Implementation Considerations for Internationally Harmonized Hazard Communication

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Abstract

For the past few years, the focus of several international regulatory agencies has been on the examination of the different systems of chemical safety regulations in an effort to define criteria that would unify various global standards. At the current time, this work in developing a globally harmonized system continues to progress and make strides towards reaching this goal. As the conclusion of these efforts nears, the attention must shift from what the criteria and regulations of the system will be to how those rules and conventions will be implemented by the various governmental agencies, and by the companies that manufacture, import or distribute chemical products.

The very nature of harmonizing different chemical regulations implies that changes will need to be made to the existing procedures in order to comply with these unified rules. As beneficial as these regulatory changes promise to be, the fact remains that much effort will be required in order for the affected governmental agencies and private companies to make these necessary adjustments. From a chemical safety perspective, these changes will include updating material safety data sheets, product labels, transportation classifications, and software packages. Before such documents can be updated, regulatory changes may prompt the need for products to be tested for additional physical and toxicological properties. All of these considerations will result in an expense of both time and resources in order to fulfill the demands of harmonization. This paper will provide some examples of what this effort may entail.

Introduction

With the attention of several international regulatory agencies on the examination of the different systems of chemical safety regulations, an effort to define criteria that would globally standardize various policies has been undertaken. Currently, this work continues to progress toward developing a universally harmonized system. As

the conclusion of at least some of these efforts approaches, the attention will change from what the criteria and regulations of the system will be to how those rules and conventions will be implemented by the various governmental agencies and by the companies that manufacture, import or distribute chemical products.

A primary implication of harmonizing different chemical regulations is that changes will need to be made to the existing requirements in each participating region in order to comply with these unified rules. Although these regulatory changes are promising to provide the beneficial results of increased chemical hazard knowledge and improved communication, the fact remains that considerable effort will be required in order for companies and government agencies to make these necessary adjustments. From a chemical safety perspective, these changes will include reviewing and updating safety data sheets, product labels, and possibly transportation classifications. In addition, changes will need to be made to software packages used in the preparation of these classifications and documents, and to training and certification programs. Prior to updating the hazard communication documents, regulatory changes to classification procedures may prompt the need for more information to be gathered for chemicals and products. This need may require that sharing of existing information take place or that some chemicals be tested for additional physical and toxicological properties. All of these considerations will result in an expense of both time and resources in order to fulfill the demands of harmonization. The creation and application of a globally harmonized hazard communication system also brings about other considerations. These items include jurisdiction, enforcement, legal and civil liability, and the necessary interaction of government agencies. Although the topic of this paper relates to global harmonization, the examples and comparisons provided will be limited primarily to the industrial or professional chemical product regulations relevant to the United States of America, Canada, and the countries of the European Union.

Background

Chemicals have been in use in various forms for a considerable portion of human history. The industrial revolution brought about an increase in the utilization of chemicals that has continued to accelerate to the present day. This increased use includes the production of higher volumes of existing chemicals as well as the development of new chemical compounds. As chemicals have become more prevalent in commerce, so too has human and environmental exposure to these substances. Several decades ago, the realization that chemical exposures, even at low levels, could lead to adverse effects on both the human population and the environment led to the origin of various governmental movements to regulate this interaction. These regulations began to a certain degree in the isolation of the nations that first enacted them. International relations and trade interactions had not evolved into the global strategies that are seen in the present, and so most countries proceeded to create regulations that were best suited to their own social, political, and economic considerations at that time. As the end of the twentieth century approached, a much more comprehensive consideration of global interactions has led to steps to harmonize international chemical regulations including the area of hazard communication.

Based on information gathered from the LOLI® for Windows™ regulatory database with regard to several chemical inventory lists, there are approximately 180,000

chemical compounds recognized for use in various regions around the world. This number increases when those chemicals considered exempt or proprietary are included. Typically, chemical inventories do not single out those chemicals that are considered hazardous, but rather only track chemicals that are in use commercially. It is when the hazardous subset of this larger number of chemicals is considered that the differences in various regulations of these substances become apparent. An examination of regulatory lists such as occupational exposure limits, designated carcinogens, and other hazardous chemical registries reveals that only a small percentage of the total substances used commercially are identified as hazardous. Since these hazardous chemical listings are not inclusive, procedures need to be in place by which to evaluate the balance of the commercial chemicals and determine the potential for detrimental effects. This area of hazard classification is one of the focal points of the global harmonization system. By coordinating the basic criteria used in the classification of hazardous substances and mixtures, the use of these compounds internationally can be facilitated.

Current Methods

A brief description of some of the current procedures in place with regard to product stewardship including registration, classification, product documentation, and health and safety training will help to illustrate both the need for harmonization, and the factors involved for an examination of its implementation.

In Europe, the majority of countries require some form of product registration. This requirement at the product level is in addition to the substance registration that is covered by the EINECS and ELINCS chemical inventories. Registration is country specific and can be as simple as requiring that a copy of the product safety data sheet be submitted. However, the process may be as complex as completing a form calling for additional information such as complete chemical composition, anticipated quantities to be produced or sold per year, type of product, and the name and address of the manufacturer contact in that country. This process may include a fee as well, however, this is required by only a few countries. In North America, the requirements are different. Neither the U.S.A nor Canada has specific product registration requirements for general industrial chemical products, however pesticide and pharmaceutical products are subject to such requirements. For industrial chemicals, registration occurs at the component or substance level. In the U.S.A. chemical substances that are manufactured, imported, or distributed for commercial use are required to be registered on the Toxic Substance and Control Act (TSCA) inventory list, unless they are exempted from such a requirement. In Canada, the procedure is similar except that the inventories are the Domestic Substance List (DSL) and the Non-Domestic Substance List (NDSL).

Perhaps the most significant factor to be considered when addressing hazard communication harmonization is that of chemical substance and product specific classification. The procedure for determining which products are hazardous, and the degree to which they are hazardous will set the tone for how other areas of harmonization will be affected. Also a factor is how much any one region's set of existing hazard criteria will need to be altered in order to comply with the new guidelines. Each of these issues will influence the amount of time and money that may be needed for the transition. In the European Union, the method of hazard

determination or classification is outlined in the Substance Directive 67/548/EEC. Classification begins at the substance level where the hazards of each chemical component are determined. Directive 67/548/EEC Annex I contains a list of hazardous chemicals that have been classified by the EU Commission. The use of these classifications is mandated whenever a listed chemical is present in a product. For those chemicals not specifically listed in Annex I, a provisional classification must be determined by the manufacturer or distributor by applying the criteria outlined in the Substance Directive. Those chemicals not listed in Annex I and determined not to meet the criteria of the Substance Directive are considered non-hazardous and are not subject to the further requirements of this directive. The criteria used for this determination is risk based such that the classification and the associated risk phrases (R – phrases) can be different depending upon the concentration of that substance in a preparation. This risk is then carried over, as the classification and risk phrases for the preparation are determined. In contrast, the systems used for component and mixture classification in the U.S.A. and Canada are hazard based. In the United States, the mandate and guidelines for conducting a hazard determination for both substances and mixtures are found in the code of federal regulations 29 CFR 1910.1200 and are enforced by the Occupational Safety and Health Administration (OSHA). These procedures are best illustrated in how the hazards of mixtures are assessed. An untested mixture is assumed to have the hazards of the components present at one percent or greater for those substances that are health hazards or contribute to any physical hazard of the product, or present at one tenth of one percent if the component is recognized as a carcinogen. In Canada, the hazard determination is directed in the Hazardous Products Act and the Controlled Products Regulations that is enforced by Health Canada. These standards outline a hazard-based system of procedures following similar one and one tenth of one percent rules. However, the specific criteria used to classify a substance or mixture as hazardous is somewhat different than in the U.S.A. Canada does employ a symbol/letter-based designation of the hazard classification as part of the Workplace Hazardous Material Identification System (WHMIS) that is in some ways analogous to the EU system. Although all three of these systems have been developed independently and have inherent differences, each is effective in its own way at providing the framework of procedures with which to evaluate and classify chemicals and chemical products.

Once the hazard classification or determination has been completed, it follows that the hazard communication documents would be created. These documents consist primarily of safety data sheets, (i.e. material safety data sheets in North America), and product labels. In the EU, the creation of these documents is covered under the Preparation Directive 91/155/EEC which is a maximum directive such that the requirement to provide a safety data sheet and the overall content and structure of the document must be followed by the member countries. In addition to this EU directive, the documents must comply with specific national legislations and language requirements. In the U.S.A., the preparation of material safety data sheets and industrial labels is required by the statute cited above for the hazard determination. This legislation lists the categories of information relating to the physical and health hazards of chemical products as well as steps to be taken to prevent and address human and environmental exposures to the products. What this regulation does not specifically address is the format that the documents should use. The formats that are in use by the majority of chemical product manufacturers in the U.S.A. are the ANSI

Z400.1-1998 *American National Standard for Hazardous Industrial Chemical – Material Safety Data Sheets – Preparation*, and the ANSI Z129.1-2000 *American National Standard for Hazardous Industrial Chemical –Precautionary Labeling,* which were developed by a technical committee of the American Chemistry Council (formerly the Chemical Manufacturers Association). The ANSI standard for material safety data sheets recommends a sixteen-section format that is very similar to the ISO 11014-1 standard used by the European Union. Additional information will appear on these documents in order to comply with specific individual state regulations including right-to-know laws. Canada's Controlled Products Regulations mandate that certain specific areas of chemical hazards and hygiene be addressed, but do not require that a specific format be used. As in the U.S.A., the ANSI and ISO sixteen-section formats are recognized and accepted, but there is no governmental regulatory body enforcing their use. The labeling requirements for each of these three regions follow a pattern similar to that of the safety data sheets. The EU directive requires that certain information appear on a professional (industrial) product label and in a particular format, while allowing for country specific regulations. Providing the information in the national language(s) is also required. In the United States, the industrial label information is regulated along the same lines as the material safety data sheet. OSHA regulations outline the categories of information that must appear on these labels, but the recommendations set forth in the ANSI labeling standard provide the framework for organizing this information. As with the MSDS, there is the use of this standard is not enforced. In Canada, the industrial labeling procedures are part of WHMIS and outline requirements for both categories of content and format that specify the structure of the content, the use of symbols, and presentation in the language requirements of both English and Canadian French.

Training is another important aspect in the process of product stewardship. Training is necessary at many levels. The personnel that are responsible for determining the hazards of the products and correctly classifying them according to the current regulatory requirements need to be fully trained in these areas as well as in chemical health effects, safety, and hygiene. Once products are classified, it is then necessary to ensure that those people who will transport the material and those people who will use the products are trained in how to read and interpret any hazard communication documents that are generated based upon the hazard classification.

Implementation Factors

From this overview of three representative systems of hazard communication currently in use, some of the obstacles inherent in harmonizing such procedures become apparent. The other items that become noticeable are the issues that will influence the implementation of these corresponding changes once the new system is in place. A better understanding and estimate of the time and cost of putting these protocols into operation can be gained by a consideration of these factors.

The first factor to be considered is that of legislative strength. The current systems each operate by having a combination of both required and recommended content and format. In each example provided above, the governing body has set a list of maximum directives that must be followed. However, other aspects of chemical hazard classification and communication are designated as minimum directives permitting individual countries in the EU and individual states or provinces in North

America, to add or modify the content or format of some portions of these documents. In some instances, supplemental information may be recommend in order for companies to comply with voluntary industry standards. In theory, a global system that is comprised of one hundred percent maximum directives would achieve complete unification of all of the various systems in use today, but would not fully meet with the approval of the participants due to the loss of country specific requirements. On the other hand, including too high of a percentage of minimum directives will achieve very little harmonization. It follows then that, from a practical point of view, the new system will also be a mix of both maximum and minimum requirements. While the benefits of harmonization would best be served with a high percentage of mandatory requirements, this will also require the highest amount of changes to each existing system. Therefore, as the level of harmonization increases, there will be an anticipated increase in the time and cost to implement such a system and an increased resistance by the individual constituencies.

The existing systems for chemical hazard communication or any newly created system of harmonized criteria and requirements is only as good as the level of enforcement of these rules. As good as participation in programs such as Responsible Care® and the ISO certifications may be, they only ensure that participating companies comply with the outlined standards, and do not guarantee that the chemical products industry, the workers, and the end users will be better served as a whole. Only through unilateral, enforceable legislation will this be possible. In addition to the statutes requiring harmonization and penalties for non-compliance, the resources must be present in order to enforce compliance with these laws. As with most legislation, it will follow that the level at which the laws regarding harmonization are enforced will correspond proportionately with the level of compliance, therefore requiring a proportional allocation of time and resources.

In chemical hazard communication, as in other areas where regulatory compliance is a prominent issue, the need to have well trained, qualified and in some cases certified individuals is very important. At many levels, the subject of chemical regulations is a dynamic field. As legislation changes, the responsibility to keep up to date falls on the regulatory specialists and hazard communication professionals as well as those in the consulting and information providing fields. The extent to which the global harmonization standard changes the existing legislation governing hazardous chemical classification and communication will be relative to the amount of training an individual will require in order to understand and employ the new criteria and protocols. This training will directly affect the efficiency with which the new system will be implemented.

Depending upon which system of classification is used in a given region, it may be the case that the criteria that is adopted for harmonization is either more stringent or wider in scope than the one currently in use. In that event, it would be necessary to reevaluate the chemicals in use based upon the new criteria. For some of these chemicals, it is possible that the available information is insufficient to meet the new requirements. There may be relevant information that is not available publicly. A mechanism for sharing existing information may need to be developed in order to facilitate the exchange of data and minimize the amount of testing that may need to be conducted in order to properly determine the chemical classification for a product. It may still be necessary to conduct tests to determine physical and chemical property

values for a substance or preparation, as well as derive toxicity information from methods not utilizing animal testing such as the Corrositex assay used to determine the corrosiveness of a chemical, and structural activity relationship studies which can lead to a measure of relative toxicity. When needed, these factors will add to the time and cost of instituting the new policies dictated by the harmonization regulations. In some regions, a reduction or elimination in permissible animal testing due to political and economic pressures may create the need to develop alternative protocols in order to comply.

Included in the differences between the EU, Canada and U.S.A. would be each region's judicial climate. In the United States, the enactment of laws and the legal challenge to those regulations has interacted to shape the statutes into the form in which they exist today. The types of extensive changes that may be brought about by a process such as regulatory harmonization could entail significant expenditures of time and money in order to withstand potential legal challenges by interested parties such as industry, labor organizations, and environmental advocacy groups. Product liability is also an issue that could be affected by regulatory standardization. The ability to supplement the required information with additional statements can be a means by which a company affords some protection from product liability. Any restrictions imposed by a maximum directive restricting or eliminating this additional information could lead to legal ramifications relative to the regions considered.

The possibility that the effects of harmonization may be felt outside of the sphere of chemical regulations can be seen when the area of confidential business information is considered. Relative to Canada and the European Union, the requirements for handling proprietary information in the United States are more liberal. There are currently no formal registration procedures at the federal levels, or are there fees involved as are present in other regional hazard communication standards. The ability to declare components within a product as trade secrets for the purpose of hazard communication is an important business consideration in the highly competitive commercial markets for certain industries. In Canada, there is a considerable fee imposed on each product declaring a trade secret component. Information regarding the claim for confidentiality must accompany the fee, and the product is reviewed every three years at which time the fee must be repaid. Changes that may restrict what is currently permissible or impose fees in order to register this confidential information will influence various business strategies and could affect both the willingness to accept the new standards and implement the new procedures. Consideration of how to implement any new legislation from a business standpoint will add to the time frame already in place for the regulatory specialists to integrate the new requirements into existing protocols.

Time

Once the harmonization legislation is enacted and is in effect, a time line will develop for the implementation process. The first stage will be to obtain a complete set of the harmonized regulations and then to acquire not just a familiarity with the requirements, but rather a command of the laws sufficient to provide classifications and documents that are compliant. Depending upon the extent of the regulatory changes and the number of persons within a company or department needing this knowledge, this period of adjustment could be weeks to months to implement. This

process could be facilitated by groups specializing in training and consulting that provide expert guidance. These groups will need to be knowledgeable with the harmonized regulations as well as the prior regional legislation. The next phase would entail applying the new classification criteria and protocols to each chemical substance and mixture preparation as required. This will include evaluating all products, even those previously considered as non-hazardous, since the new criteria may now have a broader scope than previous regulations. This period will vary due to the number of individual components used by a chemical manufacturer, the number of products, and the variability between the products. Following each new product classification will be the preparation of updated safety data sheets and product labels. The factors influencing document preparation will be the same as those for updating classifications. For end users, the time associated with harmonization will be related to the development of training programs designed to provide workers with both awareness that a new system has been implemented and an understanding of that system at a sufficient level to ensure a safe workplace and to protect the environment. Another factor that will affect the time of implementing a harmonization program will be the number of modifications that will need to be made to the various software programs that are commonly utilized by hazard communication professionals to assist in determining classifications or document preparation and distribution. Many of these systems have been designed to provide information and formatting that is highly specific to regional legislative or corporate requirements. Changes to this software in order to utilize updated standardized phrases in place of those currently in use as well as accommodate the use of symbols and provide this information in a format not presently enforced may require weeks to months to develop and to train the users in these alterations.

Cost

As there is a time frame associated with each item and phase of incorporating the unifying regulations, so too will there be a related expense. Initially there will be the cost of training personnel in the updated requirements. Concurrently, there will be the cost of modifying or possibly even replacing hazard communication authoring software as well as other packages used in determining classifications. The expenditure of software updates will also need to include the necessary training involved in order to educate product stewardship personnel in the changes. The regulatory training portion would cost a department a few thousand dollars. The software updates could add tens or hundreds of thousands of dollars more. Once the necessary knowledge and tools have been acquired, the next expense that will be incurred is that of developing and implementing a plan of product reclassification and the subsequent document updates. Although this cost will depend upon both the number of regulatory changes brought about by harmonization and the size and variability of a company's product line, this portion of the implementation project will require the most resource allocation. For example, a department responsible for approximately 100 different products would realize a cost on the order of $50,000.00 to $75,000.00 U.S. dollars for this phase of the operation while a company producing 1000 or more products would likely have an expenditure of $1,000,000.00 or more. Although these numbers may seem to be relatively small when compared to a company's other operating expenses, they are still significant considering that this cost does not directly enhance a corporation's profitability. Depending upon the size

of the project and the time needed to complete it, the implementation costs will also need to consider staffing adjustments as well.

Conclusion

Although the principles and criteria for the harmonization of international chemical safety regulations are still being formulated, there can be little debate that implementing such a system, though substantially beneficial, will inevitably require changes to the way in which hazard communication is currently being conducted. The extent of these changes will be proportional to the amount of time, effort and expense that will be needed in order to comply. This paper has addressed some of the needs for the expenditure of such time and resources. By discussing these issues, the preparation for, and the realization of, harmonization may proceed in a more efficient and predictable manner.

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Author Biographies

Mr. Moyer earned his Masters of Science Degree in Environmental and Occupational Health and a Bachelor of Science Degree in microbiology from the University of Pittsburgh, Pennsylvania. At ChemADVISOR Mr. Moyer currently holds the position of Hazard Communication Manager, and has the principle responsibility of supervising the technical staff in the preparation of Material Safety Data Sheets (MSDS), consumer and industrial labels, hazard evaluations, toxicological reviews, transportation classifications and other issues related to chemical hazard communication under various government and industry standards. Mr. Moyer is a co-author/instructor for several hazard communication related courses developed by ChemADVISOR, and also provides demonstrations and instruction for the ChemSDS+® MSDS Authoring and LOLI® Regulatory software. Mr. Moyer is a member of both the local and national chapters of the Society of Toxicology (SOT), and a member of the Society for Chemical Hazard Communication (SCHC) where he is currently a member of the professional development committee. Mr. Moyer has completed a DOT certification course on classifying hazardous goods for domestic shipments, and a course on European Union hazard communication.

Mrs. Dsida received her Masters Degree in Pharmacology/Toxicology from the State University of New York at Buffalo. Ms. Dsida began her career as a chemist after attaining a bachelor's of science degree in Chemistry from the University of Michigan. She has worked in the regulatory field at Westwood Pharmaceuticals and with the U.S. Food and Drug Administration (FDA) on the preparation of two New Drug Applications (NDAs) and several Investigational New Drug Exemptions (INDs). She later worked with the Motor Vehicle Manufacturer's Association on the then-proposed OSHA labeling standard. From the MVMA she switched to the Ford Motor Company where she developed the company's Hazard Communication Program. Ms. Dsida is currently president of ChemADVISOR, a company that she founded in 1986. ChemADVISOR specializes in the preparation of hazard communication documents, regulatory training and the company also provides and maintains the LOLI regulatory database product. Ms. Dsida is a member of many professional organizations including the American Conference on Chemical Labeling (ACCL), the American Industrial Hygiene Association (AIHA), the Society of Toxicology (SOT) and the Society for Chemical Hazard Communication (SCHC). She is currently a board member of the SCHC. She has worked on the National Advisory Council on Occupational Safety and Health (NACOSH). Ms. Dsida has completed a DOT certification course and she is an EPA certified trainer.