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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1910, 1915, 1917, 1918, and 1926

[Docket No. H-022K]

RIN 1218-AC20

Hazard Communication

AGENCY: Occupational Safety and Health Administration (OSHA),
Department of Labor.

ACTION: Advance Notice of Proposed Rulemaking (ANPRM).

SUMMARY: OSHA, other Federal agencies, and stakeholder representatives have participated in long-term international negotiations to develop a Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The GHS has been adopted by the United Nations, and there is an international goal for as many countries as possible to implement the GHS by 2008. The GHS includes harmonized provisions for classification of chemicals for their health, physical, and environmental effects, as well as for labels on containers and safety data sheets (SDS). Adoption of the GHS by OSHA would require modifications to the Agency's Hazard Communication Standard (HCS). For example, an order of information would be established for safety data sheets. In this notice, OSHA is providing further information about the GHS, the benefits of adopting it, and its potential impact on the HCS. OSHA is seeking input from the public on a number of issues related to implementation of the GHS. The Agency is simultaneously announcing the availability of a new guide on its Web site at <http://www.osha.gov> that describes the GHS.

DATES: Comments must be submitted by the following dates:

Hard copy: Your comments must be submitted (postmarked or sent) by November 13, 2006.

Facsimile and electronic transmission: Your comments must be sent by November 13, 2006.

ADDRESSES: You may submit comments, identified by OSHA Docket No. H-022K, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov> Follow the instructions below for submitting comments.

Agency Web Site: <http://ecomments.osha.gov> Follow the instructions on the OSHA web page for submitting comments.

FAX: If your comments, including any attachments, are 10 pages or fewer, you may fax them to the OSHA Docket Office at (202) 693-1648.

Mail, express delivery, hand delivery, and courier service: You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. H-022K, Room N2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-2350 (OSHA's TTY number is (877) 889-5627). OSHA Docket Office and Department of Labor hours of operation are 8:15 a.m. to 4:45 p.m., ET.

Instructions: All submissions received must include the Agency name and docket number (H-022K). Comments received will be posted without change on OSHA's Web page at <http://www.osha.gov>, including any

personal information provided. For detailed instructions on submitting comments, see the ``Public Participation'' heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read comments or background documents received, go to OSHA's Web page. Comments and submissions are also available for inspection and copying at the OSHA Docket Office at the address above.

FOR FURTHER INFORMATION CONTACT: Press inquiries: Kevin Ropp, OSHA Office of Communications, Room N3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-1999. General and technical information: Maureen O'Donnell, Industrial Hygienist, or David O'Connor, Health Scientist, Directorate of Standards and Guidance, Room N3718, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-1950.

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I. Background

A. History of the OSHA Hazard Communication Standard

OSHA's Hazard Communication Standard (HCS) (29 CFR 1910.1200; 1915.1200; 1917.28; 1918.90; and 1926.59) was first adopted in 1983 for the manufacturing sector of industry (48 FR 53280; November 25, 1983). Later, the Agency expanded the scope of coverage to all industries where employees are potentially exposed to hazardous chemicals (52 FR 31852; August 24, 1987). The HCS requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import. The rule provides definitions of health and physical hazards to use as the criteria for determining hazards in the evaluation process. The information about the hazards and protective measures is then required to be conveyed to downstream employers and employees by putting labels on containers and preparing and distributing safety data sheets. All employers with hazardous chemicals in their workplaces are required to have a hazard communication program, including container labels, safety data sheets, and employee training. (Note: The HCS uses the term ``material safety data sheet'' or MSDS, while the GHS uses safety data sheet or SDS. For convenience, safety data sheet or SDS is being used throughout this document.)

OSHA has updated estimates in the standard's regulatory impact analysis, and found that the HCS now covers over 7 million workplaces, more than 100 million employees, and some 945,000 hazardous chemical

products. Ensuring that hazard and protective measure information is available in workplaces through hazard communication programs helps employers design and implement appropriate controls for chemical exposures, and gives employees the right-to-know the hazards and identities of the chemicals, as well as allowing them to participate actively in the successful control of exposures. Together, these actions of employers and employees reduce the potential for adverse effects to occur. The information transmitted under the HCS requirements provides the foundation upon which a chemical safety and health program can be built in the workplace.

The HCS is performance-oriented, i.e., it establishes requirements for labels and safety data sheets but does not provide the specific language to convey

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the information or a format in which to provide it.

B. OSHA Involvement in the Development of the GHS

OSHA's HCS is designed to disseminate information on chemicals to users to precipitate changes in handling methods and thus protect those exposed to the chemical from experiencing adverse effects. Since the United States (U.S.) is both a major importer and exporter of chemicals, the manner in which the U.S. and other countries choose to regulate information dissemination on hazardous chemicals not only has an impact on the protection of employees in the U.S. but also may pose potential barriers to international trade in chemicals.

To protect employees and members of the public who are potentially exposed to chemicals during their production, transportation, use, and disposal, a number of countries have developed laws that require information about those chemicals to be prepared and transmitted to affected parties. These laws vary with regard to the scope of chemicals covered, definitions of hazards, the specificity of requirements (e.g., specification of a format for safety data sheets), and the use of symbols and pictograms. The inconsistencies between the various laws are substantial enough that different labels and safety data sheets must often be developed for the same product when it is marketed in different nations. For example, Canada has established requirements for labels under its Workplace Hazardous Materials Information System (WHMIS). WHMIS requires that labels include specified symbols within a defined circle. U.S. chemical manufacturers must label chemicals accordingly for marketing in Canada.

Within the U.S., several regulatory authorities exercise jurisdiction over chemical hazard communication. In addition to OSHA's HCS, the Department of Transportation (DOT) regulates chemicals in

transport, the Consumer Product Safety Commission (CPSC) regulates consumer products, and the Environmental Protection Agency (EPA) regulates pesticides, as well as having other authority over labeling under the Toxic Substances Control Act. Each of these regulatory authorities operates under different statutory mandates, and have adopted varying approaches to hazard communication requirements.

The diverse and sometimes conflicting national and international requirements can create confusion among those who seek to use hazard information effectively. For example, labels and safety data sheets may include symbols and hazard statements that are unfamiliar to readers or not well understood. Containers may be labeled with such a large volume of information that important statements are not easily recognized. Given the differences in hazard classification criteria, labels may also be incorrect when used in other countries. This is particularly true with regard to workplace hazard communication in the U.S. Since the U.S. OSHA system is performance-oriented, labels meeting the specification requirements of other countries are often seen in the U.S. workplace. While there are no format requirements in the U.S. that are violated by these differing formats, the underlying hazard criteria from another country may be different and that could make the information on the labels out of compliance with the U.S. HCS.

Development of multiple sets of labels and safety data sheets for each product when shipped to different countries is a major compliance burden for chemical manufacturers, distributors, and transporters involved in international trade. Small businesses may have particular difficulty in coping with the complexities and costs involved.

When the HCS was first issued in 1983, the preamble included a commitment by OSHA to review the standard regularly to address international harmonization of hazard communication requirements. OSHA was asked to include this commitment in the final rule in recognition of an interagency trade policy that supported the U.S. pursuing international harmonization of requirements for chemical classification and labeling. The potential benefits of harmonization were noted in the preamble:

* * * [O]SHA 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 identified 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. (48 FR 53287; November 25, 1983)

OSHA was the only Federal agency that had a public commitment to pursue harmonization. We have actively participated in a number of such efforts in the years since that commitment was made, including participation in trade-related discussions on the need for harmonization with major U.S. trading partners. The Agency also issued a Request for Information (RFI) in the Federal Register in January 1990, to obtain input regarding international harmonization efforts, and on work being done at that time to develop a convention and recommendation on safety in the use of chemicals at work in the International Labor Organization (55 FR 2166).

Little progress was made regarding international harmonization until June 1992, when a mandate from the United Nations Conference on Environment and Development (UNCED) (Chapter 19 of Agenda 21), supported by the U.S., called for development of a globally harmonized chemical classification and labeling system:

A globally harmonized hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000.

UNCED further noted that an internationally harmonized system for transport of dangerous goods was already available. However:

* * * [G]lobally harmonized hazard classification and labelling systems are not yet available to promote the safe use of chemicals, inter alia, at the workplace or in the home. Classification of chemicals can be made for different purposes and is a particularly important tool in establishing labelling systems. There is a need to develop harmonized hazard classification and labelling systems, building on ongoing work.

This international mandate initiated an extensive effort to develop the GHS. It involved numerous international organizations, many countries, and extensive stakeholder representation. The work was managed by the Coordinating Group on the Harmonization of Chemical Classification Systems, under the umbrella of the Interorganization Programme for the Sound Management of Chemicals. OSHA chaired the international coordinating group that managed the harmonization work. The technical work was divided among several international organizations. Development of criteria for health and environmental hazards, as well as mixture classification for chemicals having these hazards, was done under the auspices of the Organization for Economic

Cooperation and Development (OECD). Criteria for physical hazards were based on the already harmonized criteria for transportation, and developed by the United Nations Subcommittee of Experts on the Transport of Dangerous Goods and the International Labor

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Organization. The overall management of the process, as well as the work on aspects of the system for communicating hazards on labels and safety data sheets, were done by the International Labor Organization. OSHA participated in all of this work, and took the U.S. lead on classification of mixtures and hazard communication.

The negotiations were extensive and spanned a number of years. The primary approach involved identifying the relevant provisions in each of the major existing systems, developing background documents that compared, contrasted, and explained the rationale for such provisions, and undertaking negotiations to find an agreed approach that addressed the needs of the countries and stakeholders involved. The major existing systems were those of the U.S., Canada, and Europe, and the United Nations Recommendations for the Transport of Dangerous Goods. Principles to guide the work were established, including an agreement that protections of the existing systems were not to be reduced as a result of harmonization. Thus countries could be assured that the existing protections of their longstanding systems would be maintained or enhanced in the resulting harmonized approach.

In the U.S., an interagency committee under the auspices of the U.S. Department of State coordinated the various agencies involved. In addition to the four core agencies that have requirements that are potentially impacted by the GHS, there were a number of other agencies involved that had interests related to trade or other aspects of the GHS process. Different agencies had the lead in various parts of the discussions. Positions for the U.S. in these negotiations were coordinated through the interagency committee. Interested stakeholders were kept informed through e-mail dissemination of information, as well as periodic public meetings. The U.S. Department of State also published a notice in the Federal Register that described the harmonization activities, the agencies involved, the principles of harmonization, and other information, as well as invited public comment on these issues (62 FR 15951; April 3, 1997). Stakeholders also actively participated themselves in the discussions in the international organizations and were able to present their views directly in the negotiating process.

The product resulting from this effort, the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), was formally adopted by the new United Nations Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification

and Labelling of Chemicals in December 2002. In 2003, the adoption was endorsed by the Economic and Social Council of the United Nations. While the GHS has been adopted, it is considered to be a living document that will be updated as necessary to reflect new technology and scientific developments, or provide additional explanatory text. OSHA expects to propose adoption of the 2005 version, Revision 1. Modifications to the GHS that are made after the GHS is adopted in the U.S. would require additional rulemaking.

It should be noted that the GHS document consists of non-mandatory recommendations and explanatory text. It is not a model regulation or a standard that is to be adopted verbatim. Countries like the U.S., and agencies such as OSHA, will propose converting the recommendations into appropriate regulatory text consistent with national requirements while ensuring that the specific provisions are consistent with the GHS and thus harmonized. OSHA expects to propose modifying the HCS to address the changes in hazard criteria, adopt the specific labeling requirements, and adopt the SDS order of information. Other parts of the framework of the HCS (such as the coverage of articles, trade secrets, and scope) would likely remain the same.

While the GHS text is available to everyone on the UN Web site, it will be the proposed rule to adopt the GHS that OSHA plans to issue rather than the detailed GHS document that will be of primary interest to U.S. stakeholders. To help those who are not familiar with the approach in the GHS, OSHA has prepared a guide that summarizes the GHS requirements, and it is available on our Web site (click on the Hazard Communication button on <http://www.osha.gov>). In addition, the Agency

also has a detailed comparison of the HCS to the GHS available on the Web site so that interested parties can review the types of changes that would need to be made for the current U.S. workplace requirements to be harmonized with the international approach.

A review of these differences reveals that the primary impact of revising the HCS to adopt the GHS would be on compliance obligations for producers of hazardous chemicals. The modifications to the HCS would involve a review of the classifications of these chemicals, as well as preparation and distribution of new labels and revised safety data sheets. Employers who use chemicals, and exposed employees, would benefit from receiving the revised labels and safety data sheets prepared in a consistent format. The information should be easier to comprehend and access in the new approach, allowing it to be used more effectively for the protection of employees. The primary change in workplaces where chemicals are used but not produced will be to integrate the new approach into the workplace hazard communication program, including assuring that both the employers and employees understand the pictograms and other information provided on the

chemicals.

The GHS is now available for worldwide implementation, and countries have been encouraged to implement the GHS as soon as possible, with the goal of a fully operational system by 2008. This goal was adopted by countries in the Intergovernmental Forum on Chemical Safety, as well as endorsed by the World Summit on Sustainable Development. In addition, countries involved in the Asia-Pacific Economic Cooperation have endorsed a goal of 2006. The U.S. participates in all of these international groups, and has agreed to working toward achieving these goals.

The U.S. is also a member of both the United Nations Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labeling of Chemicals, as well as the Subcommittee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals. These permanent UN bodies have international responsibility for maintaining, updating as necessary, and overseeing the implementation of the GHS. OSHA and other affected Federal agencies actively participate in these UN groups. In addition, OSHA, EPA and the U.S. State Department also participate in the GHS Programme Advisory Group that functions under the United Nations Institute for Training and Research (UNITAR). UNITAR is responsible internationally for helping countries implement the GHS, and has ongoing programs to prepare guidance documents, conduct regional workshops, and implement pilot projects in a number of interested nations.

C. Other OSHA Activities Related to the GHS

OSHA and the other three core agencies continue interagency discussions related to coordination of domestic implementation of the GHS, in addition to ongoing discussions and coordination related to international work to implement and maintain the GHS.

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OSHA also has ongoing activities related to the GHS under the North American Free Trade Agreement (NAFTA) discussions on handling of hazardous substances, and in discussions with the European Union on issues related to the global management of chemicals.

In addition, a number of organizations with whom OSHA has Alliances have expressed an interest in hazard communication, and in working together with each other on the subject. The Alliance program is a cooperative program that enables organizations committed to occupational safety and health to work with OSHA to prevent injuries, illnesses, and fatalities in the workplace (click on the Alliances button on OSHA's home page for an explanation of the program and a list

of participants). One of the issues they have identified to work together on is related to the GHS, and making the business case for GHS adoption, particularly for small businesses. OSHA has conducted a roundtable of Alliances interested in this topic, and will continue these meetings to get their input and work with them on products they identify as appropriate for development. Products under consideration include a document addressing frequently asked questions and the corresponding answers, as well as a document that addresses why the GHS is needed.

D. Benefits of the GHS

Development of this system required extensive work by a great number of people, and resources from many countries and organizations. The reason it received such support is that there is a widespread belief that there are significant benefits associated with implementation of a globally harmonized approach to hazard communication. Countries, international organizations, chemical producers and users of chemicals will all benefit.

First and foremost, implementation of the GHS will enhance protection of people potentially exposed to chemicals and the environment. While some countries such as ours already have the benefits of protection under existing systems, the majority of countries do not have such comprehensive approaches. Thus implementation of the GHS will provide these countries with the important protections that result from dissemination of information about chemical hazards and protective measures. In our country, we expect that adoption of the GHS would improve and build on protections we already have. Refinement of the information provided would help improve comprehensibility and thus make it more likely that the information will result in workplace changes to protect employees. As has already been noted, the majority of affected employers and employees should benefit from adoption of the GHS through receipt of better, more standardized, and consistent information about chemicals in their workplaces.

Secondly, implementation of such an approach would facilitate international trade in chemicals. It will reduce the burdens caused by having to comply with differing requirements for the same product, and allow companies that have not had the resources to deal with those burdens to be involved in international trade. This is particularly important for small producers who may be precluded currently from international trade because of the compliance resources required to address the extensive regulatory requirements for classification and labeling of chemicals.

Third, one of the initial reasons this system was pursued internationally involved concerns about animal welfare and the

proliferation of requirements for animal testing and evaluation. Where existing systems have different definitions of hazards, it often results in duplicative testing to produce data related to the varying levels of toxicity or cut-offs used to define the hazards in the different systems. Having one agreed definition will reduce this duplicative testing. It should be noted that OSHA has no testing requirements. The HCS is based on collecting and evaluating the best available evidence on the hazards of each chemical.

Information transmittal systems provide the underlying infrastructure for the sound management of chemicals in a country. Those countries that do not have the resources to develop and maintain such a system can use the GHS to build their chemical safety and health programs. Unlike some other safety and health issues, a country's approach to the sound management of chemicals definitely affects other countries. In some cases, bordering countries may experience pollution and other effects of uncontrolled chemical exposures. In all countries, there is a need to acquire sufficient information to properly handle the chemical when it is imported from other countries. Thus having a coordinated and harmonized approach to the development and dissemination of information about chemicals will be mutually beneficial to both importing and exporting countries.

In the U.S., the four primary regulatory agencies (OSHA, EPA, CPSC, and DOT) that would be responsible for GHS implementation are not domestically harmonized in terms of definitions of hazards and other requirements related to classification and labeling of chemicals. Thus, if all four agencies adopt the GHS, the U.S. would have the additional benefit of harmonizing the overall U.S. approach to classification and labeling. Since most chemicals are produced in a workplace and shipped elsewhere, every manufacturer deals with at least two of the U.S. systems. Thus every producer is likely to experience some benefits from domestic harmonization, in addition to the benefits that will accrue to producers involved in international trade.

OSHA believes that adoption of the GHS could also address some of the issues that have been discussed in the U.S. regarding the HCS and its implementation, such as improving labels and SDS comprehensibility through implementation of a standardized approach. The current regulatory system includes a performance-oriented approach to labels and SDSs, allowing the producers to use whatever language or format they choose to provide the necessary information. This often results in a lack of consistency that makes it difficult for some users of chemicals to properly identify the hazards and the protective measures, particularly when purchasing the same product from multiple suppliers. Having the information provided in the same words and pictograms on labels, as well as having a standardized order of information on SDSs, would help all users identify the critical information necessary to

protect employees.

E. State Plan States

If Federal OSHA promulgates a final rule amending its HCS in response to the GHS, the 26 States and U.S. Territories with their own OSHA-approved occupational safety and health plans would be required to revise their standards to reflect the new amendment within six months of Federal promulgation. 29 CFR 1953.5(a). A revised State hazard communication standard must be applicable to both the private and public (State and local government employees) sectors. Some States may have statutory provisions that would require amendment in order to conform to a revised Federal HCS.

Section 18(c)(2) of the OSH Act requires that State standards applicable to products distributed or used in interstate commerce, if not identical to the Federal standard, must be required by compelling local conditions and must not unduly burden interstate

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commerce, in addition to being ``at least as effective'' as the Federal standard. The amended HCS, like the original standard, would be `applicable to products' in the sense that it would permit the distribution and use of hazardous chemicals in commerce only if they are in labeled containers accompanied by safety data sheets[.]'' 48 FR 53280, 53323, November 25, 1983. In order to assure that State standards do not pose an undue burden on interstate commerce, and to advance the goals of the GHS, OSHA would expect to closely scrutinize resultant State standards to assure not only equal or greater effectiveness, but also that any different or additional requirements do not conflict with, or adversely affect, the effectiveness of the national application of OSHA's standard.

II. Provisions of OSHA's HCS and the GHS

A. Scope of the GHS

The GHS covers chemicals in various stages of their life cycle, from production to disposal. It is based primarily on the hazards of chemicals. The GHS is designed to allow regulatory authorities to choose provisions that are appropriate to their particular scope of regulation. This is referred to as the ``building block approach.'' The GHS includes all of the building blocks or possible regulatory components that might be needed for classification and labeling requirements in the workplace as well as for regulation of classification and labeling of pesticides, chemicals in transport, and

consumer products. Therefore, regulatory authorities such as OSHA would choose the provisions of the GHS that are necessary for the protection of employees, but would not adopt others that address other types of protection. For example, the GHS includes harmonized criteria for classifying chemicals for aquatic toxicity. Since OSHA does not have the regulatory authority to address environmental concerns, OSHA would not adopt the GHS criteria for aquatic toxicity. It is expected that other U.S. agencies that regulate environmental issues will consider adopting this definition. Similarly, the GHS safety data sheet format includes a section that addresses environmental information. OSHA would not require inclusion of environmental information for SDSs used in workplaces.

The building block approach may also be applied in other ways when deciding which parts of the system to adopt. For example, the GHS includes classification criteria, labels, and SDSs. While workplace authorities such as OSHA are likely to adopt all of these elements, it is expected that consumer product authorities will not have SDS requirements, nor will transport authorities. The building block approach may also be applied to the criteria for defining hazards. For example, the acute toxicity criteria are much broader than those we currently have in the HCS for workplace exposures. This is to allow consumer product authorities the tools they need to address the protection of children who might accidentally be exposed. OSHA would not need to adopt all of the categories of acute toxicity in order to protect employees from the types of exposures they may have.

In addition to the building block approach, the GHS also contains a number of areas that are left to the competent authority to determine how to apply the provision. Where OSHA is the competent authority, i.e., in terms of workplace protections in the U.S., the Agency expects to maintain its current approaches in terms of interpretations and accommodations regarding application. These approaches are based on the rulemaking record, as well as implementation experiences in the U.S., and have been determined to be an appropriate application. For example, the scope and application provisions in the GHS address the interface of the OSHA requirements to requirements in other agencies that address the same products. These scope interpretations are expected to be the same if OSHA adopts the GHS.

Overall, the scope of the GHS with regard to chemicals covered, as well as types of chemicals and workplaces that are covered, is very similar to the HCS. The HCS has a very broad scope of coverage, ensuring that information is provided on all potential hazards in American workplaces. Adoption of the GHS should maintain this broad coverage of hazards and chemicals. It should be noted that the GHS, like the HCS, does not require any new testing of chemicals. Evaluations of chemical hazards are to be based on the best available

evidence.

As has been described above, the HCS consists of requirements for defining health and physical hazards, preparing a written hazard communication program, preparing and distributing labels on containers that are shipped as well as containers in the workplace, preparing and distributing safety data sheets for all hazardous chemicals, and employee training. The GHS addresses classification of health and physical hazards, and preparation and distribution of labels and safety data sheets. It does not include requirements for a written hazard communication program or for employee training. Training is noted in the GHS as an important adjunct to label and safety data sheet requirements, but the harmonization process did not include such provisions. Countries are thus free to determine what training will be applicable in their own regulatory approach. OSHA believes that training is critical to ensuring the effectiveness of hazard communication, and anticipates maintaining current HCS requirements that training be part of a hazard communication program. OSHA also expects to propose some additional training to ensure understanding of the new approach regarding labels and SDSs in the GHS.

B. Definitions of Hazards Covered

The HCS covers a broad range of both health and physical hazards. The standard is performance-oriented, providing definitions of hazards and parameters for evaluating the best available evidence to determine whether a chemical has a hazardous effect under the standard. In particular, with regard to health hazards, one toxicological study, conducted according to established scientific principles and reporting a statistically significant adverse health effect, is sufficient for a finding of hazard under the rule. The principle behind the standard is that it is to address dissemination of information, and thus complete information about all of the potential hazards should be disseminated to ensure that employers and employees can make appropriate decisions about the level of protection required in their particular workplaces. Hazard information, in combination with information about the exposures occurring in each workplace, allows decisions to be made by employers regarding the appropriate risk management to implement based on the specific conditions in their workplace. Chemical manufacturers and importers do not have information about the exposures to their products in each workplace where their product may be used, so they must prepare their labels and safety data sheets based on the hazards of the chemicals.

C. Health Hazards

The HCS thus covers every type of health effect that may occur,

including both acute and chronic effects. The standard describes different systems of the body and indicates that target organ effects are to be considered in the hazard evaluation. The definitions provided are indicative of the wide range of coverage, but are not exclusive.

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Any type of adverse health effect that is reported and substantiated by a scientific study is covered. The standard specifically includes the following in the definition of ``health hazard'':

Carcinogens

Toxic or highly toxic agents (all routes of entry)

Reproductive toxins

Irritants

Corrosives

Sensitizers

Hepatotoxins

Nephrotoxins

Neurotoxins

Agents which act on the hematopoietic system

Agents which damage the lungs, skin, eyes, or mucous membranes

The GHS also has a very broad approach to the range of health effects covered:

Acute toxicity (any route of entry)

Skin corrosion/irritation

Serious eye damage/eye irritation

Respiratory or skin sensitizer

Germ cell mutagenicity

Carcinogenicity

Reproductive toxicity

Specific target organ systemic toxicity--single exposure

Specific target organ systemic toxicity--repeated use

Aspiration hazard

Under the GHS, each hazard or endpoint as listed above is considered to be a hazard class. The classes are generally sub-divided into categories of hazard. The definitions of hazards are much more specific and detailed than what is in the HCS. For example, under the HCS, a chemical is either a potential carcinogen or it is not. The evaluation is a yes or no response. Under the GHS, there are two categories of carcinogenicity, based on the weight of the evidence involved. The hazard communication consequences of this classification also vary as a result for each category in a hazard class. The hazard communication

elements allocated to each category reflect the degree of severity of the hazard.

There are advantages to this more specific and delineated approach. First, the detailed criteria for classification should lead to more accurate hazard determinations and more consistency among multiple classifiers. There is less likely to be room for different interpretations of the same data. This addresses some of the concerns that have been raised about the HCS. In addition, introducing categories gives an indication of the degree of severity of the hazard. This is helpful to employers and employees determining what the appropriate course of action should be when exposures to the chemical occur.

There may be some changes in what the hazard of certain chemicals is determined to be based on a consideration of the data available on a chemical in light of these new criteria. It is expected that chemical manufacturers and importers will be required to re-evaluate their chemicals according to the GHS criteria. But given the current broad nature of the HCS, it is not expected that the number of chemicals covered would change in any significant way. The most likely difference would be that the chemical may be characterized in categories for certain hazards based on the weight of the evidence.

With regard to mixtures of chemicals, the HCS requires the evaluation of mixtures to be based either on data for the mixture as a whole, or, where that is not available, the mixture's health hazards are to be based on the presence of ingredients with health hazards over a specified percentage. That percentage is 0.1% for carcinogens, and 1.0% for all other types of health effects. The HCS also recognizes that risk may remain below these cut-offs, and where there is evidence that is the case, the mixtures are still covered.

The GHS has what has been described as a tiered approach to mixture evaluation. The first step is consideration of data on the mixture as a whole, similar to the HCS. The second step allows the use of ``bridging principles'' to estimate the hazards of the mixture based on information about its components. For example, if a chemical is considered to be acutely toxic, but it is diluted with something that is not toxic, the GHS allows the employer to take the dilution into consideration when evaluating the hazards of the product rather than simply basing it on a percentage cut-off approach like the HCS. This extrapolation of data will mean that fewer mixtures will be evaluated on the basis of the presence of a chemical above a specific cut-off. The third part of the tiered approach does involve cut-offs, but they vary by the type of effect. In particular, for acute effects, there is a formula for determining whether the mixture is considered to be toxic. The formula is based to some extent on one that is currently used in transport.

Overall, the approach is generally consistent with the current HCS requirements, but provides more detail and specification and allows more extrapolation of data available on the components of a mixture--particularly for acute effects. It is thus more complicated than the approach in the HCS, and it is likely that additional guidance, particularly electronic tools, may need to be made available to assist with compliance.

As a result of these differences in health hazard criteria and the accompanying approaches to classifying mixtures, another provision of the standard that is potentially impacted by adoption of the GHS is the process of hazard determination. Under the current rule, this process is performance-oriented, allowing for a significant degree of professional judgment on the part of the hazard evaluator. No specific procedures are provided, but there are certain parameters established. The scientific literature must be reviewed, and if there is at least one toxicological study, conducted according to established scientific principles, and providing statistically significant results indicating an adverse health effect, this hazard must be disclosed under the HCS.

The HCS also includes references to sources of information that were identified in the rulemaking record as one basis for making an initial determination of hazard. Among these listed sources are OSHA's substance-specific standards (those chemicals for which OSHA has promulgated a permissible exposure limit (PEL) in Subpart Z, Toxic and Hazardous Substances), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), International Agency for Research on Cancer (IARC) monographs, and the National Toxicology Program (NTP) list of carcinogens. These sources provide employers a list of hazardous chemicals. However, manufacturers and importers are still required to review the available information to determine specifically what the hazards of these chemicals are, and to disclose them on labels and safety data sheets.

The GHS provides much more specific criteria for defining health hazards than the HCS does. If OSHA adopts the GHS, these more specific criteria will be part of the HCS. This will eliminate the need for a specific listing of hazardous chemicals as part of the hazard determination procedures. Chemical manufacturers and importers are much more likely to make consistent hazard determination evaluations following the specific criteria in the GHS, thus addressing the concerns that led to the inclusion of lists in the original Hazard Communication Standard. References to the chemicals for which there are ACGIH TLVs, and those chemicals addressed in IARC Monographs and the NTP lists, would no longer be specifically addressed in the HCS. Chemical manufacturers and importers would retain the

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responsibility for evaluating all relevant data on the chemicals they produce or import.

Similarly, the provisions for disclosing the hazardous ingredients of mixtures under the GHS are much more detailed than the HCS. The simple across-the-board cut-offs for all types of hazards would no longer be part of the rule if it is changed to adopt the GHS. Modifying the HCS to align with the GHS would also eliminate the current references to ACGIH TLVs as part of the mixture provisions.

D. Physical Hazards

With regard to physical hazards, the current definitions in the HCS are drawn from other standards we have that address such chemicals (e.g., flammable chemicals), or from what were the DOT criteria for physical hazards at the time OSHA promulgated the HCS. OSHA includes definitions for the following physical hazards in the HCS:

- Combustible liquid
- Compressed gas
- Explosive
- Flammable (aerosol, gas, liquid, solid)
- Organic peroxide
- Oxidizer
- Pyrophoric
- Unstable (reactive)
- Water-reactive

The GHS includes criteria for the following physical hazards:

- Explosives
- Flammable (aerosol, gas, liquid (including combustible liquid), solid)
- Oxidizing (liquids, solids, gases)
- Gases under pressure
- Self-reactive substances and mixtures
- Pyrophoric (liquid, solid)
- Self-heating substances and mixtures
- Substances and mixtures which in contact with water emit flammable gases
- Organic peroxide
- Corrosive to metals

DOT subsequently changed their criteria to be consistent with the international transport requirements. The international transport requirements for classification of physical hazards have now been

incorporated into the GHS. While DOT must make a few changes to be consistent with the GHS, their requirements are mostly already the same.

OSHA is not harmonized with current DOT requirements. Changing the HCS to adopt the GHS criteria would also ensure that DOT and OSHA requirements are consistent. This is an important improvement in the current situation where the outside of a truck may be placarded with a different hazard than the workplace labels convey on the containers inside the truck. Again, chemical manufacturers and importers would have to re-evaluate their chemicals according to the new criteria in order to ensure they are classified appropriately. However, if they are chemicals that are transported, i.e., not produced and used in the same workplace, this classification should largely be done already for purposes of complying with DOT's existing transport provisions. This should minimize the additional work required to review the physical hazard classifications to be consistent with the GHS for purposes of workplace classification and labeling.

One issue of concern is whether OSHA should also propose to change the physical hazard definitions in other standards when it proposes to change the HCS criteria to be consistent with the GHS. For example, if the HCS definitions are changed with regard to the definition of flammable liquids, there is a concern as to whether definitions in the flammable liquids standard need to be changed as well, and what the impact of this would be beyond classification and labeling. This is one of the areas that needs to be further explored in terms of impact and possible consequences.

E. Labels

The HCS requirements for labels simply indicate the minimal information required to be on them. At the time the standard was promulgated, OSHA reviewed the current industry consensus standards for labels, and basically focused on requiring information that was not generally present on most labels in use by industry. The additional information included an identity that could be traced to more detailed information, and specific information about both the health and physical hazards. In particular, OSHA did not consider a label statement indicating possible harm but no specific health effect to be a sufficient hazard communication. Other types of information such as precautionary statements were not included in the requirements.

This performance-oriented approach was strongly supported by the chemical industry at the time the standard was adopted. Taking such an approach allowed existing labels to continue to be used in many situations, thus minimizing the impact on a number of producers.

However, it also has resulted in labels that are not consistent, and may not communicate adequately to users. While some producers

follow voluntary industry consensus standards, others do not. Many large companies have developed their own libraries of phrases to be used on labels and safety data sheets, and undertaken translation of them into multiple languages. This is a considerable burden for a company to develop and maintain.

Other major existing systems considered in the harmonization process included specific label phrases to convey hazards and other information. Symbols and pictograms were also part of these systems. For purposes of developing an agreed harmonized approach, it was thus necessary to consider including such elements in the GHS.

For each class and category of hazard under the GHS that OSHA is considering adopting, there is a harmonized hazard statement, a signal word, and a pictogram specified. This is referred to as the core information for a chemical. Thus once an employer classifies a chemical, the GHS provides the specific core information to convey to users on that chemical. There are provisions to allow supplementary information as well so the chemical manufacturer is not limited to the specified core information. This should address product liability concerns for U.S. employers and ensure they can include other information they consider to be necessary for that purpose. Precautionary statements are also provided as examples in the GHS, but they have not yet been agreed and harmonized. This is expected to occur in the future as work on the system continues. Figure 1 is an example of how the core labeling elements (harmonized hazard statement, signal word, and pictogram) are assigned in one hazard class covered under the GHS.

These labeling provisions will likely be the biggest difference between the HCS and the GHS. There are benefits to this standardized approach. First, employers and employees will be given the same information on a chemical regardless of the supplier. This consistency will improve communication of the hazards. It may also improve communication for those who are not functionally literate, or who are not literate in the language written on the label. Literacy of both types is a significant concern in American workplaces. Secondly, having the core information developed already, translated into multiple languages, and readily available to whomever wishes to access it, will eliminate the burden of chemical manufacturers and importers developing and maintaining their own such systems. Thus the specification approach should be beneficial both to

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the producers and the users of chemicals.

[GRAPHIC] [TIFF OMITTED] TP12SE06.019

United Nations Globally Harmonized System of Classification and

Labeling of Chemicals, First Revised Edition, 2005, Annex I. Diamond frames for pictograms in the top row are red.

The use of symbols and pictograms will require some training and familiarization to be effective. One of the issues OSHA is considering is whether generic training on this aspect of the GHS can be developed and made available to employers and employees.

There is another significant benefit that will be achieved by adopting a system that has harmonized hazard statements in it. ``Control banding,' a guidance approach to recommending control measures for chemical exposures, is attracting significant attention around the world. The approach uses information that is readily available to small and medium-sized employers with chemicals in their workplaces to provide them with workplace-specific control recommendations. Basically, the system uses such information to estimate the degree of severity of the hazard and the amount of chemical present, and relates that to the degree of control needed. The control banding approach relies on harmonized hazard statements to allow the system to estimate the degree of severity of the hazard. Initially based on the European hazard classification system, it has now been converted to the GHS phrases. The use of control banding to provide guidance for chemical safety and health approaches in U.S. workplaces cannot be accomplished until harmonized hazard statements are readily available. Adoption of the GHS and its phrases would open up the possibility that control banding guidance can be used in the U.S. to help small and medium-sized employers select and implement appropriate control measures. In addition, the possibility of addressing control banding recommendations in GHS SDSs in the section on controls is also being explored. For more information on control banding, please see <http://www.cdc.gov/niosh/topics/ctrlbanding/>.

F. Safety Data Sheets

Under the HCS, the SDS is the detailed reference source on the chemical. While labels provide a quick snapshot to remind employers and employees of the hazards of the chemical, the SDS addresses all aspects of hazard information as well as methods for handling and use. The HCS specifies what information must be included on the SDS, but does not specify a format or order of information. Again, this approach was supported by producers to minimize the impact of the standard for those who already developed and disseminated SDSs. Currently, safety data sheets under the HCS are required to include:

Identification of the chemical or hazardous ingredients of a mixture
 Physical and chemical characteristics
 Health hazards, including signs, symptoms, and medical conditions

that could be aggravated by exposure

The primary routes of entry

The OSHA permissible exposure limit, ACGIH Threshold Limit Value,
and any other recommended exposure limits

Whether the chemical is considered to be a carcinogen by OSHA, the
International Agency for Research on Cancer, or the National
Toxicology Program

Precautions for safe handling and use

Control measures

Emergency and first aid procedures

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Date of preparation of the safety data sheet

Contact information for the responsible party

Users of chemicals have always preferred a standardized approach. Many believe that having the information in the same place on every data sheet allows them to access it more effectively. OSHA published a request for information regarding ways to improve the information provided under the HCS (55 FR 20580; May 17, 1990), and received around 600 comments in response. The majority of them were in favor of a standardized format or order of information.

As a result of the users' expressed preferences, chemical manufacturers in the U.S. developed a voluntary industry consensus standard that included an order of information for safety data sheets (ANSI Z400.1). This approach was later adopted into international voluntary industry consensus standards as well.

The HCS allows any format to be used, so many producers have been following the consensus standard order of information for some years. In negotiating the GHS, it was decided that this format should be adopted there as well. One change was made, reversing the order of sections 2 and 3 so the hazard information appeared earlier in the sheet than information on chemical composition. Both the national and international industry consensus standards are being changed to be consistent with this approach. The GHS data sheet is to include the following in this order:

Identification

Hazard identification

Composition/information on ingredients

First aid measures

Firefighting measures

Accidental release measures

Handling and storage

Exposure controls/personal protection

Physical and chemical properties
Stability and reactivity
Toxicological information
Ecological information
Disposal considerations
Transport information
Regulatory information
Other information

Having a standardized order of information should improve comprehensibility, which has been a continuing issue with regard to safety data sheets. It should also make it easier for chemical producers to comply by providing them with a template to follow. Using the industry consensus standards should also minimize the burden of preparing new safety data sheets since many chemical producers already use the format specified. While the GHS safety data sheet does not address exposure limits in the titles of the sections, guidance on what should be included indicates that occupational exposure limits would be addressed under the ``exposure controls'' section. Countries may choose what to require in these sections in terms of occupational exposure limits, but it is anticipated that OSHA would require the PELs to be included.

Under the auspices of the International Program on Chemical Safety (IPCS), a series of over 1300 international chemical safety cards has been developed and translated into 14 languages. These cards are developed and peer reviewed by participating institutions in a number of countries, including the U.S. The National Institute for Occupational Safety and Health (NIOSH) is undertaking this work. The cards are similar to SDSs in terms of the information provided, but they are in a concise format of two pages. The cards are going to be updated to reflect the GHS criteria and hazard information. They may be found on NIOSH's Web page at: <http://www.cdc.gov/niosh/ipcs/nicstart.html>

OSHA also has a link to them on our hazard communication page. These cards are an excellent resource for many of the most common chemicals found in the workplace. When updated to be GHS-consistent, they will also be a useful resource for GHS compliance and for implementation of control banding.

As mentioned earlier, there is information required on a GHS SDS that is outside OSHA's jurisdiction to regulate. This includes environmental and transport information. We do not intend to propose requiring it on safety data sheets, but will provide information about the provisions so chemical producers can include it if they wish to be completely consistent with the GHS. OSHA does not preclude such information being on a safety data sheet, but will not review or enforce such provisions.

III. Public Resources for Further Information on the GHS

OSHA has a safety and health topic page on hazard communication available as part of our Web site. There is a hazard communication button on the Agency's home page (<http://www.osha.gov>) that leads to a portal page on the topic, including a box on the GHS. There is a page devoted to the GHS that is reached through clicking on this box. It gives additional background information, and has links to the GHS official text, Web pages of other U.S. agencies, international organizations, and countries involved in GHS implementation.

As noted earlier, a substantive guide to the GHS is available on this page to describe the system in more detail for those who are interested. There is also a detailed comparison of the HCS to the GHS that notes the areas of difference that would have to be addressed in adopting the GHS.

IV. Request for Input

In order to prepare for rulemaking proposing adoption of the GHS and modification of the HCS to accomplish that, OSHA is seeking input from the public on a number of issues related to implementation. This information will be used by OSHA to prepare cost analyses and other documents required to support the rulemaking. These requests are divided into several categories of information below. Please provide comments, evidence, data, and other input for those categories that affect you or for which you have relevant information. The details for submitting this information are specified in Section V.

Current situation. Modifying the HCS to adopt the GHS would have the greatest impact on chemical manufacturers, importers, and employers who produce or distribute hazardous chemicals as currently covered under the HCS. In order to be harmonized, the hazard classifications of each product will need to be reviewed according to the classification criteria of the GHS, and new labels and safety data sheets will have to be prepared.

1. How many hazardous chemicals as defined by the HCS do you produce, import or distribute? How many hazardous chemicals do you export? How many different labels or data sheets do you need to prepare for each chemical you export?

2. Who is responsible for reviewing the data on chemicals and preparing appropriate labels and safety data sheets? What is their professional background? Do you make independent determinations or rely largely on labels or data sheets developed by others (suppliers, materials available on the Internet, etc.)?

3. How long does it take on average for each hazardous chemical to

complete the review and prepare new labels and safety data sheets? How much does it cost for each chemical product? Please break down the cost for the classification, preparation of a new label, and revision of a safety data sheet.

4. Would the time required to prepare a GHS SDS be more, less, or about the same as currently required for preparing an SDS? What time and costs would be required to convert existing SDSs to the

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GHS format? Would the costs depend on the amount of time allowed for the conversion process?

5. Please describe any electronic tools you have to assist with this process, such as systems that classify chemicals or prepare labels or safety data sheets. How long would it take to update those systems to make them GHS-consistent?

6. How many of your employees receive hazard communication training? How many hours of training at what frequency (on hire, annually, as needed, etc.)? How long would it take to teach employees to recognize GHS pictograms? Would more standardized labels and SDSs make it easier to use the available hazard communication information?

7. What savings will you incur when you only have to classify a chemical once instead of multiple times depending on how many agencies and countries are involved? What other benefits do you anticipate?

Timing. As has been noted, the international goal is for as many countries as possible to adopt the GHS by 2008. Since OSHA has longstanding requirements for labels and safety data sheets, the Agency expects to allow a significant phase-in period for compliance in order to give people sufficient time to review their classifications and amend them as necessary, and subsequently revise labels and safety data sheets to reflect the new requirements. It seems probable at this point that the revised requirements could potentially be in place by 2008, but the phase-in period for compliance may have to extend beyond that time period.

8. What is a reasonable time period for phasing in the modifications? Should the phasing be done by size of business? Are there any other factors that should be considered to differentiate the phasing?

9. What is the normal cycle for updating labels and safety data sheets?

10. Do you have stockpiles of product that are already labeled? How long will those stockpiles last?

11. Do you have any other information or data that would help OSHA determine the appropriate phasing in of the new requirements or other issues related to timing?

Technical issues. As discussed, the scope of hazards covered by the

GHS is similar to that of the HCS. OSHA anticipates adopting all of the health and physical hazard criteria in the GHS. Definitions in the HCS will need to be the same as the GHS in order to be harmonized. However, there are some determinations that are left to countries to decide in terms of whether all categories and all hazards are adopted.

12. Are there any health or physical hazards that are currently covered by the HCS that you think are not adequately addressed in the GHS criteria? What are they and why do you think they are not adequately addressed? Are there any health or physical hazards that aren't covered in either the HCS or the GHS that should be added?

13. In addition to references to hazardous chemicals with OSHA PELs, should OSHA propose to include any other listing of hazardous chemicals when aligning the hazard determination provisions of the HCS to the GHS? Should OSHA propose that the mixture provisions only reference exceeding the OSHA PEL when revised to adopt the GHS? Should OSHA propose deleting the requirement that the ACGIH TLV be included on the SDS when the requirements are changed to be consistent with the GHS? Should other recommended exposure limits be included on the SDS?

14. Within the health hazard criteria, are there any categories of hazard that should not be adopted in the HCS? For example, should OSHA adopt all of the categories addressed in the acute toxicity criteria? If not, what categories would be appropriate to address anticipated workplace exposures?

15. If OSHA changes the HCS to adopt the physical hazard criteria, how will that impact other OSHA standards that use the same criteria as the HCS? Does OSHA need to change those criteria at the same time the HCS is changed? Storage and handling requirements for flammable liquids are one example that has been identified as a potential problem if different definitions apply, and information on a safety data sheet is linked to the definition in the HCS but not consistent with other definitions.

16. Are there any other technical issues that need to be considered in adopting the GHS? Please explain.

Compliance Assistance and Outreach. OSHA is interested in getting input on the types of materials or products that would assist employers in understanding whatever modifications OSHA makes to the HCS to adopt the GHS, and to help them achieve compliance. To this end, we would like to get input now on the types of outreach that would be most helpful. As has been noted, there are some explanatory documents that are already available on OSHA's Web site.

17. What products would be most useful to employers? Employees? Do you prefer paper publications? Electronic tools?

18. What subjects would be of most interest? Classification criteria and procedures for substances and mixtures? Labels? Safety data sheets?

19. What is the best way to distribute the materials to reach affected employers and employees?

20. Are there any types of materials that would be especially appropriate for small businesses? Most small businesses would be users of chemicals, rather than producers, so they will be receiving labels and safety data sheets prepared according to the new approach. Are there training materials that would be helpful to learn or teach about the new approach? In particular, would training on symbols or pictograms be of use?

V. Public Participation

You may submit comments in response to this document by (1) hard copy, (2) fax transmission (facsimile), or (3) electronically through the OSHA Web page or the Federal Rulemaking Portal. Because of security-related problems, there may be a significant delay in the receipt of comments by regular mail. Please contact the OSHA Docket Office at (202) 693-2350 for information about security procedures concerning the delivery of materials by express delivery, hand delivery, and courier service.

All comments and submissions are available for inspection and copying at the OSHA Docket Office at the above address. Comments and submissions posted on OSHA's Web page are available at <http://www.osha.gov> (click on ``Dockets & E-Comments``). OSHA cautions you

about submitting personal information such as Social Security numbers and birth dates. Contact the OSHA Docket Office for information about materials not available through the OSHA Web page and for assistance in using the Web page to locate docket submissions.

Electronic copies of this Federal Register notice, as well as news releases and other relevant documents, are available on OSHA's Web page.

VI. Authority and Signature

This document was prepared under the direction of Edwin G. Foulke, Jr., Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor. It is issued pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911, and Secretary's Order 5-2002 (67 FR 65008).

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Edwin G. Foulke, Jr.,

Assistant Secretary of Labor for Occupational Safety and Health.
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