics (BLS) data taken from Worker's Compensation initial reports and extrapolated to national incidence rates, this data source seriously underreports occupational illness cases.

Studies suggest that occupational illnesses may be underreported by as much as a factor of 50 because of variables such as latency periods which obscure the connection between occupational exposures and the onset of disability (Ex. 16–35). (See Chapter III of the Regulatory Impact Analysis for a more detailed discussion of these studies and the factors affecting this underreporting bias.) It was therefore necessary to adjust the chemical source illness data to account for this underreporting. Likewise, there is considerable scientific controversy over the specific fraction of cancers associated with occupational exposure to chemicals. Estimates of occupational cancers range from 1 to 5 percent of total U.S. cancers, all the way up to 40 percent. Unfortunately, all these studies suffer from various methodological limitations. In view of these and because of the multiple causal agents which impact on carcinogenicity, OSHA has used an estimate of 5 percent of all cancers as work-related. It should be noted that this 5 percent is further adjusted to account for the percent of work-related cancers in manufacturing to yield an estimate of 2.5 percent of all cancers as work-related in manufacturing. Thus, in the 10th year, using the methodology outlined previously, the expected reduction in the social cost of work-related cancers is 0.05 percent. At equilibrium in the 20th year, using this methodology, the expected reduction in the social costs due to cancer illness is 0.5 percent.

A second source of difficulty involves assessing the likely risk reduction benefits resulting from improved flows of information as distinct from measuring the benefits of lowered exposures. With current information it is simply not possible to estimate precisely the impacts on risk. Several studies have reported significant changes in various indicators of health improvement as a consequence of implementation of some component of a hazard communication program. (Exs. 153, 155, 160H, L–8, Tr. 3709). (A full discussion of these studies is presented in Chapter III of the Regulatory Impact Analysis.) The patterns of likely risk reduction assumed by OSHA are constructed based on best available evidence of the likely effects.

All of the assumptions and possible sources of data error have been carefully analyzed in terms of their influence on the benefit estimates. Chapter III of the Regulatory Impact Analysis describes the benefit estimation procedures used in this study and data limitations in greater detail.

As shown in Table 4, the largest category of benefits attributed to a reduction in chemical source injuries and illnesses comes from a reduction in the social costs of cancer illness. Using the methodology outlined previously, the undiscounted production benefits from a reduction in cancer illnesses are estimated to be zero for the first 10 years to account for the latency. In the 40th year, the expected undiscounted benefits are estimated to be $808.68 million from increased production and $306.22 million from medical cost savings. Using a 10 percent discount rate, the present value of the benefits for a 40-year period is estimated to be $1047.5 million from increased

production and $393.3 million from medical cost savings.

TABLE 4.—SUMMARY OF QUANTIFIED BENEFITS

[Millions 1982]

Source	Undiscounted			Discounted for 40-year period [1]
	1st year	20th year	40th year	
Non-Lost Workday Cases				
Production lost	$0.030	$1.360	$3.600	$5.660
Medical cost	0.020	1.000	2.800	4.200
Lost Workday Cases				
Production lost	0.720	30.600	81.400	147.200
Medical cost	0.130	4.533	12.000	25.490
Disabling Illness				
Production lost	1.410	70.170	189.220	301.420
Medical cost	0.004	0.199	0.536	0.726
Cancer Illness				
Production lost		305.144	808.680	1,047.500
Medical cost		115.440	306.220	393.200
Turnover cost	0.070	4.060	10.780	16.400
Chemical fire	1.000	1.800	3.300	13.700
Reduced search costs	211.971	381.066	691.445	3,092.445
Uniform standard	74.800	135.410	244.580	1,093.880
Total	290.155	1,050.782	2,354.561	6,141.821

[1] The discount rate is 10 percent.

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

The second largest category of benefits is associated with a reduction in the incidence of disabling illnesses caused by exposure to toxic chemicals in the work environment. The undiscounted benefits in the 1st year are expected to be $1.414 million as presented in Table 4. Using the "1 percent" pattern, these benefits will increase such that the undiscounted benefits in the 40th year are estimated to be $189.756 million. The present value of the cost savings is expected to be $302.146 million for a 40-year period.

Similarly, for chemically induced injuries or illnesses involving the loss of one or more workdays, Table 4 shows the undiscounted production benefits from a reduction in lost workdays to be $0.72 million in the 1st year and $81.4 million in the 40th year, with a present discounted value of $147.2 million for a 40-year period. The corresponding benefits from expected reduction in medical payments amount to $0.13 million in the 1st year and $12 million in the 40th year with a present discounted value of $25.49 million.

The other estimated benefit categories include reductions in non-lost workday injury and illness cases, turnover costs, and property cost due to chemical fires. The present discounted values of these benefits over the 40-year period are estimated at $9.86 million, $16.4 million, and $13.7 million respectively.

While these various estimates are clearly not exact, they do provide a reasonable order of magnitude of the likely beneficial impact of the proposed hazard communication standard. Moreover, they do not incorporate intangible costs important to the individual and associated with premature death, pain, suffering, and family bereavement. Nor do the estimates include firm-based costs, and productivity gains. Indeed, as noted above, there is not even a complete accounting of the medical and wage lost costs. Finally, changing some of the key assumptions regarding the extent of health and safety improvements and occupational cancer incidence will not alter the basic conclusion that the proposed standard constitutes an inpressive reduction in societal costs.

Reduction in Search Costs

Because of inadequate documentation provided with purchased chemical products, many user employers and employees have incurred substantial costs of searching for the necessary information. Several users of chemical products in the manufacturing sector presented testimony during the public hearing on the resource cost of searching for chemical information. Using these submitted estimates of cost currently incurred, the expected total annual cost of searches for chemical information by employer and employee groups has been determined. The OSHA standard will require the provision of complete chemical information to all manufacturing employers and employees. Thus, the cost associated with the redundant searches will be eliminated. As presented in Table 4, the undiscounted benefits in the 1st year are estimated to be $211.971 million. The undiscounted benefits in the 40th year are expected to be $691.445 million. The present value of the benefits using a 10 percent discount rate is expected to be $3,092.445 million. These benefits are likely to be underestimated since the potential savings in search costs by industrial users outside of manufacturing have not been included. A full discussion of the methodology and assumptions used to derive these estimates is available in Chapter III of the Regulatory Impact Analysis.

Reduction in the Cost Compliance With State and Local Laws

The promulgation of a cost-effective federal standard is likely to reduce the cost of complying with the various state and local right-to-know laws. OSHA and several industry representatives have evaluated the expected additional cost of complying with the proposed state and local right-to-know laws. The estimate on methodology is discussed fully in Chapter III of the Regulatory Impact Analysis. The expected undiscounted cost savings *at minimum* using the parameter estimates provided by industry representatives or the estimates presented by OSHA are expected to be $74.8 million in the 1st year and $244.58 million in the 40th year. The present value of the cost savings is expected to be $1093.88 million using a 10 percent discount rate. The estimate does not include the additional cost of hazard evaluations that may be required by a state or local jurisdiction which will be avoided with the promulgation of a Federal standard. Furthermore, the estimates only include the additional cost of providing some form of information sheet and label. Thus, the cost of any other requirements has not been included. Also, any inefficiencies created due to the location of a plant or due to the change in the route of a chemical shipment have not been evaluated.

Discounted Cost Per Case

The monetized health benefits using the human capital approach do not represent the total expected benefits, but simply the portion of the benefits that could be quantified in dollar terms. A more appropriate measure of the benefits of health risk reduction is the workers' willingness to pay for the reduction in risk. Willingness to pay values invariably exceed the monetized human capital value by roughly a factor of 10: Workers have a much stronger stake in their individual health than would be reflected simply in foregone earnings or medical care bills.

To correct for the shortcoming of the human capital approach, an alternative method has been used to valuate the benefits from reduction in health improvements. The discounted cost per case has been estimated using an assumption of immediate effectiveness of either 5 or 10 percent. This estimate can then be compared to the estimates of the average willingness to pay to prevent a lost workday injury or illness, or $30,000. A full discussion of the methodology is provided in Chapter III and Appendix D of the Regulatory

Impact Analysis. It must be noted that this approach represents an alternative to the human capital method. Hence, these benefit values cannot be added to the benefits attributed to the reduction in chemical source injuries and illnesses.

The aggregation of the various categories of illness is achieved by weighting the illness and injury categories. The weights on non-loss workday cases, lost workday cases, disabling cases, and cancer cases are (½, 1, 1, 20) respectively. The discounted cost per case using an alternative weight of 5 on disabling illnesses is also estimated. Using the alternative assumptions and weighting schemes, the discounted cost per case ranges from $5,405 to $23,984. Thus, in light of the value of the willingness to pay the standard is justifiable using a wide range of effectiveness assumptions.

Effects on Small Entities

The final OSHA standard has included several provisions that will directly benefit small entities. In addition OSHA has designed the compliance activities and the phase-in of the final standard to reduce the regulatory burden for small entities in Standard Industrial Classification (SIC) Codes 20–39.

Relative Impact of Provision of MSDS Upon Request Versus With First Shipment

The final OSHA standard requires chemical manufacturers, repackagers, or other suppliers to provide material safety data sheets (MSDSs) with the first shipment of a chemical product. Several participants in the public hearing indicated that this requirement was necessary to ensure the effectiveness of a hazard communication program for small entities:

> Thousands of feed manufacturers are very small firms and most of them use a large number of ingredients. There is no practical way for the average feed manufacturer to determine if one of many products which he uses in his business is hazardous if he is not informed of this by the supplier of the product. MSDS are important sources of information to feed companies. Without them a feed company: (1) Would have no idea if a substance was hazardous or not; (Most feed manufacturers have neither the expertise nor resources to evaluate substances or mixtures.) (2) would be unable to evaluate what hazards the substance presents in order to determine any safety precautions necessary for employee safety. Feed manufacturers are at the mercy of their upstream suppliers to provide accurate MSDS's. OSHA needs to express clearly the responsibility of all upstream suppliers to supply downstream users with MSDS's (Ex. L–16).

> * * * the printing industry feels strongly that it is the distributors, repackagers, and importers who must furnish to the user employer material safety data sheets. This is essential in our industry since the fact (sic) majority of companies in printing purchase their supplies from distributors and repackagers. MSDS sheets from these firms will be the only way that thousands of small companies can gain access to the material and the information (Tr. 1315–16).

> * * * the small foundry and 80 percent of the 4300 foundries employ fewer than 100 people, so this is primarily and industry of small business. They do not have, I guess the word would be clout to obtain additional information from the vendors of the products (Tr. 1812).

Thus, the evidence in the public record supports the conclusion that one element of the market failure problem is the inability of managers of small manufacturing establishments to obtain the necessary information to implement a hazard communication program.

OSHA estimated the relative cost of an approach to require industrial users of chemical products to request an MSDS versus an approach to require chemical suppliers to provide an MSDS with the first shipment. These costs of the alternative approaches can be allocated to the respective employment categories in SIC 20–39 by weighting the total cost. The weights are simply the estimated total shares of shipments of regulated chemicals for each SIC/employment category.

The costs of developing the MSDSs, evaluating the hazards, and keeping records on the hazard evaluation process have been allocated to the entity size categories by weighting the total cost of compliance figures by the respective shares of regulated products for each employment category for SIC 28. A full discussion of the methodology and assumptions is available in Chapter V of the Regulatory Impact Analysis.

As presented in Table 5, the expected initial cost of the approach to require manufacturers to request MSDSs assuming $18.40 per request is $95.093 million for entities with 19 or fewer employees or $459 per establishment. The initial cost for this approach assuming $14.40 per request is $74.172 million for these entities or $358 per establishment. The final OSHA standard requires the MSDSs be provided with the first shipment of a chemical product. The expected initial cost for entities with 19 or fewer employees is $4.614 million or $23 per establishment.

TABLE 5.—DISTRIBUTION OF INITIAL COSTS OF ALTERNATIVE APPROACHES TO PROVISION OF MSDS

(Millions 1982)

Alternative approach	Entity size by number of employees (number of entities)			
	1–19 (207,103)	20–99 (76,933)	100–249 (20,807	250 or greater (13,592)
Upon Request: [1]				
$18.40 per Request	$95.093	$53.490	$21.792	$27.735
(Cost per Establishment	(459)	(695)	(1,047)	(2,040)
$14.40 per Request	74.172	41.722	16.998	21.633
(Cost per Establishment)	(358)	(542)	(817)	(1,592)
First Shipment [1]	4.614	3.345	1.384	2.191
(Cost per Establishment)	(23)	(43)	(66)	(161)

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis, Tables IV-7, IV-8.

[1] Assumes 60 percent prior compliance. Provision of the MSDS with the first shipment is the approach selected by OSHA.

Relative Impact of Limited Versus Extended Responsibility of Hazard Determination

The final OSHA standard requires that a chemical manufacturer conduct a hazard evaluation of the chemicals he or she produces. The results of this preliminary evaluation are then to be provided to industrial customers in SIC 20–39 via hazard warning labels and MSDSs. This provision assigns the responsibility for the hazard determination to the employer who is most likely to have the evaluation expertise and data on the specific chemical. This delegation of responsibility for the initial hazard evaluation will prove beneficial to managers of small entities who do not have the staff and other support facilities to evaluate chemicals purchased. This conclusion was supported by testimony such as that provided by Vulcan Chemicals:

> * * * we do not agree that each employer should *develop* a MSDS for hazardous chemicals purchased for use. The development of MSDS should be the responsibility of the manufacturers of hazardous chemicals or products which contain hazardous chemicals. It would be unreasonable to require each employer to evaluate each and every chemical-containing

product which he purchases in order to determine whether or not it contains a hazardous chemical. It would also be unreasonable to require that each employer develop a MSDS for each product which he purchases and which contains a hazardous chemical (Ex. 19–165).

OSHA has evaluated the relative cost of the approach to limit responsibility for the hazard evaluation to chemical manufacturers or other suppliers versus the approach to extend responsibility to all manufacturing employers. Using the weighing procedure, the expected initial cost of limiting the responsibility for the hazard determination to chemical manufacturers as presented in Table 6, assuming an average cost of $650 per search, is $71.76 million for entities with 19 employees or fewer or $346 per establishment. The expected initial cost of extending responsibility to all employers in manufacturing assuming $650 per search is $83.982 million for entities with 19 employees or fewer or $405 per establishment. The initial cost for these entities if some testing of chemical products is necessary is expected to be $585.158 million or $2,825 per establishment assuming 1 percent of the chemical products would be tested for acute hazards.

TABLE 6.—DISTRIBUTION OF INITIAL COSTS OF LIMITED VERSUS EXTENDED RESPONSIBILITY FOR HAZARD DETERMINATION

(Millions 1982)

Alternative approach	Entity size by number of employees (number of entities)			
	1–19 (207,103)	20–99 (76,933)	100–249 (20,807)	250 or greater (13,592)
Limited Responsibility [1]				
$650 per Search	$71,760	$41.400	$16.450	$20.930
(Cost per Establishment)	(346)	(525)	(791)	(1,540)
Extended Responsibility [1]				
$650 per Search	83.982	47.239	19.246	24.495
(Cost per Establishment)	(405)	(614)	(925)	(1,802)
$4,529 per Test	585.158	329.152	134.099	170.671
(Cost per Establishment)	(2,825)	(4,278)	(6,445)	(12,557)

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis, Tables IV-7, IV-8.

[1] Assumes 60 percent prior to compliance. The limited responsibility alternative is the approach selected by OSHA.

Relative Impact of Allowance for Optional Labeling of Reactor Vessels

Many participants recommended that the final standard amend the labeling requirement to allow for the use of batch tickets, operating procedures, production sheets, and the like (Exs. 19–43, 19–44, 19–46, 19–48, 19–55, 19–58, 19–59, 19–60, 19–61, 19–64, 19–67, 19–71, 19–73, 19–76, 19–79, 19–88, 19–110, 19–111, 19–115, 19–119, 19–122, 19–126, 19–134, 19–137, 19–138, 19–140, 19–152, 19–158, 19–160, 19–162, 19–167, 19–176, 19–188, 19–190, 19–192, 19–194, 19–196, 19–204, 19–209, 19–215). The evidence presented in the public record indicates that this change will reduce the regulatory burden on small entities. Many small scale chemical specialty manufacturers, pesticide producers, etc., are characterized by operations which include such processing. Hence, eliminating the perceived need to continually relabel in the case of a reaction process will not only reduce the cost of compliance for small entities, but also will enhance the effectiveness of a hazard communication program.

Relative Impact of Provision of Lists of Substances

Many participants requested that OSHA provide further guidance on the hazardous substances that would be covered by the standard (Exs. 19–65, 19–74, 19–109, 19–148, 19–166 and 19–175). A large segment of this population was representative of small entities. OSHA has included lists of chemicals that have been evaluated and found to be hazardous. This will provide a floor to the coverage of the standard.

Relative Impact of Exemption for Other Agency Labeling

Many participants, especially those representing small entities requested an exemption from the labeling requirement if a label was already required by another Federal agency (Exs. 19–51, 19–84, 19–110, 19–119, 19–143, 19–145, 19–162, 19–199, 19–204, 19–214). OSHA has included in the final standard a labeling exemption for hazardous chemicals that are subject to other Federal labeling requirements. This change should reduce the costs of compliance, especially for pesticide production, frequently a small scale operation.

Inclusion of Importers and Distributors

The final OSHA standard requires these employers to transmit labeled containers and MSDSs to manufacturing employers. The SIC 516 (Merchant Wholesalers of Chemicals and Allied Products) and SIC 517 (Merchant Wholesalers of Petroleum Products) are expected to be affected by this provision. A large proportion of these establishments are small entities: for SIC 516 and 517 respectively, 87 and 86 percent of the establishments have 19 employees or fewer. The additional cost that would be incurred by these employers, however, is expected to be minimal. These employers will merely be passing on information obtained from the chemical manufacturers. The benefits to these employers may be significant. The provision of hazard information will encourage the adoption of safer handling procedures.

Inclusion of Laboratories

The final OSHA standard requires that laboratory employees be apprised of the hazards of the chemical products used in their respective workplaces. The final standard exempts these entities, generally small scale production processes, from the labeling and MSDS requirements (except to maintaining existing labels), but subjects them to the education and training requirements. The additional cost of compliance for these entities is expected to be minimal, because testimony presented during the public hearing indicated that such education and training is already provided as a general rule.

Relative Impact of the Phase-In

The March 1982 proposal included different compliance periods for substances and mixtures and for employers as a function of employment size. The Small Business Administration (SBA) has indicated, however, that supply channels are not a function of size (Ex. 19–158). Large chemical manufacturers will demand information from small chemical suppliers, especially if the large manufacturer is developing a chemical mixture that will in turn be purchased by industrial users in SIC 20–39. As suggested by SBA, OSHA has therefore adopted a uniform effective date for chemical manufacturers and a delay in the effective date for industrial users:

Chemical manufacturers must be in compliance with the requirements to provide MSDSs and labels to industrial customers within 24 months. All employers in SIC 20–39 must be in compliance with all components of the standard within 30 months.

This phase-in will affect the total initial costs of the activities as well as distribution across entity size categories. The costs for development of MSDSs, labeling, hazard evaluation, and recordkeeping will be significantly reduced for small entities as a consequence of this phase-in of the standard. This is demonstrated in the following way. First, the expected distribution of the initial cost of compliance for the final standard allowing for the regulatory flexibility is presented. Second, the expected additional cost of compliance with the standard omitting the regulatory flexibility is presented.

As presented in Table 7, the total initial cost for small entities (establishments with 19 employees or fewer) is 30 percent of the total initial cost of the final standard. The hazard determination activity is approximately 34 percent of the total cost for these entities. It must be noted, however, that the weights applied may not fully capture the effects of regulatory flexibility on small entities. (A full explanation of the weights is available in Chapter V of the Regulatory Impact Analysis). The compliance time made available to chemical producers will allow employers in small establishments to use chemical hazard information generated by employers in larger establishments in SIC 28. The actual quantity of regulated chemical products that are purchased from large chemical manufacturers (with greater than 19 employees) by small chemical manufacturers (with 19 employees or fewer) was not available. In addition, the cost of labeling was not fully adjusted for the allowance for use of batch tickets and the like. Information on the exact number and distribution of containers that would qualify for such an option was not available. Evidence in the record suggests that this adjustment will reduce the relative costs for small entities. In the absence of these adjustments., the costs of some of the activities for small entities may be overstated.

TABLE 7.—DISTRIBUTION OF EXPECTED INITIAL COSTS BY ESTABLISHMENT SIZE ALLOWING FOR REGULATORY FLEXIBILITY

(Millions 1982)

Provision	Entity size by number of employees (number of entities)			
	1–19 (207,103)	20–99 (76,933)	100–249 (20,807)	250 or greater (13,592)
Review of Labels and MSDSs	$3.864	$2.601	$1.159	$1.835
Review of Education and Training	2.568	1.444	0.588	0.749
Hazard Determination	59.800	43.355	17.940	28.405
Labeling:				
Containers Shipped	20.240	14.674	6.072	9.614
Large In-Plant	3.031	1.705	0.694	0.884
Small In-Plant	17.774	9.998	4.073	5.184
Subtotal	41.045	26.377	10.839	15.682
MSDS:				
Preparation	6.794	4.926	2.038	3.227
Provision	4.614	3.445	1.384	2.191
Filing	4.434	2.494	1.016	1.293
Subtotal	15.842	10.865	4.438	6.711
Education and Training	37.693	57.067	46.911	129.133
Recordkeeping:				
Compiling	1.386	0.991	0.410	0.649
Accessing	10.155	5.712	2.327	2.962
Compliance Plan	6.069	3.355	1.427	1.652
Subtotal	17.610	10.058	4.164	5.263
Total	178.422	151.967	86.039	187.778

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

As presented in Table 8, the average initial cost per establishment allowing for regulatory flexibility is influenced significantly by the size of employment. The average expected initial cost per entity for those with fewer than 19 employees is $861. For relatively large entities with 250 employees or greater, the average initial cost is $13,815.

TABLE 8.—DISTRIBUTION OF EXPECTED AVERAGE COST ALLOWING FOR REGULATORY FLEXIBILITY (1982)

Employment size category	Average initial cost per entity	Average employment per entity	Average initial cost per employee
1–19	$861	5	$172
20–99	1,975	37	54
100–249	4,135	124	33
250 or greater	13,815	559	25

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

Scale economies do occur, however, as reflected by the estimates of average initial cost per employee for each entity size category. Larger establishments can effectively spread much of the overhead cost of a hazard communication program over a larger work force. The average cost for large entities with 250 employees or greater is approximately $25. For relatively small entities with 19 employees or fewer, the average initial cost per employee is $172.

Without the allowance for regulatory flexibility, each employer in the manufacturing sector may have to inventory the chemical products in the workplace, evaluate the chemical products in his or her workplace for health hazards, develop MSDSs for the chemical product in the workplace if they are not already available, and review the labels on some of the chemical containers in the workplace. Assuming a worst case scenario, each employer in manufacturing would be required to conduct an immediate inventory of chemical products in his or her workplace. The employer would then evaluate the chemical products for health hazards, review the labels on containers of such products, and develop an appropriate MSDS for each product if one does not exist in the workplace. The potential costs associated with this scenario have been estimated as follows.

It is assumed that a supervisor would spend an average of 5 minutes per chemical developing a chemical inventory and reviewing the label on the container. Supervisory time is valued at $21 per hour. Thus, as presented in Table 9 an additional cost of $21.619 million would be incurred by small entities and an additional cost of $44.59 million would be incurred by all entities in manufacturing. As presented in Table 9, the expected additional cost for each employer to evaluate immediately the chemical products in his or her workplace would be $4,941.5 million for small entities and $10,182.835 million for all of the entities in the manufacturing sector.

The expected incremental cost of MSDS development as presented in Table 9 would be $183.33 million for small entities and $377.783 million for all of the entities in the manufacturing sector. The expected total additional cost for all of these activities would then be $5,146.499 million for small entities and $10,605.208 million for all entities in the manufacturing sector. These estimates are conservative in that only 5 minutes of the supervisor's time has

been allocated to the inventory and the label review. Furthermore, it has been assumed that appropriate labels would be readily available from the producers of the chemical products. Relaxing these assumptions would imply that additional costs for the chemical inventory, label review, and label modification and redesign would be incurred by all entities.

TABLE 9.—DISTRIBUTION OF ADDITIONAL COSTS ATTRIBUTED TO THE ELIMINATION OF REGULATORY FLEXIBILITY

(Millions 1982)

Provision	Entity size by number of employees				
	1–19	20–99	100–249	250 or greater	Total
MSDS Development	$183.330	$101.383	$43.127	$49.943	$377.783
Chemical Inventory	21.619	11.995	5.086	5.890	44.590
Hazard Evaluation	4,941.500	2,732.686	1,162.462	1,346.187	10,182.835
Total	5,146.449	2,846.064	1,210.675	1,402.02	10,605.208

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

Industry Effects

The expected compliance cost for the final OSHA standard has been calculated for each industry in manufacturing. The cost estimates are approximations and may not sum to the total figures provided in Chapter IV of the Regulatory Impact Analysis. These cost figures do, however, indicate the relative impact on the respective industry. The costs of hazard evaluation, labeling of chemical shipments, label review, label modification and redesign, MSDS development. MSDS provision with shipments, and hazard recordkeeping have been attributed to SIC 28. Some of these costs may actually be incurred by establishments in SIC 2911 or perhaps by other industrial suppliers.[1] Further disaggregation of these costs, however, was not possible. In the absence of the necessary information for an accurate adjustment for the industry groups, the costs assigned to SIC 28 may be overestimated.

As presented in Table 10, the industries associated with a relatively high compliance cost include Food and Kindred Products (SIC 20). Lumber and Wood Products (SIC 24), Printing and Publishing (SIC 27), Chemical and Allied Products (SIC 28), Fabricated Metal Products (SIC 34), Machinery Except Electrical (SIC 35), Electrical Equipment and Supplies (SIC 36), and Transportation Equipment (SIC 37). The cost as a percent of payroll and value-added are the highest for SIC 28 at 2.1 percent and 0.14 percent, respectively. As noted previously, some of the cost attributed to producers of chemical products is likely to be incurred by employers in other industries.

[1] The distributional impact on importers, repackagers, and distributors was discussed in a previous section.

TABLE 10.—EXPECTED TOTAL INITIAL COST AS A PERCENT OF PAYROLL, AND AS A PERCENT OF VALUE-ADDED BY INDUSTRY (1982)

(SIC)	Expected total cost (millions)	Cost as percent of payroll [1]	Cost as percent of value-added [2]	Average cost per employee
(20) Food and Kindred Products	$27.428	0.15	0.04	$23.82
(21) Tobacco Manufacturers	0.872	0.12	0.02	17.60
(22) Textile Mill Products	13.979	0.19	0.09	20.84
(23) Apparel and Other Textile Products	22.809	0.27	0.13	20.60
(24) Lumber and Wood Products	17.391	0.28	0.13	33.68
(25) Furniture and Fixtures	9.134	0.24	0.12	25.78
(26) Paper and Allied Products	11.663	0.14	0.05	24.31
(27) Printing and Publishing	38.105	0.30	0.13	44.00
(28) Chemicals and Allied Products	260.018	2.10	0.14	408.09
(29) Petroleum and Coal Products	2.252	0.09	0.02	25.55
(30) Rubber and Plastic Products	14.200	0.21	0.09	26.51
(31) Leather and Leather Products	4.314	0.24	0.12	22.48
(32) Stone, Clay and Glass Products	12.533	0.18	0.07	26.91
(33) Primary Metal Industries	18.024	0.11	0.05	19.96
(34) Fabricated Metal Products	30.674	0.17	0.08	27.21
(35) Machinery, Except Electrical	41.247	0.16	0.07	28.48
(36) Electrical Equipment and Supplies	29.355	0.15	0.07	21.58
(37) Transportation Equipment	27.368	0.10	0.05	21.25
(38) Instruments and Related Products	10.163	0.15	0.06	25.69
(39) Misc. Manufacturing Products	11.555	0.29	0.13	34.36

[1] The payroll (1976) for each SIC category is taken from U.S. Department of Commerce, Bureau of Census, *Statistical Abstract of the U.S.*, 1979.
[2] The value-added (1976) for each SIC category is taken from U.S. Department of Commerce, Bureau of Census, *Statistical Abstract of the U.S.*, 1979.

Source: U.S. Department of Labor, Occupational Safety and Health Administration, Office of Regulatory Analysis.

OSHA has determined that the final standard will not impose a substantial burden on the affected industries. Hence, OSHA has concluded that the standard is economically feasible.

Environmental Assessment—Finding of No Significant Impact

The Hazard Communication standard and its major alternatives, as well as responses to OSHA's Notice of Proposed Rulemaking (NPRM) (47 FR 12092–12123, March 19, 1982) have been reviewed. No comments were received which specifically addressed the

environmental assessment for this standard.

In accordance with the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.), as interpreted by the Council on Environmental Quality (CEQ) guidelines (40 CFR Part 1500 et seq.), and with the Department of Labor (DOL) NEPA Compliance Regulations (29 CFR Part 11; 45 FR 51187 et seq., August 1, 1980), the Assistant Secretary for OSHA has determined that the proposed rule will have no significant environmental impact.

As presented in the NPRM and as outlined in earlier sections of this preamble, this action would allow employees easier access to information on hazardous chemical substances present in the workplace through the use of labels and hazard warnings, material safety data sheets, information and training, and access to written records. The worker population, in effect, is expected to experience a significant benefit in health and safety from the improved workplace environment that is expected to result from implementation of the standard.

A review of the summary and explanation of this rule indicates that the standard is unlikely to result in the occurrence of significant health or environment effects outside of the workplace. The labeling of chemical containers to identify their contents would not have a direct or significant impact on air or water quality, land or energy use, or waste disposal outside of the workplace, because the nature of a substance would not be changed through its identification. For example, the labeling of a container would not eliminate the possibility of the chemical contents leaking into the external environment. However, it is possible that there would be some potential, indirect benefit to the external environment as a result of the proposed regulation. The labeling of toxic substances generally would create a greater awareness of their nature and effects, which in turn could lead to a more careful handling of them. To the extent that these substances are handled more carefully, there would be a beneficial impact on air and water quality and on solid waste disposal, although containers of hazardous waste are exempt from the labeling requirements. In cases where reclamation or recycling of materials from solid waste occurs, or where cleanup of abandoned or contaminated landfills takes place, identification of hazardous substances may prove useful and cost-effective. Such benefits of course depend on the continued presence of the hazard information itself, and labels can deteriorate or be removed over time. Moreover, because hazard warning information on the label is intended to alert employees to hazardous materials in the workplace, this information will not identify or encompass all of the potential hazards that may occur outside of the workplace.

In addition, for reasons discussed elsewhere in this preamble, none of the alternatives considered by OSHA would significantly increase the effectiveness of the standard. Other provisions, such as expanded requirements of material safety data sheets, chemical listing, education and training, compliance periods, and recordkeeping, would have no significant environmental impacts outside of the workplace.

Moreover, no evidence has been presented to show that the regulation would have any significant adverse impacts on the external environment, would result in any irreversible or irretrievable commitment of resources, or would adversely affect the short-term uses of the human environment and the maintenance or enhancement of long-term productivity.

Accordingly, on the basis of the discussion presented earlier in this notice, OSHA has determined that the hazard communication standard does not significantly affect the quality of the human environment and that preparation of an EIS is not required.

IV. Summary and Explanation of the Standard

The following is a paragraph-by-paragraph summary of the provisions of the final standard:

(a) *Purpose.* In the final standard, a paragraph has been added to specify what OSHA intends to accomplish through promulgation of the standard. In essence, the paragraph states that the final Hazard Communication standard is intended to ensure that all employees in the manufacturing sector, Standard Industrial Classification (SIC) Codes 20 through 39, are apprised of the hazards they work with through a hazard communication program. This program is to include container labeling material safety data sheets, and employee training.

The paragraph goes on to state that OSHA intends to comprehensively address the issue of evaluating and communicating chemical hazards to employees in the manufacturing sector in this standard, and to preempt any state law pertaining to this subject. Thus if a state wishes to regulate in this area, it can only do so if the standard is approved by OSHA under section 18(b) of the Act which deals with state plans. This preemption will serve to reduce the burden on interstate commerce produced by conflicting state and local regulations and will ensure that all employees in the manufacturing sector are accorded the same degree of protection. OSHA will examine carefully any state requests to regulate in this area to determine any potentially burdensome impact on interstate commerce as well as to ascertain whether there is a compelling need for a separate regulation.

(b) *Scope and application.* The final hazard communication standard applies to employers and employees in the manufacturing SIC Codes, 20 through 39. The manufacturers in these SIC codes who produce chemicals for use or distribution, and importers of such chemicals, must evaluate the hazards of these substances. All employers in the manufacturing sector must establish a hazard communication program for their employees. In addition, distributors of hazardous chemicals are required to transmit hazard information to their manufacturing sector customers.

The proposed standard also applied to the manufacturing SIC codes. As discussed elsewhere in this preamble, OSHA has concluded that the need for hazard communication is greatest in the manufacturing sector, and is exercising its priority setting authority by choosing to regulate this segment of industry at this time, and reserving the right to separately regulate other segments in the future.

The scope of the final standard has been expanded to cover importers and distributors. The rulemaking record indicated that in order for the flow of hazard information from upstream manufacturers to downstream users to be continuous and effective, all aspects of the supply chain have to be specifically included in the scope of the standard. Thus, in the final standard importers are required to supply the same information as domestic manufacturers of a hazardous chemical. Distributors are to ensure the downstream flow of information by shipping labeled containers and making an appropriate material safety data sheet available to downstream purchasers.

The standard also applies only to chemicals which are known to be present in the workplace and to which employees may be exposed under normal conditions of use or in a foreseeable emergency. This means that employers must assess and communicate the hazards of any such chemicals, but do not have to analyze complex chemical mixtures in the

workplace to determine the precise composition and components. That is, the term "known" means the employer need not analyze intermediate process streams, for example, to determine the presence of quantity of trace contaminants. However, where the employer knows of such contaminants, and they are hazardous, then they fall under the provisions of the standard.

There are a number of laboratories in the manufacturing facilities covered by this standard, and they receive different treatment in terms of hazard communication requirements. Employers are to ensure that labels on incoming containers of hazardous chemicals are not removed or defaced. Furthermore, any material safety data sheets received with such chemicals are to be maintained, and accessible to employees. Employers are also to ensure that laboratory employees are apprised of the hazards of the chemicals they work with in accordance with the training provisions of this standard. In all other respects laboratories in the covered SIC Codes are exempt from the provisions of the hazard communication standard. For example, employers need not label every container used in the laboratory with an identity and hazard warning as would otherwise be required.

The standard also exempts potentially hazardous chemicals that are brought into the workplace for the personal consumption of employees, such as foods, drugs, cosmetics or tobacco products.

The standard also included specific labeling exemptions for chemicals which are regulated by other Federal agencies, and total exemptions for certain classes of substances which are not expected to be hazardous for purposes of this standard.

(c) *Definitions.* The final standard includes a number of definitions which provide the framework to determine which employers are covered by the standard; what substances are covered by the standard; how the standard defines hazards; and how OSHA defines other key terms for purposes of the standard, such as what constitutes a trade secret. Since a number of these definitions are unique to this standard, they should be consulted to ensure that the provisions are properly understood.

The standard applies to several different groups of businesses, in varying degrees of coverage. All of the hazard communication provisions apply to "employers" who are defined as businesses within SIC Codes 20 through 39 where chemicals are "either used, or are produced for use or distribution." "Produce" means to "manufacture, process, formulate, or repackage." "Use" means to "produce, handle, react, or transfer." Those "employers" who "produce" chemicals for "use or distribution" are considered to be "chemical manufacturers," and thus have additional hazard evaluation duties to perform.

The standard also requires "importers" to evaluate the hazards of chemicals. An importer "receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or manufacturing purchasers within the United States." "Distributors" supply "hazardous chemicals to other distributors or to manufacturing purchasers." "Manufacturing purchasers" are "employers" who purchase a hazardous chemical for use within a workplace in SIC Codes 20 through 39.

The standard applies to any chemical which is known to be present in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency. A "chemical" is broadly defined as "any element, chemical compound, or mixture of elements and/or compounds." "Articles" are excluded under the scope of the standard from being covered as a "chemical." A mixture is defined as "any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction". "Exposure" occurs when an employee may inhale, ingest, or absorb a hazardous chemical during the course of employment. The definition includes both potential and current "exposure." A "foreseeable emergency" is one which employers would normally plan for as a presumed potential occurrence determined by the nature of the operation, i.e. equipment failure or rupture of containers.

The standard applies to both "physical" and "health" hazards. Each of these terms is defined by listing the various types of "physical" and "health" hazards covered. These listed hazards are then individually defined, or in the case of "health" hazards, further explained in Appendix A.

If a "container" of a hazardous chemical is present in, or leaves the workplace, it must be labeled with an "identity" and "hazard warning." A "container" is anything that holds hazardous chemicals except pipes and piping systems. A "label" is any written, printed, or graphic material displayed on or affixed to containers of hazardous chemicals. An "identity" is any name used on the material safety data sheet for the chemical, and on the list of hazardous chemicals in the workplace. The name used should permit cross-references to be made among these three items. The "hazard warning" conveys the hazards of the chemical(s) in the container to employees. This message may be conveyed by words, symbols, pictures, or any combination thereof.

(d) *Hazard determination.* A new paragraph has been added to the final standard to separate out and highlight the provisions concerning the determination of what constitutes a hazard for purposes of the standard.

The primary duty for hazard evaluation lies with the chemical manufacturers and importers of hazardous chemicals. Under the provisions of this paragraph, they are required to evaluate the chemicals they produce or import in their workplaces to determine if they are hazardous. Employers may rely on the evaluation performed by the chemical manufacturer or importer for chemicals they use within their workplaces to satisfy this requirement.

The chemical manufacturers, importers, or employers are to be held accountable for the quality of the hazard determinations they perform. Each chemical is to be evaluated for its potential to cause adverse health effects, as well as its potential to pose physical hazards, such as flammability. The particular health and physical hazards to be considered are enumerated in the definition for a "hazardous chemical." Additional definitions are provided for the terms used in the definition for a hazardous chemical. The specific physical hazards are also defined in the definitions paragraph. The health hazard definitions are contained in Appendix A. Appendixes A and B are integral parts of this hazard determination paragraph.

Appendix A contains a discussion of the difficulty in definitively identifying all possible health effects, and indicates the broad approach the standard intends in its coverage of such effects. It further provides specific definitions for certain acute hazards, such as "corrosive" and "sensitizer." In addition, the Appendix includes a target organ categorization of health effects which gives examples of signs and symptoms of exposure as well as indications of substances which have been found to affect the target organ. This information is also provided to indicate the broad scope of health hazards to be covered. Essentially, the employer must report any adverse health effect for which there is scientific (i.e. statistically significant) evidence based on at least one positive study conducted in accordance with established scientific principles, that it

may occur as a result of employee exposure.

Appendix B provides further guidance to the employer in terms of the criteria to be applied in determining whether or not a chemical is hazardous for purposes of the standard. As examples of evidence to be considered, OSHA indicates that both human and animal data must be evaluated. Furthermore, if an available study indicates that an adverse health effect is likely to occur, and that study is conducted according to scientific principles and results in statistically significant findings, the employer is required to report it whether he agrees with the finding or not. Employers are free to report such findings in a non-conclusionary fashion, i.e. they don't have to agree with it, but they do have to report it. Employers may also report any negative data they believe is relevant to the hazard potential of the chemical. An additional Appendix C lists a number of sources which are available for employers in their search for information on hazards.

The hazard determination paragraph also includes two provisions which establish certain substances as being hazardous chemicals in any occupational setting. These substances are those currently regulated by OSHA under 29 CFR Part 1910, General Industry Standards, and those listed by the American Conference of Governmental Industrial Hygienists (ACGIH) in their latest edition of the *Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment.* This provision establishes a "floor" of over 600 substances to be communicated to employees.

In addition, OSHA has defined a carcinogen for purposes of communication of hazards as any substance found to be a confirmed or suspected carcinogen by the International Agency for Research on Cancer, the National Toxicology Program, or OSHA. Use of these sources should eliminate much controversy involved in defining and identifying carcinogens. The hazard determination paragraph (d) also addresses the coverage of hazardous chemicals which are mixtures. Mixture coverage is divided into several considerations. First of all, if the employer has objective test data on the mixture as an entity, that data must be used to determine the hazards. If such data are not available for the health hazard determination, then the employer must consider the mixture to have the health hazards of those components which comprise one percent or more of the total composition. If any of the components are carcinogens, the mixture must be considered to be carcinogenic if the component is present in concentrations of 0.1% or more.

If the mixture has not been objectively evaluated to determine its physical hazard potential, the employer may use whatever scientifically valid information is available to subjectively assess the potential hazards.

Finally, if the employer has evidence to indicate that a component which comprises less than one percent of the mixture could be released in concentrations which would exceed an established permissible exposure limit under normal conditions of use, it must be identified. Furthermore, if the employer has reason to believe that the component could be released in quantities hazardous to the health of employees, it shall also be identified even though present in quantities less than one percent of the total weight or volume, or less than 0.1% in the case of a carcinogen. The procedures used to evaluate hazards must be prepared in writing. The written description may be included in the written hazard communication program required under paragraph (e).

(e) *Written hazard communication program.* The final standard requires each employer to establish a comprehensive hazard communication program for their employees, which includes at least the mandated container labeling, material safety data sheets, and an employee training program. The program is to be written, and is to include how the employer plans to meet the criteria of the standard regarding labels, material safety data sheets, and training; a list of the hazardous chemicals in each work area, the methods the employer will use to inform employees of the hazards of non-routine tasks, as well as of the hazards associated with chemicals contained in unlabeled pipes in their work areas; and the methods employers will use to inform contractors in manufacturing facilities of the hazards to which their employees may be exposed.

The written program need not be lengthy or complicated, but should adequately address each of the required components in the program. Some employers already have aspects of their existing hazard communication programs in written form. These need not be modified to comply with this requirement as long as they address the minimal criteria established in the standard.

The written program is to be made available to employees, their designated representatives, the Assistant Secretary for OSHA and the Director of NIOSH.

(f) *Labels and other forms of warning.* Chemical manufacturers, importers and distributors are required to ensure that containers of hazardous chemicals leaving the workplace are labeled, tagged or marked with the identity, appropriate hazard warnings, and the name and address of the manufacturer or other responsible party. Additionally, they are to ensure that these labels do not conflict with those applied in accordance with Department of Transportation regulations under the Hazardous Materials Transportation Act. If labels already applied by the manufacturer, importer, or distributor contain the minimal information required by OSHA, additional labels need not be affixed.

The final standard requires that each container in the workplace be labeled, tagged or marked with the identity of hazardous chemicals contained therein, and hazard warnings appropriate for employee protection. The term "identity" is defined for purposes of this standard as being any designation the employer chooses to use, as long as it also appears on the list of hazardous chemicals for the work area, and on the associated material safety data sheet. The hazard warning is to be any type of message, words, pictures, or symbols, which convey the hazards of the chemical(s) in the container. The employer is responsible for selecting the message and ensuring that it is effective for the purpose involved.

OSHA recognizes that container labeling may be difficult, or in some cases impractical, to accomplish within a plant. Therefore, several exemptions to in-plant individual container labels have been included in the final standard. If there are a number of stationary containers within a work area which have similar contents and hazards, the employer may post signs or placards which convey the hazard information required rather than individually labeling each piece of equipment. Employers may also use various types of standard operating procedures, process sheets, batch tickets, blend tickets, or other such written materials as substitutes for individual container labels on stationary process equipment. However, these written materials must contain the same information as is required on the labels, and must be readily accessible to workers in the work areas. This requirement does not apply to pipes or piping systems, which are exempted altogether from the labeling requirements.

One additional exemption is included for in-plant containers. Employers are not required to label portable containers, into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. According to the definition of immediate use, the container must be under the control of the employee performing the transfer, and used within the workshift when the transfer has been made, for the exemption to apply.

The standard also requires that employers ensure that labels on incoming containers of hazardous chemicals are not removed or defaced, unless they are immediately replaced with another label with the required information. In addition, labels are to be legible, in English and prominently displayed on the container. Employers may add information in other languages as well, as long as the message also appears in English.

(g) *Material safety data sheets.* The final standard requires chemical manufacturers and importers to develop material safety data sheets for each hazardous chemical they produce or import. Employers are required to obtain or develop a material safety data sheet for each hazardous chemical used in their workplaces.

Specific requirements are included for the information to be provided on the MSDS. Such information is to be in English, and includes the identity, as well as chemical and common names, for the hazardous chemical. Special provisions apply to the listing of ingredients for hazardous chemicals which are mixtures. For physical hazards, the employer is to list those ingredients which he or she has determined present a physical hazard. For health hazards, the employer must list each component which comprises 1% or more, and which is itself a health hazard. Any chemical which is determined to be a carcinogen must be listed if it is present in quantities of 0.1% or greater. Employers must also list ingredients present in concentrations of less than one percent if there is evidence that the permissible exposure limit may be exceeded or if it could present a health hazard in those concentrations.

In addition to identity information, the employer must provide information specified on the physical and chemical characteristics of the hazardous chemical, known acute and chronic health effects and related health information, as well as information concerning exposure limits, whether the chemical is considered to be a carcinogen by NTP, IARC, or OSHA, precautionary measures, emergency and first aid procedures, and identification of the person responsible for the sheet.

In some situations, employers may have more than one complex mixture in the workplace which have similar contents and hazards. For example, petroleum streams have essentially the same chemical components, but may vary slightly in concentrations of these components. The hazards are essentially the same. Employers may prepare one MSDS for all of these similar mixtures in order to comply with the provisions of this standard.

If a manufacturer or importer cannot find the appropriate information to complete a specified category, then the MSDS must be marked to indicate that no information was found. In other words, the employer must not leave blank spaces on the sheets which would then be open to interpretation as to the significance of not having an entry in them. If the category is not applicable to the chemical involved, the space should be marked to indicate that as well.

The chemical manufacturer, importer or employer is to ensure that the MSDS accurately reflects the scientific evidence which formed the basis for the determination that the chemical in question is hazardous. The chemical manufacturers, importers, and employers should remain aware of the development of new and significant information regarding the potential health hazard of a chemical in their workplace. When they do obtain such information, they must add it to the MSDS within three months. If the chemical is not being produced at the time of the information is discovered, the information need not be entered onto the MSDS until the chemical is reintroduced into the workplace, and thus employees are potentially exposed.

An MSDS is to be provided to manufacturing purchasers of hazardous chemicals with their first shipment. Providing an MSDS does not imply that the sheet need be physically attached to the shipment. It may be transmitted by mail, through a computer link-up, or in any other effective manner the manufacturer chooses. When an MSDS is updated, the new version must be transmitted to the manufacturing purchaser with the next shipment. Although the chemical manufacturers and importers have a positive duty to provide such information, there may be situations where the MSDS is lost or misplaced. If one is not received as anticipated, the manufacturing purchaser must make efforts to obtain one as soon as possible.

Distributors are responsible for ensuring that manufacturing purchasers of their hazardous chemicals are provided an appropriate MSDS. This may be accomplished by providing an MSDS prepared by the producer of the chemical.

Copies of the MSDSs for hazardous chemicals in a given work area are to be readily accessible to employees in that work area. In order for the MSDS to serve as a source of detailed information on hazards, it must be located close to workers, and readily available to them during each workshift.

As was the case with labels, alternatives to MSDSs within a plant are also permitted as long as they provide the appropriate information, and are readily accessible to employees. These would be expected to take the form of written operating procedures, manuals, etc. The employer may also use this alternative approach to address the hazards of a process, rather than individual chemicals. However, information must still be available to employees for each hazardous chemical involved.

MSDSs are to be made available to employees and their designated representatives, the Assistant Secretary and the Director. They must be maintained in a current fashion, and need not be retained for any specified period of time beyond that, except to the extent required by the Employee Access to Exposure and Medical Records rule, 29 CFR 1910.20.

(h) *Employee information and training.* Employers are to establish a training and information program for employees exposed to hazardous chemicals. Such training is to be provided at the time of initial assignment, and whenever a new hazard is introduced in their work area. Of course, any emplyees who have not been trained previously must receive training equivalent to the required initial assignment training when this standard takes effect.

The standard specifies the information to be transmitted to employees. First they are to be informed of the requirements of this regulation, i.e., that it exists, that employers are required to have hazard communication programs, and the components of the programs in their workplaces. Employees are also to be informed of any operations in their work area where hazardous chemicals are present, and where the employer will be keeping the written materials required under this standard, including the written hazard evaluation procedures, written program, lists of hazardous chemicals, and MSDSs required by this section.

Employees are also to be trained regarding methods and observations they may use to detect the presence of a hazardous chemical in their work area. For example, employees should be informed of the visual appearance or smell of the chemicals they may be exposed to, so they will know when they are being released into the work atmosphere. Employees are also to be trained specifically about the hazards of the chemicals in their work areas. This may be done by specific chemical or by categories of hazards, but in any case, the employee is to be aware that information is available on the specific hazards of individual chemicals through the material safety data sheets. Training is to include the measures employees can take to protect themselves from the hazards, and is to indicate the specific procedures implemented by the employer to provide protection, such as work practices and the use of personal protective equipment. In addition, the employer is to explain the hazard communication program implemented in that workplace, including how to read and interpret information on labels and material safety data sheets, and how employees can obtain and use the available hazard information.

(i) *Trade secrets.* OSHA recognizes in the final standard that specific chemical identity information can constitute a *bona fide* trade secret, and thus provisions are made to protect such an identity while providing for the proper protection of exposed employees. This is accomplished by providing for limited trade secret disclosure to health professionals under prescribed conditions of need and confidentiality. The term "specific chemical identity" is used to describe the trade secret information being discussed. This term refers to the chemical name, the Chemical Abstracts Services (CAS) Registry Number, or any other specific information which reveals the precise chemical designation. It does not include common names.

The proposed standard did not include a definition for the term "trade secret," although OSHA stated that the Agency considered the definition derived from the Restatement of Torts to be the appropriate one. In response to comments suggesting that the definition be explicitly stated in the final standard, a slightly modified version of that definition has been added to clarify what the Agency considers to be a trade secret for purposes of this standard.

Given that it is recognized that the specific chemical identity of a chemical may be a trade secret, the standard establishes an information disclosure scheme which requires the release of essential hazard information, and defines the terms under which the specific chemical identity must also be released.

The chemical manufacturer, importer or employer is permitted to withhold the specific chemical identity from the MSDS if certain conditions can be met: (1) The chemical manufacturer, importer or employer can support the claim that the information withheld is a trade secret; (2) information concerning the properties and effects of the hazardous chemical is disclosed as required on the appropriate material safety data sheet; (3) the chemical manufacturer, importer, or employer indicates on the MSDS that the specific chemical identity is being withheld as a trade secret; and (4) the specific chemical identity is made available to health professionals under certain specified situations. Health professionals are considered to be physicians. Industrial hygienists, toxicologists, or any other person providing medical or other occupational health services to exposed employees.

The final standard's provisions make a distinction between the trade secret disclosure requirements in the event of a medical emergency and in non-emergency situations.

In the case of a medical emergency, the chemical manufacturer, importer, or employer must immediately disclose the specific chemical identity of a hazardous chemical to a treating physician or nurse when the information is needed for proper emergency or first aid treatment. As soon as circumstances permit, however, the chemical manufacturer, importer, or employer may obtain a written statement of need and a confidentiality agreement as provided for below.

OSHA considers it to be appropriate for the treating physician or nurse to have the ultimate responsibility for determining that a medical emergency exists. At the time of the medical emergency, their professional judgment regarding the situation must form the basis for triggering the immediate disclosure requirement. Although there will undoubtedly be situations which, when viewed in retrospect, do not appear to be genuine emergencies, OSHA has determined that the short-term necessity for appropriate emergency treatment far outweighs the risk of unnecessary disclosure of secret information. Since the chemical manufacturer, importer, or employer can require a written statement of need and a confidentiality agreement to be completed after the emergency is abated, further disclosure of the trade secret can be effectively controlled. If a chemical manufacturer, importer or employer refuses to provide specific chemical identity information in the event of a medical emergency, OSHA regulations would provide appropriate enforcement remedies.

In drafting the medical emergency disclosure requirement, OSHA considered whether to allow the chemical manufacturer, importer, or employer to suggest alternatives to disclosure of the type stated in the provisions for non-emergency situations (paragraph (i)(7)(v)). However, OSHA determined that the emergency nature of the situation addressed necessitiates disclosure of the specific chemical identity immediately without the opportunity for the chemical manufacturers, importer or employer to explore possible suitable alternatives with the treating physician or nurse.

In non-emergency situations, chemical manufacturers, importers, or employers are required to disclose the withheld specific chemical identity to health professionals providing medical or other occupational health services to exposed employees if certain conditions are met. The concept of "health professional" is more broadly stated than for emergency situations, and includes any physicians, industrial hygienists, toxicologists, or epidemiologists who provide these medical or other occupational health services to exposed employees. Nurses are not included among the health professionals entitled to access to specific chemical identities in non-emergency situations. OSHA has determined that it is more appropriate, given the competing interests balanced in this standard, to entrust such information to the physician to whom a nurse would normally report. The request for information must be in writing, and must describe with reasonable detail the medical or occupational health need for the information. To be considered a medical or occupational health need for purposes of this standard, the health professional must be planning to use the specific chemical identity information for one or more of the following activities:

1. To assess the hazards of the chemicals to which employees will be exposed.
2. To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels.
3. To conduct pre-assignment or periodic medical surveillance of exposed employees.
4. To provide medical treatment to

exposed employees.
5. To select or assess appropriate personal protective equipment for exposed employees.
6. To design or assess engineering controls or other protective measures for exposed employees.
7. To conduct studies to determine the health effects of exposure.

It should be noted that for purposes of this standard, exposure includes potential, as well as current, exposure situations. Thus the health professionals will be able to obtain the necessary information prior to the actual exposure of employees, and can implement preventive measures to avoid the occurrence of health effects.

In addition, the written request must also explain in detail why the disclosure of the specific chemical identity is essential to providing the occupational health services, and why disclosure of the following types of information would not satisfy the health professional's need:

1. Properties and effects of the chemical.
2. Measures for controlling workers' exposure to the chemical.
3. Methods of monitoring and analyzing worker exposure to the chemical.
4. Methods of diagnosing and treating harmful exposures to the chemical.

OSHA anticipates that in many situations this alternative information will be sufficient to satisfy the health professional's needs.

The request for the information must further provide a description of the procedures to be used to protect the confidentiality of the information. An agreement not to use the information for any purpose other than the health need asserted or to release it under any circumstances other than to OSHA must also be included, and signed by the health professional as well as the employer or contractor of the health professional's services. The requirement that the employer or contractor of the health professional's services be a co-signatory to the agreement applies equally regardless of whether the health professional is providing occupational health or medical services to a downstream employer, labor organization, or individual employees, and regardless of whether the health professional is being paid for his services. This makes explicit that both the principal and the agent are legally responsible for compliance with the agreement, although only the health professional may actually have access to the specific chemical identity information.

The provisions of the confidentiality agreement may not include requiring the posting of a penalty bond. It may restrict use of the information to the purposes indicated in the statement of need, prohibit disclosure to anyone other than OSHA who has not signed an agreement, and provide for appropriate legal remedies, including stipulation of a reasonable pre-estimate of likely damages. Nothing in the standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

If the health professional decides there is a need to disclose the information to OSHA, the chemical manufacturer, importer, or employer who provided the information must be informed by the health professional prior to, or at the same time as, such disclosure.

If the chemical manufacturer, importer, or employer denies the written request for information, the denial must also be in writing, and be provided to the health professional within thirty days of the request. The denial must provide evidence to support the claim that the chemical identity is a trade secret, state the specific reasons why the request is being denied, and explain in detail how alternative information may satisfy the occupational health need without revealing the specific chemical identity.

The requesting health professional who still needs the information may then refer the matter to OSHA for consideration. The original request, as well as the written denial, must be provided to OSHA at the time of this referral. OSHA will review these documents to determine whether the chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity is a trade secret, and that the health professional has demonstrated a medical or occupational health need for the information, as well as adequate means to protect the confidentiality of the information.

If OSHA determines that the specific chemical identity is not a trade secret, the employer will be subject to citation. Similarly, the employer will be subject to citation if the specific chemical identity is a trade secret, but the requesting health professional has demonstrated a medical or occupational health need, executed a confidentiality agreement, and has shown adequate means for complying with the terms of the confidentiality agreement. Abatement of the citation will most likely be to divulge the specific chemical identity subject to the confidentiality agreement. However, consistent with the power given to the Secretary in Section 15 of the Act, if the chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon disclosure as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer. It is contemplated that the Assistant Secretary would personally review and approve such orders, limitations or conditions. If the employer continues to withhold the requested information after a citation has been issued, the contested citation will go to the Occupational Safety and Health Review Commission (OSHRC) for adjudication.

In accordance with OSHRC rules, The Administrative Law Judge (ALJ) from OSHRC may decide to review the matter *in camera*. At all stages of the proceeding, the normal OSHRC and judicial review procedures will be followed.

As a further clarification of the disclosure requirements of the final standard, the provisions specifically exclude trade secret processes or percentage of mixture information from disclosure. This is the type of information which is most likely to be trade secret and least likely to be of medical or occupational health interest. OSHA recognizes that, in rare cases, process information (such as where an intermediate hazardous chemical is not present in the final product) or even percentage of mixture information (such as for antidote treatment) may be necessary in an emergency situation. OHSA believes that responsible chemical manufacturers, importers, or employers will appropriately respond to such emergencies. Thus such information was not included in the concept of specific chemical identity.

The chemical manufacturer, importer or employer is required to divulge to the Assistant Secretary or designee any information required under this standard. However, the chemical manufacturer, importer, or employer may claim trade secret status at the time the information is provided, and the Assistant Secretary will make the necessary arrangements to ensure protection of such trade secrets, in accordance with the provisions of

section 15 of the Act and Agency procedures.

(j) *Effective dates.* The effective dates of the final standard are structured according to activity; that is, information being sent downstream must be prepared first, then other provisions of the hazard communication program are to be complied with by a later date. Chemical manufacturers and importers have two years in which to comply with the labeling of containers shipped downstream, and to provide material safety data sheets to manufacturing purchasers. Distributors must also begin transferring information downstream by this initial compliance date. All employers must be in compliance with all provisions of the standard within 2½ years.

V. Authority, Signature and the Standard

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, U.S Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Pursuant to Sections 6(b) and 8(g) of the Act, 29 CFR is hereby amended by adding a new § 1910.1200 to read as set forth below.

List of Subjects in 29 CFR Part 1910

Occupational safety and health, Hazard communication.

(Sec. 6(b), 8(c), and 8(g), Pub. L. 91–596, 84 Stat. 1593, 1599, 1600; 29 U.S.C. 655, 657; 29 CFR Part 1911; Secretary of Labor's Order No. 9–83 (48 FR 35736))

Signed at Washington, D.C. this 21st day of November 1983.

Thorne G. Auchter,

Assistant Secretary for Occupational Safety and Health.

PART 1910—[AMENDED]

Subpart 2 of Part 1910 of Title 29 of the Code of Federal Regulations (CFR) is hereby amended by adding a new § 1910.1200 to read as follows:

§ 1910.1200 Hazard communication.

(a) *Purpose.* (1) The purpose of this section is to ensure that the hazards of all chemicals produced or imported by chemical manufacturers or importers are evaluated, and that information concerning their hazards is transmitted to affected employers and employees within the manufacturing sector. This transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, material safety data sheets and employee training.

(2) This occupational safety and health standard is intended to address comprehensively the issue of evaluating and communicating chemical hazards to employees in the manufacturing sector, and to preempt any state law pertaining to this subject. Any state which desires to assume responsibility in this area may only do so under the provisions of § 18 of the Occupational Safety and Health Act (29 U.S.C. 651 et. seq.) which deals with state jurisdiction and state plans.

(b) *Scope and application.* (1) This section requires chemical manufacturers or importers to assess the hazards of chemicals which they produce or import, and all employers in SIC Codes 20 through 39 (Division D, Standard Industrial Classification Manual) to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, material safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers in SIC Codes 20–39.

(2) This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

(3) This section applies to laboratories only as follows:

(i) Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

(ii) Employers shall maintain any material safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory employees; and,

(iii) Employers shall ensure that laboratory employees are apprised of the hazards of the chemicals in their workplaces in accordance with paragraph (h) of this section.

(4) This section does not require labeling of the following chemicals:

(i) Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

(ii) Any food, food additive, color additive, drug, or cosmetic, including materials intended for use as ingredients in such products (e.g., flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and regulations issued under that Act, when they are subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Food and Drug Administration;

(iii) Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, and Firearms; and,

(iv) Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission.

(5) This section does not apply to:

(i) Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 et seq.), when subject to regulations issued under that Act by the Environmental Protection Agency;

(ii) Tobacco or tobacco products;

(iii) Wood or wood products;

(iv) Articles; and,

(v) Foods, drugs, or cosmetics intended for personal consumption by employees while in the workplace.

(c) *Definitions.* "Article" means a manufactured item: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which does not release, or otherwise result in exposure to, a hazardous chemical under normal conditions of use.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Chemical" means any element, chemical compound or mixture of elements and/or compounds.

"Chemical manufacturer" means an employer in SIC Codes 20 through 39 with a workplace where chemical(s) are produced for use or distribution.

"Chemical name" means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS)

rules of nomenclature, or a name which will clearly identify the chemical for the purpose of conducting a hazard evaluation.

"Combustible liquid" means any liquid having a flashpoint at or above 100°F (37.8°C), but below 200°F (93.3°C), except any mixture having components with flashpoints of 200°F (93.3°C), or higher, the total volume of which make up 99 percent or more of the total volume of the mixture.

"Common name" means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

"Compressed gas" means:

(i) A gas or mixture of gases having, in a container, an absolute pressure exceeding 40 psi at 70°F (21.1°C); or

(ii) A gas or mixture of gases having, in a container, an absolute pressure exceeding 104 psi at 130°F (54.4°C) regardless of the pressure at 70°F (21.1°C); or

(iii) A liquid having a vapor pressure exceeding 40 psi at 100°F (37.8°C) as determined by ASTM D–323–72.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that containes a hazardous chemical. For purposes of this section, pipes or piping systems are not considered to be containers.

"Designated representative" means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

"Distributor" means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to manufacturing purchasers.

"Employee" means a worker employed by an employer in a workplace in SIC Codes 20 through 39 who may be exposed to hazardous chemicals under normal operating conditions or foreseeable emergencies, including, but not limited to production workers, line supervisors, and repair or maintenance personnel. Office workers, grounds maintenance personnel, security personnel or non-resident management are generally not included, unless their job performance routinely involves potential exposure to hazardous chemicals.

"Employer" means a person engaged in a business within SIC Codes 20 through 39 where chemicals are either used, or are produced for use or distribution.

"Explosive" means a chemical that causes a sudden, almost instantaneous release of pressure, gas, and heat when subjected to sudden shock, pressure, or high temperature.

"Exposure" or "exposed" means that an employee is subjected to a hazardous chemical in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes potential (e.g., accidental or possible) exposure.

"Flammable" means a chemical that falls into one of the following categories:

(i) "Aerosol, flammable" means an aerosol that, when tested by the method described in 16 CFR 1500.45, yields a flame projection exceeding 18 inches at full valve opening, or a flashback (a flame extending back to the valve) at any degree of valve opening;

(ii) "Gas, flammable" means:

(A) A gas that, at ambient temperature and pressure, forms a flammable mixture with air at a concentration of thirteen (13) percent by volume or less; or

(B) A gas that, at ambient temperature and pressure, forms a range of flammable mixtures with air wider than twelve (12) percent by volume, regardless of the lower limit;

(iii) "Liquid, flammable" means any liquid having a flashpoint below 100°F (37.8°C), except any mixture having components with flashpoints of 100°F (37.8°C) or higher, the total of which make up 99 percent or more of the total volume of the mixture.

(iv) "Solid, flammable" means a solid, other than a blasting agent or explosive as defined in § 1910.109(a), that is liable to cause fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious hazard. A chemical shall be considered to be a flammable solid if, when tested by the method described in 16 CFR 1500.44, it ignites and burns with a self-sustained flame at a rate greater than one-tenth of an inch per second along its major axis.

"Flashpoint" means the minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite when tested as follows:

(i) Tagliabue Closed Tester (See American National Standard Method of Test for Flash Point by Tag Closed Tester, Z11.24–1979 (ASTM D 56–79)) for liquids with a viscosity of less than 45 Saybolt Universal Seconds (SUS) at 100°F (37.8°C), that do not contain suspended solids and do not have a tendency to form a surface film under test; or

(ii) Pensky-Martens Closed Tester (see American National Standard Method of Test for Flash Point by Pensky-Martens Closed Tester, Z11.7–1979 (ASTM D 93–79)) for liquids with a viscosity equal to or greater than 45 SUS a 100°F (37.8°C), or that contain suspended solids, or that have a tendency to form a surface film under test; or

(iii) Setaflash Closed Tester (see American National Standard Method of Test for Flash Point by Setaflash Closed Tester (ASTM D 3278–78)).

Organic peroxides, which undergo autoaccelerating thermal decomposition, are excluded from any of the flashpoint determination methods specified above.

"Foreseeable emergency" means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

"Hazard warning" means any words, pictures, symbols, or combination thereof appearing on a label or other appropriate form of warning which convey the hazards of the chemical(s) in the container(s).

"Hazardous chemical" means any chemical which is a physical hazard or a health hazard.

"Health hazard" means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. Appendix A provides further definitions and explanations of the scope of health hazards covered by this section, and Appendix B describes the criteria to be used to determine whether or not a chemical is to be considered hazardous for purposes of this standard.

"Identity" means any chemical or common name which is indicated on the material safety data sheet (MSDS) for the chemical. The identity used shall permit cross-references to be made

among the required list of hazardous chemicals, the label and the MSDS.

"Immediate use" means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

"Importer" means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or manufacturing purchasers within the United States.

"Label" means any written, printed, or graphic material displayed on or affixed to containers of hazardous chemicals.

"Manufacturing purchaser" means an employer with a workplace classified in SIC Codes 20 through 39 who purchases a hazardous chemical for use within that workplace.

"Material safety data sheet (MSDS)" means written or printed material concerning a hazardous chemical which is prepared in accordance with paragraph (g) of this section.

"Mixture" means any combination of two or more chemicals if the combination is not, in whole or in part, the result of a chemical reaction.

"Organic peroxide" means an organic compound that contains the bivalent -O-O-structure and which may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

"Oxidizer" means a chemical other than a blasting agent or explosive as defined in § 1910.109(a), that initiates or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

"Physical hazard" means a chemical for which there is scientifically valid evidence that it is a combustible liquid, a compressed gas, explosive, flammable, an organic peroxide, an oxidizer, pyrophoric, unstable (reactive) or water-reactive.

"Produce" means to manufacture, process, formulate, or repackage.

"Pyrophoric" means a chemical that will ignite spontaneously in air at a temperature of 130° F (54.4° C) or below.

"Responsible party" means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

"Specific chemical identity" means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

"Trade secret" means any confidential formula, pattern, process, device, information or compilation of information (including chemical name or other unique chemical identifier) that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it.

"Unstable (reactive)" means a chemical which in the pure state, or as produced or transported, will vigorously polymerize, decompose, condense, or will become self-reactive under conditions of shocks pressure or temperature.

"Use" means to package, handle, react, or transfer.

"Water-reactive" means a chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

"Work area" means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

"Workplace" means an establishment at one geographical location containing one or more work areas.

(d) *Hazard determination.* (1) Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to determine if they are hazardous. Employers are not required to evaluate chemicals unless they choose not to rely on the evaluation performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

(2) Chemical manufacturers, importers or employers evaluating chemicals shall identify and consider the available scientific evidence concerning such hazards. For health hazards, evidence which is statistically significant and which is based on at least one positive study conducted in accordance with established scientific principles is considered to be sufficient to establish a hazardous effect if the results of the study meet the definitions of health hazards in this section. Appendix A shall be consulted for the scope of health hazards covered, and Appendix B shall be consulted for the criteria to be followed with respect to the completeness of the evaluation, and the data to be reported.

(3) The chemical manufacturer, importer or employer evaluating chemicals shall treat the following sources as establishing that the chemicals listed in them are hazardous:

(i) 29 CFR Part 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration (OSHA); or,

(ii) *Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment,* American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition).

The chemical manufacturer, importer, or employer is still responsible for evaluating the hazards associated with the chemicals in these source lists in accordance with the requirements of the standard.

(4) Chemical manufacturers, importers and employers evaluating chemicals shall treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes:

(i) National Toxicology Program (NTP), *Annual Report on Carcinogens* (latest edition);

(ii) International Agency for Research on Cancer (IARC) *Monographs* (latest editions); or

(iii) 29 CFR Part 1910, Subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.

Note.—The *Registry of Toxic Effects of Chemical Substances* published by the National Institute for Occupational Safety and Health indicates whether a chemical has been found by NTP or IARC to be a potential carcinogen.

(5) The chemical manufacturer, importer or employer shall determine the hazards of mixtures of chemicals as follows:

(i) If a mixture has been tested as a whole to determine its hazards, the results of such testing shall be used to determine whether the mixture is hazardous;

(ii) If a mixture has not been tested as a whole to determine whether the mixture is a health hazard, the mixture shall be assumed to present the same health hazards as do the components which comprise one percent (by weight or volume) or greater of the mixture, except that the mixture shall be assumed to present a carcinogenic hazard if it contains a component in concentrations of 0.1 percent or greater which is considered to be a carcinogen under paragraph (d)(4) of this section;

(iii) If a mixture has not been tested as a whole to determine whether the mixture is a physical hazard, the chemical manufacturer, importer, or employer may use whatever scientifically valid data is available to evaluate the physical hazard potential of the mixture; and

(iv) If the employer has evidence to indicate that a component present in the mixture in concentrations of less than

one percent (or in the case of carcinogens, less than 0.1 percent) could be released in concentrations which would exceed an established OSHA permissible exposure limit or ACGIH Threshold Limit Value, or could present a health hazard to employees in those concentrations, the mixture shall be assumed to present the same hazard.

(6) Chemical manufacturers, importers, or employers evaluating chemicals shall describe in writing the procedures they use to determine the hazards of the chemical they evaluate. The written procedures are to be made available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director. The written description may be incorporated into the written hazard communication program required under paragraph (e) of this section.

(e) *Written hazard communication program.* (1) Employers shall develop and implement a written hazard communication program for their workplaces which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, material safety data sheets, and employee information and training will be met, and which also includes the following:

(i) A list of the hazardous chemicals known to be present using an identity that is referenced on the appropriate material safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas);

(ii) The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas; and,

(iii) The methods the employer will use to inform any contractor employers with employees working in the employer's workplace of the hazardous chemicals their employees may be exposed to while performing their work, and any suggestions for appropriate protective measures.

(2) The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

(3) The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of 29 CFR 1910.20(e).

(f) *Labels and other forms of warning.* (1) The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged or marked with the following information:

(i) Identity of the hazardous chemical(s);

(ii) Appropriate hazard warnings; and

(iii) Name and address of the chemical manufacturer, importer, or other responsible party.

(2) Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.

(3) If the hazardous chemical is regulated by OSHA in a substance-specific health standard, the chemical manufacturer, importer, distributor or employer shall ensure that the labels or other forms of warning used are in accordance with the requirements of that standard.

(4) Except as provided in paragraphs (f)(5) and (f)(6) the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged, or marked with the following information:

(i) Identity of the hazardous chemical(s) contained therein; and

(ii) Appropriate hazard warnings.

(5) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(4) of this section to be on a label. The written materials shall be readily accessible to the employees in their work area throughout each work shift.

(6) The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(7) The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

(8) The employer shall ensure that labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

(9) The chemical manufacturer, importer, distributor or employer need not affix new labels to comply with this section if existing labels already convey the required information.

(g) *Material safety data sheets.* (1) Chemical manufacturers and importers shall obtain or develop a material safety data sheet for each hazardous chemical they produce or import. Employers shall have a material safety data sheet for each hazardous chemical which they use.

(2) Each material safety data sheet shall be in English and shall contain at least the following information:

(i) The identity used on the label, and, except as provided for in paragraph (f) of this section on trade secrets:

(A) If the hazardous chemical is a single substance, its chemical and common name(s);

(B) If the hazardous chemical is a mixture which has been tested as a whole to determine its hazards, the chemical and common name(s) of the ingredients which contribute to these known hazards, and the common name(s) of the mixture itself; or,

(C) If the hazardous chemical is a mixture which has not been tested as a whole:

(*1*) The chemical and common name(s) of all ingredients which have been determined to be health hazards, and which comprise 1% or greater of the composition, except that chemicals identified as carcinogens under paragraph (d)(4) of this section shall be listed if the concentrations are 0.1% or greater; and,

(*2*) The chemical and common name(s) of all ingredients which have been determined to present a physical hazard when present in the mixture;

(ii) Physical and chemical characteristics of the hazardous chemical (such as vapor pressure, flash point);

(iii) The physical hazards of the hazardous chemical, including the potential for fire, explosion, and reactivity;

(iv) The health hazards of the hazardous chemical, including signs and symptoms of exposure, and any medical conditions which are generally recognized as being aggravated by exposure to the chemical;

(v) The primary route(s) of entry;

(vi) The OSHA permissible exposure limit, ACGIH Threshold Limit Value, and any other exposure limit used or

recommended by the chemical manufacturer, importer, or employer preparing the material safety data sheet, where available;

(vii) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) *Annual Report on Carcinogens* (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) *Monographs* (latest editions), or by OSHA;

(viii) Any generally applicable precautions for safe handling and use which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for clean-up of spills and leaks;

(ix) Any generally applicable control measures which are known to the chemical manufacturer, importer or employer preparing the material safety data sheet, such as appropriate engineering controls, work practices, or personal protective equipment;

(x) Emergency and first aid procedures;

(xi) The date of preparation of the material safety data sheet or the last change to it; and,

(xii) The name, address and telephone number of the chemical manufacturer, importer, employer or other responsible party preparing or distributing the material safety data sheet, who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

(3) If no relevant information is found for any given category on the material safety data sheet, the chemical manufacturer, importer or employer preparing the material safety data sheet shall mark it to indicate that no applicable information was found.

(4) Where complex mixtures have similar hazards and contents (i.e. the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one material safety data sheet to apply to all of these similar mixtures.

(5) The chemical manufacturer, importer or employer preparing the material safety data sheet shall ensure that the information recorded accurately reflects the scientific evidence used in making the hazard determination. If the chemical manufacturer, importer or employer becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the material safety data sheet within three months. If the chemical is not currently being produced or imported the chemical manufacturer or importer shall add the information to the material safety data sheet before the chemical is introduced into the workplace again.

(6) Chemical manufacturers or importers shall ensure that distributors and manufacturing purchasers of hazardous chemicals are provided an appropriate material safety data sheet with their initial shipment, and with the first shipment after a material safety data sheet is updated. The chemical manufacturer or importer shall either provide material safety data sheets with the shipped containers or send them to the manufacturing purchaser prior to or at the time of the shipment. If the material safety data sheet is not provided with the shipment, the manufacturing purchaser shall obtain one from the chemical manufacturer, importer, or distributor as soon as possible.

(7) Distributors shall ensure that material safety data sheets, and updated information, are provided to other distributors and manufacturing purchasers of hazardous chemicals.

(8) The employer shall maintain copies of the required material safety data sheets for each hazardous chemical in the workplace, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s).

(9) Material safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

(10) Material safety data sheets shall also be made readily available, upon request, to designated representatives and to the Assistant Secretary, in accordance with the requirements of 29 CFR 1910.20(e). The Director shall also be given access to material safety data sheets in the same manner.

(h) *Employee information and training.* Employers shall provide employees with information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new hazard is introduced into their work area.

(1) *Information.* Employees shall be informed of:

(i) The requirements of this section;

(ii) Any operations in their work area where hazardous chemicals are present; and,

(iii) The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and material safety data sheets required by this section.

(2) *Training.* Employee training shall include at least:

(i) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

(ii) The physical and health hazards of the chemicals in the work area;

(iii) The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to the used; and,

(iv) The details of the hazard communication program developed by the employer, including an explanation of the labeling system and the material safety data sheet, and how employees can obtain and use the appropriate hazard information.

(i) *Trade secrets.* (1) The chemical manufacturer, importer or employer may withhold the specific chemical identity, including the chemical name and other specific identification of a hazardous chemical, from the material safety data sheet, provided that:

(i) The claim that the information withheld is a trade secret can be supported;

(ii) Information contained in the material safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

(iii) The material safety data sheet indicates that the specific chemical identity is being withheld as a trade secret; and,

(iv) The specific chemical identity is made available to health professionals, in accordance with the applicable provisions of this paragraph.

(2) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical

manufacturer, importer, or employer shall immediately disclose the specific chemical identity of a trade secret chemical to that treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i) (3) and (4) of this section, as soon as circumstances permit.

(3) In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (i.e. physician, industrial hygienist, toxicologist, or epidemiologist) providing medical or other occupational health services to exposed employee(s) if:

(i) the request is in writing;

(ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:

(A) To assess the hazards of the chemicals to which employees will be exposed;

(B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

(C) To conduct pre-assignment or periodic medical surveillance of exposed employees;

(D) To provide medical treatment to exposed employees;

(E) To select or assess appropriate personal protective equipment for exposed employees;

(F) To design or assess engineering controls or other protective measures for exposed employees; and,

(G) To conduct studies to determine the health effects of exposure.

(iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information would not enable the health professional to provide the occupational health services described in paragraph (ii) of this section:

(A) The properties and effects of the chemical;

(B) Measures for controlling workers' exposure to the chemical;

(C) Methods of monitoring and analyzing worker exposure to the chemical; and,

(D) Methods of diagnosing and treating harmful exposures to the chemical;

(iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

(v) The health professional, and the employer or contractor of the health professional's services (i.e., downstream employer, labor organization, or individual employer), agree in a written confidentiality agreement that the health professional will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

(4) The confidentiality agreement authorized by paragraph (i)(3)(iv) of this section:

(i) May restrict the use of the information to the health purposes indicated in the written statement of need;

(ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

(iii) May not include requirements for the posting of a penalty bond.

(5) Nothing in this standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

(6) If the health professional receiving the trade secret information decides that there is a need to disclose it to OSHA, the chemical manufacturer, importer, or employer who provided the information shall be informed by the health professional prior to, or at the same time as, such disclosure.

(7) If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity, the denial must:

(i) Be provided to the health professional within thirty days of the request;

(ii) Be in writing;

(iii) Include evidence to support the claim that the specific chemical identity is a trade secret;

(iv) State the specific reasons why the request is being denied; and,

(v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.

(8) The health professional whose request for information is denied under paragraph (i)(3) of this section may refer the request and the written denial of the request to OSHA for consideration.

(9) When a health professional refers the denial to OSHA under paragraph (i)(8) of this section, OSHA shall consider the evidence to determine if:

(i) The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity is a trade secret;

(ii) The health professional has supported the claim that there is a medical or occupational health need for the information; and,

(iii) The health professional has demonstrated adequate means to protect the confidentiality.

(10) (i) If OSHA determines that the specific chemical identity requested under paragraph (i)(3) of this section is not a *bona fide* trade secret, or that it is a trade secret but the requesting health professional has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by OSHA.

(ii) If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

(11) If, following the issuance of a citation and any protective orders, the chemical manufacturer, importer, or employer continues to withhold the information, the matter is referrable to the Occupational Safety and Health Review Commission for enforcement of the citation. In accordance with Commission rules, the Administrative Law Judge may review the citation and supporting documentation *in camera* or issue appropriate protective orders.

(12) Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade

secret status can be made and the necessary protections can be implemented.

(13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is trade secret.

(j) *Effective dates.* Employers shall be in compliance with this section within the following time periods:

(1) Chemical manufacturers and importers shall label containers of hazardous chemicals leaving their workplaces, and provide material safety data sheets with initial shipments by November 25, 1985.

(2) Distributors shall be in compliance with all provisions of this section applicable to them by November 25, 1985.

(3) Employers shall be in compliance with all provisions of this section by May 25, 1986, including initial training for all current employees.

Appendix A to § 1910.1200—Health Hazard Definitions (Mandatory)

Although safety hazards related to the physical characteristics of a chemical can be objectively defined in terms of testing requirements (e.g. flammability), health hazard definitions are less precise and more subjective. Health hazards may cause measurable changes in the body—such as decreased pulmonary function. These changes are generally indicated by the occurrence of signs and symptoms in the exposed employees—such as shortness of breath, a non-measurable, subjective feeling. Employees exposed to such hazards must be apprised of both the change in body function and the signs and symptoms that may occur to signal that change.

The determination of occupational health hazards is complicated by the fact that many of the effects or signs and symptoms occur commonly in non-occupationally exposed populations, so that effects of exposure are difficult to separate from normally occurring illnesses. Occasionally, a substance causes an effect that is rarely seen in the population at large, such as angiosarcomas caused by vinyl chloride exposure, thus making it easier to ascertain that the occupational exposure was the primary causative factor. More often, however, the effects are common, such as lung cancer. The situation is further complicated by the fact that most chemicals have not been adequately tested to determine their health hazard potential, and data do not exist to substantiate these effects.

There have been many attempts to categorize effects and to define them in various ways. Generally, the terms "acute" and "chronic" are used to delineate between effects on the basis of severity or duration. "Acute" effects usually occur rapidly as a result of short-term exposures, and are of short duration. "Chronic" effects generally occur as a result of long-term exposure, and are of long duration.

The acute effects referred to most frequently are those defined by the American National Standards Institute (ANSI) standard for Precautionary Labeling of Hazardous Industrial Chemicals (Z129.1–1982)—irritation, corrosivity, sensitization and lethal dose. Although these are important health effects, they do not adequately cover the considerable range of acute effects which may occur as a result of occupational exposure, such as, for example, narcosis.

Similarly, the term chronic effect is often used to cover only carcinogenicity, teratogenicity, and mutagenicity. These effects are obvious a concern in the workplace, but again, do not adequately cover the area of chronic effects, excluding, for example, blood dyscrasias (such as anemia), chronic bronchitis and liver atrophy.

The goal of defining precisely, in measurable terms, every possible health effect that may occur in the workplace as a result of chemical exposures cannot realistically be accomplished. This does not negate the need for employees to be informed of such effects and protected from them.

Appendix B, which is also mandatory, outlines the principles and procedures of hazard assessment.

For purposes of this section, any chemicals which meet any of the following definitions, as determined by the criteria set forth in Appendix B are health hazards:

1. *Carcinogen:* A chemical is considered to be a carcinogen if:

(a) It has been evaluated by the International Agency for Research on Cancer (IARC), and found to be a carcinogen or potential carcinogen; or

(b) It is listed as a carcinogen or potential carcinogen in the *Annual Report on Carcinogens* published by the National Toxicology Program (NTP) (latest edition); or,

(c) It is regulated by OSHA as a carcinogen.

2. *Corrosive:* A chemical that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. For example, a chemical is considered to be corrosive if, when tested on the intact skin of albino rabbits by the method described by the U.S. Department of Transportation in Appendix A to 49 CFR Part 173, it destroys or changes irreversibly the structure of the tissue at the site of contact following an exposure period of four hours. This term shall not refer to action on inanimate surfaces.

3. *Highly toxic:* A chemical falling within any of the following categories:

(a) A chemical that has a median lethal dose (LD_{50}) of 50 milligrams or less per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.

(b) A chemical that has a median lethal dose (LD_{50}) of 200 milligrams or less per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.

(c) A chemical that has a median lethal concentration (LC_{50}) in air of 200 parts per million by volume or less of gas or vapor, or 2 milligrams per liter or less of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.

4. *Irritant:* A chemical, which is not corrosive, but which causes a reversible inflammatory effect on living tissue by chemical action at the site of contact. A chemical is a skin irritant if, when tested on the intact skin of albino rabbits by the methods of 16 CFR 1500.41 for four hours exposure or by other appropriate techniques, it results in an empirical score of five or more. A chemical is an eye irritant if so determined under the procedure listed in 16 CFR 1500.42 or other appropriate techniques.

5. *Sensitizer:* A chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.

6. *Toxic.* A chemical falling within any of the following categories:

(a) A chemical that has a median lethal dose (LD_{50}) of more than 50 milligrams per kilogram but not more than 500 milligrams per kilogram of body weight when administered orally to albino rats weighing between 200 and 300 grams each.

(b) A chemical that has a median lethal dose (LD_{50}) of more than 200 milligrams per kilogram but not more than 1,000 milligrams per kilogram of body weight when administered by continuous contact for 24 hours (or less if death occurs within 24 hours) with the bare skin of albino rabbits weighing between two and three kilograms each.

(c) A chemical that has a median lethal concentration (LC_{50}) in air of

more than 200 parts per million but not more than 2,000 parts per million by volume of gas or vapor, or more than two milligrams per liter but not more than 20 milligrams per liter of mist, fume, or dust, when administered by continuous inhalation for one hour (or less if death occurs within one hour) to albino rats weighing between 200 and 300 grams each.

7. *Target organ effects.* The following is a target organ categorization of effects which may occur, including examples of signs and symptons and chemicals which have been found to cause such effects. These examples are presented to illustrate the range and diversity of effects and hazards found in the workplace, and the broad scope employers must consider in this area, but are not intended to be all-inclusive.

a. Hepatotoxins:	Chemicals which produce liver damage.
Signs and Symptons:	Jaundice; liver enlargement.
Chemicals:	Carbon tetrachloride; nitrosamines.
b. Nephrotoxins:	Chemicals which produce kidney damage.
Signs and Symptons:	Edema; proteinuria.
Chemicals:	Halogenated hydrocarbons; uranium.
c. Neurotoxins:	Chemicals which produce their primary toxic effects on the nervous system.
Signs and Symptons:	Narcosis; behavioral changes; decrease in motor functions.
Chemicals:	Mercury; carbon disulfide.
d. Agents which act on the blood or hemapoietic system:.	Decrease hemoglobin funciton; deprive the body tissues of oxygen.
Signs and Symptons:	Cyanosis; loss of consciousness.
Chemicals:	Carbon monoxide; cyanides.
e. Agents which damage the lung:	Chemicals which irritate or damage the pulmonary tissue.
Signs and Symptons:	Cough; tightness in chest; shortness of breath.
Chemicals:	Silica; asbestos.
f. Reproductive toxins:	Chemicals which affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis).
Signs and Symptons:	Birth defects; sterility.
Chemicals:	Lead; DBCP.
g. Cutaneous hazards:	Chemical which affect the dermal layer of the body.
Signs and Symptons:	Defatting of the skin; rashes; irritation.
Chemicals:	Ketones; chlorinated compounds.
h. Eye hazards:	Chemicals which affect the eye or visual capacity.
Signs and Symptons:	Conjunctivitis; corneal damage.
Chemicals:	Organic solvents; acids.

Appendix B to § 1900.1200—Hazard Determination (Mandatory)

The quality of a hazard communication program is largely dependent upon the adequacy and accuracy of the hazard determination. The hazard determination requirement of this standard is performance-oriented. Chemical manufacturers, importers, and employers evaluating chemicals are not required to follow any specific methods for determining hazards, but they must be able to demonstrate that they have adequately ascertained the hazards of the chemicals produced or imported in accordance with the criteria set forth in this Appendix.

Hazard evaluation is a process which relies heavily on the professional judgment of the evaluator, particularly in the area of chronic hazards. The performance-orientation of the hazard determination does diminish the duty of the chemical manufacturer, importer or employer to conduct a thorough evaluation, examining all relevant data and producing a scientifically defensible evaluation. For purposes of this standard, the following criteria shall be used in making hazard determinations that meet the requirements of this standard.

1. *Carcinogenicity:* As described in paragraph (d)(4) and Appendix A of this section, a determination by the National Toxicology Program, the International Agency for Research on Cancer, or OSHA that a chemical is a carcinogen or potential carcinogen will be considered conclusive evidence for purposes of this section.

2. *Human data:* Where available, epidemiological studies and case reports of adverse health effects shall be considered in the evaluation.

3. *Animal data:* Human evidence of health effects in exposed populations is generally not available for the majority of chemicals produced or used in the workplace. Therefore, the available results of toxicological testing in animal populations shall be used to predict the health effects that may be experienced by exposed workers. In particular, the definitions of certain acute hazards refer to specific animal testing results (see Appendix A).

4. *Adequacy and reporting of data:* The results of any studies which are designed and conducted according to established scientific principles, and which report statistically significant conclusions regarding the health effects of a chemical, shall be a sufficient basis for a hazard determination and reported on any material safety data sheet. The chemical manufacturer, importer, or employer may also report the results of other scientifically valid studies which tend to refute the findings of hazard.

Appendix C to § 1900.1200—Information Sources (Advisory)

The following is a list of available data sources which the chemical manufacturer, importer, or employer may wish to consult to evaluate the hazards of chemicals they produce or import:

— Any information in their own company files such as toxicity testing results or illness experience of company employees.

— Any information obtained from the supplier of the chemical, such as material safety data sheets or product safety bulletins.

— Any pertinent information obtained from the following source list (latest editions should be used):

Condensed Chemical Dictionary
Van Nostrand Reinhold Co., 135 West 50th Street, New York, NY 10020

The Merck Index: An Encyclopedia of Chemicals and Drugs
Merck and Company, Inc., 126 E. Lincoln Avenue, Rahway, NJ 07065

IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man
Geneva: World Health Organization, International Agency for Research on Cancer, 1972–1977. (Multivolume work), 49 Sheridan Street, Albany, New York

Industrial Hygiene and Toxicology, by F. A. Patty
John Wiley & Sons, Inc., New York, NY (Five volumes)

Clinical Toxicology of Commercial Products
Gleason, Gosselin and Hodge

Casarett and Doull's Toxicology; The Basic Science of Poisons
Doull, Klaassen, and Amdur, Macmillan Publishing Co., Inc., New York, NY

Industrial Toxicology, by Alice Hamilton and Harriet L. Hardy
Publishing Sciences Group, Inc., Acton, MA

Toxicology of the Eye, by W. Morton Grant
Charles C. Thomas, 301–327 East Lawrence Avenue, Springfield, IL

Recognition of Health Hazards in Industry
William A. Burgess, John Wiley and Sons, 605 Third Avenue, New York, NY 10158

Chemical Hazards of the Workplace
Nick H. Proctor and James P. Hughes, J. P. Lipincott Company, 6 Winchester Terrace, New York, NY 10022

Handbook of Chemistry and Physics
Chemical Rubber Company, 18901 Cranwood Parkway, Cleveland, OH 44128

Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment with Intended Changes
American Conference of Governmental Industrial Hygienists, 6500 Glenway Avenue, Bldg. D–5, Cincinnati, OH 45211

Note.—The following documents are on sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Occupational Health Guidelines
NIOSH/OSHA (NIOSH Pub. No. 81–123)
NIOSH/OSHA Pocket Guide to Chemical Hazards
NIOSH Pub. No. 78–210
Registry of Toxic Effects of Chemical Substances
U.S. Department of Health and Human Services, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health (NIOSH Pub. No. 80–102)
The Industrial Environment—Its Evaluation and Control
U.S. Department of Health and Human Services, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health (NIOSH Pub. No. 74–117)
Miscellaneous Documents—National Institute for Occupational Safety and Health
1. Criteria for a recommended standard * * * Occupational Exposure to "——"
2. Special Hazard Reviews
3. Occupational Hazard Assessment
4. Current Intelligence Bulletins

Bibliographic Data BAses

Service Provider and *File Name*

Bibliographic Retrieval Services (BRS), Corporation Park, Bldg. 702, Scotia, New York 12302
AGRICOLA
BIOSIS PREVIEWS
CA CONDENSATES
CA SEARCH
DRUG INFORMATION
MEDLARS
MEDOC
NTIS
POLLUTION ABSTRACTS
SCIENCE CITATION INDEX
SSIE

Lockheed—DIALOG, Lockheed Missiles & Space Company, Inc., P.O. Box 44481, San Francisco, CA 94144
AGRICOLA
BIOSIS PREV. 1972–PRESENT
BIOSIS PREV. 1969–71
CA CONDENSATES 1970–71
CA SEARCH 1972–76
CA SEARCH 1977–PRESENT
CHEMNAME
CONFERENCE PAPERS INDEX
FOOD SCIENCE & TECH. ABSTR.
FOODS ADLIBRA
INTL. PHARMACEUTICAL ABSTR.
NTIS
POLLUTION ABSTRACTS
SCISEARCH 1978–PRESENT
SCISEARCH 1974–77
SSIE CURRENT RESEARCH

SDC—ORBIT, SDC Search Service, Department No. 2230, Pasadena, CA 91051
AGRICOLA
BIOCODES
BIOSIS/BIO6973
CAS6771/CAS7276
CAS77
CHEMDEX
CONFERENCE
ENVIROLINE
LABORDOC
NTIS
POLLUTION
SSIE

Chemical Information System (CIS), Chemical Information Systems Inc., 7215 Yorke Road, Baltimore, MD 21212
Structure & Nomeclature Search System
Acute Toxicity (RTECS)
Clinical Toxicology of Commercial Products
Oil and Hazardous Materials Technical Assistance Data System

National Library of Medicine, Department of Health and Human Services, Public Health Service, National Institutes of Health, Bethesda, MD 20209
Toxicology Data Bank (TDB)
MEDLIN
TOXLINE
CANCERLIT
RTECS

[FR Doc. 83–31527 Filed 11–22–83; 8:45 am]
BILLING CODE 4510–26–M