Toward a Globally Harmonized System: Negotiating to Promote Public Health, Environmental Protection, and International Trade

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A relatively obscure United Nations committee met in the Palais des Nations in Geneva in December 2002 to adopt one of the most complex and ambitious international voluntary health and environmental protection agreements ever negotiated: the Globally Harmonized System for Classification and Labeling of Chemicals, or GHS. The GHS agreement includes detailed classification criteria for physical hazards, health hazards, and one environmental hazard (aquatic toxicity), along with standardization of key label elements and guidance for formats and contents of safety data sheets. The intent is that countries that already have well-developed systems for chemical hazard classification and communication will adapt them to be consistent with the GHS, and countries that lack such systems will adopt the GHS as the fundamental basis for building national programs to promote the sound management of chemicals.

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One of the more tangible successes to come out of the 1992 UN Conference on Environment and Development (UNCED), the GHS agreement is the product of more than a decade of negotiations spanning three U.S. presidential administrations. It holds significant promise in terms of enhancing public health and environmental protection worldwide, while facilitating international trade. It is a landmark achievement in harmonizing widely divergent international approaches in the highly technical field of chemical regulation. Perhaps most surprising of all, the system was developed and is expected to be adopted by consensus reflecting the perspectives not only of governments, but also of key stakeholders.

This paper will explore how the GHS negotiation process worked, illustrate what will be necessary to ensure that the promised gains in health, environmental protection, and international trade are realized, and offer possible lessons for future international efforts in this and other highly complex technical fields.

GENESIS OF THE GHS

For many years, there has been significant international concern about gaps in chemical hazard classification and communication programs, and the resulting lack of protection, particularly in developing countries. In the workplace alone, the International Labor Organization (ILO) estimated that over 340,000 deaths worldwide are attributable to occupational exposure to hazardous chemicals each year.[1] The toll in disease, disability, and death from all exposures in all settings cannot be reliably estimated.

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At the same time, companies involved in international trade in chemical products have been frustrated by inconsistencies in existing systems of hazard classification and labeling, and the inefficiencies involved in complying with multiple requirements of various systems, depending on where they are doing business. According to the Organization for Economic Cooperation and Development (OECD), world wide chemical sales in 1998 amounted to approximately $1.5 trillion, which is "more than twice the size of the world market for telecommunications equipment and services," and accounted for seven percent of global income and nine percent of international trade. Sales have increased ninefold since 1970, and the industry is expected to continue to expand. Industrialized countries will remain the highest producers and consumers of chemicals over the next 20 years, but the share of manufacturing and consumption attributable to developing countries is rising at a proportionally higher rate.[2]

Several international organizations also have programs covering some aspects of chemical classification and labeling.[3] None are comprehensive, however, and none provide a common and consistent basis for classifying chemicals according to the hazards they pose to people and the environment, which is the first, fundamental step in establishing systems for communicating hazards to those who are exposed to chemicals and for managing chemical risks to protect people and the environment.

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These concerns came into a clear focus at the 1992 UNCED Earth Summit Conference in Rio de Janeiro. As stated in the conference agenda,

> Globally harmonized hazard classification and labeling 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 labeling systems. There is a need to develop harmonized hazard classification and labeling systems, building on ongoing work.[4]

The charge from Rio was to develop "a globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols..."[5]

GUIDING PRINCIPLES AND GROUND RULES

Overall responsibility for managing the GHS work mandated by UNCED fell to the Coordinating Group for the Harmonization of Chemical Classification Systems, which was organized under the auspices of the Inter-Organization Program for the Sound Management of Chemicals (IOMC).[6] From the outset, it was clear that the effort needed guiding principles and basic ground rules, and would have to draw on the knowledge and resources of many experts and organizations. Thus, GHS developers agreed on a number of general premises:[7]

- The scope of the system should include all types of chemicals.
- Harmonization should not lower the levels of protection afforded by existing systems to workers, consumers, the general public, and the environment.
- Four major existing systems would be the basis for the harmonized system: the United Nations Recommendations for the Transport of Dangerous Goods; the U.S. system governing chemicals in the workplace, pesticides, and consumer products (in reality, three systems that themselves are not

fully harmonized); the Canadian workplace, pesticide, and consumer product systems; and European Union directives on classification and labeling of substances and preparations (mixtures). In practice, requirements from other existing systems were also considered at certain points in the process.

- The classification system should be based on the intrinsic hazard properties of chemicals, without consideration of exposure or risk. The distinction between hazard and risk was particularly important to the manageability of the GHS task. The intrinsic hazard properties of a chemical (e.g., is it acutely toxic or corrosive, does it cause cancer or birth defects, does it kill fish) can be expected to remain constant. Although in specific cases scientists may differ in their interpretations of available data, in many areas it is possible to reach agreement on appropriate tests and the significance of test results in determining whether a hazard is present. Risk, on the other hand, is dependent on the level of exposure to the hazardous chemical. Exposure, and hence risk, is much more difficult, if not impossible, to estimate reliably in different settings even within a single geographical area, except in such extreme, *de minimis* cases as when a chemical is present but totally bound or contained, and therefore no exposure is reasonably anticipated.[8]
- Physical hazards (flammability, explosivity, etc.), health hazards, and environmental hazards should all be covered.
- The system should be as simple and straightforward as possible, to permit self-classification (e.g., under most existing workplace systems, the primary responsibility for classification and labeling rests with chemical suppliers, without prior review by a regulatory agency).
- The needs of all target audiences should be considered; comprehension by the target audiences would be key to an effective hazard communication system.
- Harmonization would entail the establishment of a common and coherent basis for hazard classification and communication from which appropriate elements relevant to various sectors could be selected. This concept of selection was later known as the "building block" approach, under which countries would retain flexibility as to which hazards to cover, subject to certain parameters. For example, chronic hazards are not usually part of systems for hazard classification and labeling for transportation purposes, since concerns in the transport sector are focused on acute effects that could result from accidents and spills. For the hazards that are covered, however, a system should use the relevant GHS criteria and communications elements.
- Validated data already generated under existing systems should be used when reclassifying chemicals under the harmonized system.
- The system should protect the safety and health of workers, consumers, the general public, and the environment, while protecting confidential business information as prescribed by competent authorities.

- Harmonization would require all existing systems to change to align with the GHS system.
- Decisions in all international GHS negotiating groups should be taken by consensus.
- The groups charged with developing the GHS should include a wide spectrum of expertise, and involve both governments and stakeholders.
- For practical reasons, negotiations would be conducted, and working documents would be prepared, in English only.

Originally, the GHS framers also anticipated that the system might require modifications in chemical testing protocols. As the work proceeded, however, it was concluded that this was beyond the scope of the effort for health and environmental hazards and that the system should be testing as well as test-method neutral, except for physical hazards. Implementation of the GHS would be based on the best available data and information, and the GHS itself would not prescribe test protocols or new testing. Regulatory agencies that have authority to impose testing requirements would be expected to continue to do so (e.g., in connection with pre-marketing regulatory review of applications for approval of pesticides).

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ORGANIZING THE WORK

No single organization had the resources or expertise to develop the GHS. Responsibilities for formulating the principal components of the system were delegated to three focal points:

- **Classification criteria for physical hazards** were the responsibility of a joint working group of the UN Sub-Committee of Experts on the Transport of Dangerous Goods and the ILO. The working group was chaired by Germany, and the lead U.S. government agency was the Department of Transportation. The physical hazard criteria include test methods and apply to both chemical substances and chemical mixtures.
- **Classification criteria for health and environmental hazards** were developed by a Task Force on Harmonization of Classification and Labeling under the auspices of the OECD. For most of the work, the task force was chaired by the United Kingdom; the current chair is Finland. The Environmental Protection Agency Office of Prevention, Pesticides, and Toxic Substances took the lead in coordinating U.S. input into the work of the task force. Expert subgroups concentrated on particular hazards (e.g., carcinogenicity,

aquatic toxicity) and reported back to the overall task force. A special OECD expert group with expanded stakeholder participation was formed to address classification criteria for chemical mixtures, and was chaired by Canada.

- **Hazard communications elements of the GHS** were developed by the ILO Working Group for the Harmonization of Chemical Hazard Communication, chaired by Ireland. The lead U.S. agency was the Department of Labor Occupational Safety and Health Administration (OSHA).

The products of the three focal points were submitted to the IOMC Coordinating Group, chaired by the United States. The Coordinating Group directed the overall progress of the work and combined the individual components of the GHS into a single comprehensive document, including decision-making processes and other directions on application of the system. The Coordinating Group also resolved crosscutting issues, such as clarifications of the scope of the GHS in terms of human and veterinary drugs, food additives, and pesticide residues in food; the relationship between hazard and risk in the GHS and other chemical management strategies; and the structure and terms of reference for a permanent home for the GHS in the UN system. The Coordinating Group has completed its work and disbanded; the resulting comprehensive document is now pending approval at the UN.[9]

U.S. positions in the negotiations were developed through an interagency working group coordinated by the State Department and comprised of representatives from key regulatory and trade agencies. U.S. stakeholder involvement and outreach efforts included public meetings, notices in the *Federal Register*, and wide electronic circulation of working documents prepared for international meetings and U.S. delegation trip reports. Other participants also developed stakeholder involvement and interagency coordination processes to varying degrees, and European Union member states generally coordinated their participation in the discussions.

Final approval of the GHS as developed by the IOMC Coordinating Group, and the ongoing work of promoting, updating, and maintaining the GHS are the responsibility of the newly created UN Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals, which reports to the UN Economic and Social Council through the joint Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labeling of Chemicals.[10] The UN Institute of Training and Research, individual countries and experts, industry and others will also engage in efforts to promote adoption and implementation of the GHS.

WHAT HAS BEEN ACHIEVED

The core of the GHS document awaiting final international approval through the UN system[11] consists of harmonized classification criteria and

accompanying standardized symbol/pictograms, signal words ("danger," "warning"), and hazard statements ("fatal if swallowed," "may cause cancer," "may cause allergic or asthmatic symptoms or breathing difficulties if inhaled," "causes skin irritation," etc.) for each hazard class and category. Product identifiers and precautionary statements are also designated as required information if a label is to be considered consistent with the GHS, although these have not been standardized in the current document.

A technical background is not required to appreciate the difficulty and complexity of the issues GHS developers had to overcome to reach consensus on hazard communications elements and classification criteria that define the following wide range of chemical hazards. A simple listing of the hazards may suffice:

1. Health hazards

- acute toxicity, by oral, dermal, or inhalation routes of exposure
- skin irritation and corrosion
- eye irritation and serious eye damage
- skin and respiratory sensitization (allergic reactions)
- germ cell mutagenicity
- cancer
- reproductive and developmental effects, including lactation effects
- other target organ/systemic effects (e.g., kidney damage, liver damage, immunotoxicity, effects on the nervous system) resulting from single or repeated exposure

2. Environmental hazards

- hazardous to the aquatic environment

3. Physical hazards

- explosives
- flammable gases, liquids, solids, and aerosols and substances which emit flammable gases upon contact with water
- oxidizing gases, liquids and solids
- gases under pressure
- self-reactive substances
- self-heating substances
- pyrophoric liquids and solids
- organic peroxides
- metal corrosives

In addition to providing classification criteria and standardized hazard communication elements for specific hazard endpoints, the GHS addresses a range of

complex, cross-cutting issues in hazard classification and communication that will be important to its implementation on a practical level. It provides guidance on how to use existing human studies and experience, animal testing, and other scientific data and information to make "weight of the evidence" determinations to classify chemical hazards. It takes into account sensitive ethical issues related to the use of human data and animal testing. At the instigation of the U.S., which applies risk assessment in determining consumer product labeling, the GHS document describes how the elements of the GHS system might be applied in countries that use risk-based approaches to labeling chemicals for chronic effects in the consumer setting.

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In addition, the GHS includes information on the needs of key target audiences, comprehensibility issues in hazard communication, and establishes a standard format for safety data sheets (used primarily in the workplace). The system recognizes the appropriateness of supplemental, non-GHS information on labels to give more detailed hazards that are not part of the GHS, provided that the supplemental information does not detract from GHS labeling. The document also sets forth general principles for national authorities to consider in establishing policies for the protection of legitimate confidential business information while respecting worker and consumer right-to-know about the hazards of chemicals to which they may be exposed.

DISHARMONY IN THE HARMONIZED SYSTEM

While accurately describing impressive achievements in harmonization, the preceding paragraphs may leave readers with an overly incomplete and somewhat rosy picture of the development of GHS system and the degree of harmonization achieved in the document before it was submitted to the UN Committee for approval in December.

GHS framers faced many thorny issues. After thorough discussion that enabled a more complete understanding of divergent views and an identification of a way forward that would meet the essential needs of all negotiators, some concerns were resolved by clarification. In other cases, the GHS reflects compromises that acknowledge that disharmony may continue, at least for a time, until we gain more experience with the system and revisit the issue. In still other cases, GHS

negotiators recognized that disharmonies would likely persist due to factors outside the scope of GHS negotiations. The following paragraphs give some examples of issues in each of these categories and how they were resolved.

Resolved through clarification. At one point in the negotiation, concerns were raised about whether the GHS would result in unworkable and inappropriate labeling of consumer products, interfere in doctor-patient relationships, or require inappropriate labeling of foods that met the food safety standards of domestic regulatory agencies. These issues were discussed in great detail by the Coordinating Group. It was clear to most participants that the GHS should be focused on harmonizing hazard, not risk, labeling regimes, and on labeling chemicals, not foods. Clarification of the scope of the GHS largely resolved these concerns and allowed work to proceed.[12]

Resolved by compromise. Thorough discussion enabled the GHS negotiators to adopt a compromise solution to classification of chemical mixtures for chronic effects (carcinogenicity, mutagenicity, reproductive toxicity). In the European system, data on mixtures were irrelevant: mixtures were always classified based on the presence of classified ingredients at certain cut-off points. While the U.S. acknowledged that valid data on the mixture itself would not generally be available, U.S. negotiators could not rule out use of such data if they did exist. The compromise solution was to accept classification of mixtures based on their ingredients as the general rule, but allow for classification based on data on the mixture as a whole in exceptional circumstances, when sound scientific data were available. Chemicals could not "escape" classification if dilution in a mixture compromised the validity of testing with a limited number of animals, a major concern of many European (and American) scientists. At the same time, the GHS would acknowledge that data on the mixture as a whole could be used for classification purposes when scientifically justified, an important issue for industry and some other scientists.

Accepting disharmony in the short run. Perhaps the most striking area of disharmony accepted by GHS negotiators relates to cut-off points for labeling untested mixtures for chronic health effects. Based on a right-to-know philosophy in the workplace, in general, the U.S. and Canada had lower cut-offs for labeling. European negotiators had higher cut-offs and noted that accepting lower levels could trigger unwarranted downstream regulatory consequences that could not easily be de-coupled from classification. Since the stated goal of harmonization was classification for labeling and hazard communication purposes, the U.S. noted that downstream effects did not need to remain linked to GHS classification and refused to accept cut-offs that would decrease the hazard information currently available to chemical users in the U.S. The result was a compromise that acknowledged disharmony: some authorities would require labeling at one cut-off level, others would not require labeling until a higher cut-off was reached. The lower

cut-offs would be applied by all in terms of disclosing information on safety data sheets, used primarily by workers and employers. All agreed that the number of chemicals affected was expected to be small, and greater consistency would likely emerge over time. The information provided by existing U.S. and Canadian systems would not be compromised. Europe would have more time to consider decoupling downstream effects. In the meantime, as a practical matter, it seems likely that companies will label based on the lower cut-offs if they are seeking to simplify and harmonize labels worldwide. It is unlikely that European authorities will penalize them for "over-labeling" or providing more information than required on labels, but they should not suffer from the effects of downstream consequences that are currently tied to official classification and labeling in the European system.

Accepting disharmony due to factors beyond the scope of GHS. For many reasons, the GHS is a criteria-based system. There will be no international GHS authority to classify chemicals or establish lists. This is a frank acknowledgment of both practical realities and the state of the science today. For example, even when applying common classification criteria, scientists may reasonably differ on the interpretation of test results and their relevance to human health. It is beyond the scope of the GHS to deal with such issues until science progresses further and international consensus is achieved by other groups working in the field. It would also be unreasonable to expect any international group to keep an updated list of GHS-classified chemicals without significant delays in incorporating new scientific information by international consensus.

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LESSONS LEARNED AND APPLIED, AND CONSIDERATIONS FOR FUTURE

To date, the GHS is a success story in international harmonization. Continued success will require adherence to the approaches that have produced progress and avoidance of the kinds of polarizing influences that can so easily poison international negotiations. It requires continuing focus on interests, not positions, on what we want to achieve, not how we have always done things or how many votes we can get for "our system" versus "their system."

The GHS negotiation process has benefited from having technically qualified partners who share common goals of protecting public health and the environment, promoting regulatory consistency, and eliminating trade obstacles that do not contribute to gains in public health and environmental protection. These shared goals should enable us to maintain focus and deal better with other issues that sometimes befuddle regulatory and trade agencies.

While every negotiation is different, our GHS experiences to date suggest several guidelines for consideration by others who may engage in similar efforts in the future.

- Avoid mission creep, however worthy the additional goals may seem. What we were trying to do was difficult enough, and broadening the scope was more likely to result in paralysis than achievement. In terms of the GHS negotiation process, this meant that we should not allow ourselves to be diverted into attempts to harmonize intellectual property laws, risk assessment procedures or risk management measures for chemicals. While these are worthy efforts, other specialized groups are working on them.
- Take the time to clarify the scope of the undertaking, even when everything already seems clear enough to you and your negotiating partners, if it is disturbing to constituencies that fear they may be affected adversely. The GHS effort was always focused on harmonizing chemical hazard classification and labeling systems. While this was clear to those most directly involved in the negotiation, it needed further clarification after stakeholders expressed concerns that adoption of the GHS could lead to inappropriate labeling of foods, drugs, and even stainless steel pots and pans!

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- Work by consensus, and involve stakeholders in that consensus. Voting is always divisive, and if key countries are "voted down," it may mean that the measure adopted will be meaningless in terms of what actually happens on the world market. Accepting some disharmony to reach consensus is likely to lead to greater harmonization in the long run than forcing a vote to resolve an issue in a way that could lead major participants in the negotiation to refuse to accept the resulting "agreement."
- Start with voluntary agreements, especially in dealing with complex issues. It will give all countries a chance to gain experience and identify potential problems. It will also make it easier to reach consensus.
- Link public health and environmental protection goals with economic and/or trade advantages whenever possible. The connection is often very logical and appropriate, and the gains can be mutually reinforcing and sustaining. Such an approach will garner support from both health and environmental protection agencies and trade-oriented agencies, and appeal to stakeholders from many different perspectives. To the extent an

undertaking is viewed as benefiting both key government constituencies, the chances of success rise.

- Work in English on technical health and environmental issues, at least until basic understandings and agreements are reached. While this may be a controversial recommendation, it is worth noting that frequently when the issue of language is raised, our colleagues who do not speak English as their first language are the first to suggest that it should be the working language of our discussions. It is not reasonable to expect even the most skilled simultaneous interpretation services to understand and reflect subtle differences in terminology, or even, in the GHS context, the distinction between hazard and risk. Working in a single language not only saves significant amounts of time and money, but also facilitates common understanding of scientific and technical concepts.

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- Try to maintain consistency and continuity of representation in negotiations. Some personnel turnover is inevitable, but consistency in the participants in discussions allows them to build long-term relationships, trust, and shared confidence in the ability of the negotiating group to find mutually acceptable solutions. It also helps avoid delays due to the need to bring a constantly changing cast of characters up to speed on the issues.

CONCLUSION

The words of the document before the UN for final approval testify to the ambitious scope and purpose of the GHS. GHS negotiators have reached consensus on an initial package of harmonized chemical hazard classification and communication tools that, when implemented, the GHS framers anticipate will:

(a) Enhance the protection of human health and the environment by providing an internationally comprehensible system for hazard communication;
(b) Provide a recognized framework for those countries without an existing system;
(c) Reduce the need for testing and evaluation of chemicals;
(d) Facilitate international trade in chemicals whose hazards have been properly assessed and identified on an international basis.[13]

While implementation will pose many challenges, the lessons learned and applied in the development of the GHS should help keep efforts on track, and may also offer useful guidance to future negotiating efforts. ■

NOTES

1 International Labor Office, Global Estimates of Occupational Accidents and Work-Related Diseases, 2002, <http://www.ilo.org/safework>, (accessed December 10, 2002).

2 Environment Directorate, Organization for Economic Cooperation and Development, *OECD Environmental Outlook for the Chemicals Industry*, 2001, 10-11.

3 For example, World Health Organization (WHO) toxicity classifications and Food and Agriculture Organization (FAO) recommendations for pesticide labeling, the Organization for Economic Cooperation and Development (OECD) Chemicals Program, International Labor Organization (ILO) Chemical Safety Tools, UN Recommendations for the Transport of Dangerous Goods.

4 United Nations Conference on Environmental and Development, June 3-14, 1992, Rio de Janeiro, Brazil. Agenda 21: Program of Action for Sustainable Development, Chapter 19, Program Area B, paragraph 19.26.

5 Ibid, paragraph 19.27.

6 IOMC is comprised of the key international organizations with responsibilities related to chemicals management, including the WHO, FAO, ILO, UN Institute for Training and Research (UNITAR), UN Industrial Development Organization (UNIDO), the UN Environment Program (UNEP), and OECD.

7 See also IOMC, Coordinating Group for the Harmonization of Chemical Classification Systems, Revised Terms of Reference and Work Program, Document IOMC/HCW/95, January 14, 1996.

8 One example cited by a labor union participant in the GHS negotiation was that of a solvent/degreasing agent that could cause cancer or other serious acute or chronic health effects when absorbed through the skin. While a manufacturer may not be able to predict, and an employer may not intend, that workers will come into direct contact with the chemical, the practical reality is that they may use it to degrease their hands, if they are not alerted to the presence of the hazard.

9 With the exception of the OECD Task Force, which is continuing work on additional hazards and issues not resolved and included in the initial GHS document, all of the groups charged with developing the GHS have completed their work and disbanded.

10 Additional information on the composition and work of the Committee and Sub-Committees can be found at <http://www.unece.org/trans/danger/danger.htm>.

11 Current GHS documents are available at <http://www.unece.org/trans/main/dgdb/dgsubc4/c4age.html>.

12 IOMC, Coordinating Group for the Harmonization of Chemical Classification Systems, Description and Further Clarification of the Anticipated Application of the Globally Harmonized System (GHS), Document IOMC/CG12/98.2, July 6, 1998.

13 Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals, 2002, available at <http://www.unece.org/trans/danger/>.