

## APPENDIX 19

### PROGRESS ON THE IMPLEMENTATION OF GHS IN APEC ECONOMIES APEC CHEMICAL DIALOGUE VIRTUAL WORKING GROUP ON GHS SEPTEMBER 2011

#### BACKGROUND

At the 7<sup>th</sup> Chemical Dialogue (CD) meeting in Peru in 2008, the report of the Virtual Working Group on GHS titled *“Developing Clarity and Consistency in the Implementation of the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS)”* was endorsed. This recognized the progress made and difficulties faced by APEC CD Members in their work to implement GHS across the region, and with our trading partners.

The Virtual Working Group subsequently developed the GHS Implementation Reporting Template to be used for regular reporting of GHS implementation progress. Input is expected from both the regulatory authorities and industry in each of the APEC economies. Information from these reports is to be used to identify issues surrounding GHS implementation for each chemical industry sector (industrial workplace, consumer, agricultural chemical and transport).

Nine APEC CD Economies provided responses in 2008/09 using the GHS Implementation Reporting Template. Information compiled from the first round of responses was provided to the Trade Ministers highlighting the continuing progress made by the APEC region in implementing GHS, and the difficulties surrounding some aspects of implementation including continued revision of GHS at the UN level, lack of uniformity in implementation of GHS and limited access to data for classification purposes.

Participating Economies noted the positive outcomes by completing the Template, indicating that certain details of GHS implementation that were not being considered were brought to the fore, and potential issues arising from GHS implementation that would not otherwise have been considered until post-implementation were able to be discussed.

At the 8<sup>th</sup> CD meeting in Singapore in 2009, CD Members provided comments for the improvement of the GHS Implementation Progress Reporting Template. These comments were incorporated in the 2010 GHS Implementation Progress Reporting Template. APEC CD Members were encouraged to complete the 2010 GHS Implementation Progress Reporting Template in the hope that the information will help to identify and prioritize future work for the APEC CD and the Virtual Working Group to aid GHS implementation in the region.

The work of the United Nations Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCGHS) continues. At the December 2010 meeting of the UNSCGHS, the Committee considered a range of issues not yet addressed by the GHS.<sup>1</sup> The just released 4<sup>th</sup> edition of the UN GHS is a reminder that GHS is still a moving target. The lack of consistent GHS requirements worldwide manifests itself in adoption of different versions of GHS, which is published every 2 years. Some countries now adopt GHS 2<sup>nd</sup> version, some are adopting 3<sup>rd</sup> version already. This inevitably causes confusion and adds extra compliance costs to companies, especially those that supply chemicals to many countries. Trade partners need to work together to

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<sup>1</sup> Issues yet to be addressed by the GHS, include new test method for chemical instability of gases, simple asphyxiants and labelling of small packages; refinement of existing classification and communication elements for gases under pressure and for supply and use of aerosols.

implement harmonized or compatible versions of GHS, and consider methods to keep up to date with the GHS updates every biennium, to achieve the foreshadowed benefits of GHS.

More than one economy observed that as more countries adopt GHS, less time and cost will need to be dedicated to customize the labelling and safety data sheets according to the requirements of the importing country. However, the expected GHS benefit threshold will remain elusive until the major trading partners of the APEC economies, i.e. US and EU, fully adopt GHS.

### **PROGRESS REPORT**

Seven APEC CD Member Economies - Australia; Chile; Chinese Taipei; Hong Kong, China; Japan; Malaysia and Russia - have returned the 2010 GHS Implementation Progress Reporting Template to the Virtual Working Group on GHS. The American Chemistry Council (ACC) provided comments relevant to its industry sectors.

### **INDUSTRIAL WORKPLACE**

Sector appears to be the focal point for implementation of GHS, and the seven reporting economies have indicated Industrial Workplace sector as most likely to implement GHS first. In the case of Hong Kong, China; and Japan, Industrial Workplace is the only sector that will implement GHS.

For this sector, facilitation of international trade was identified as the main benefit from GHS implementation, with some economies also identifying improved workers' health. The main concern for this sector appears to be the discrepancies between economies implementation of GHS. While GHS allows certain choices within the constraints of GHS by the competent authorities, quite divergent versions of GHS are being implemented globally. This is due not only to making different choices on the details of GHS, but also to carrying over non-GHS elements from old legislation. This is a threat to achieving the identified benefit of international trade facilitation.

Industrial Workplace sector identified the following challenges for GHS implementation:

1. Lack of clear and practical information for regulatory compliance
2. Broad international implementation schedule
3. Differences in adoption of building blocks among economies and trading partners
4. Contradiction of GHS with other local chemical regulations resulting in longer time than expected for local implementation of GHS
5. Training and expertise: Lack of experts (toxicology, biology, physical properties) to classify chemicals per GHS; lack of experts who are competent to conduct GHS training or courses; level of commitment by industry in acquiring the necessary expertise in GHS; capability of local laboratories to conduct tests that may be needed to classify chemicals
6. Potentially high cost of implementation compared to expected benefits

Industrial Workplace sector made suggestions to address some GHS implementation issues:

1. Each economy to publish a clearly articulated GHS implementation plan
2. Allow lengthy and flexible transition timeframe. Example: Malaysia can accept both existing CLP and GHS-SDS versions concurrently until GHS fully implemented in Malaysia.
3. Adopt only GHS hazards, and refrain from adopting non-GHS hazard classifications
4. Conduct comparison of GHS classification lists from APAC economies (New Zealand, Japan, Chinese Taipei, Korea, China, et al) as well as trading partners (e.g., EU).
5. Provide standardized training and education campaigns for authorities and industry. .
6. Do cost analysis for GHS implementation by industry to be considered by authorities when adopting GHS elements, and in implementation timelines and transitions.

**CONSUMER:**

Most APEC economies have faced difficulties when considering GHS implementation for consumer products. Lack of international effort for harmonization has been identified as a key issue. A practical example is the difficulty to label packages (especially small containers) in multiple languages to simplify trade. Within the APEC economies, the definition of “small container” varies from 100 ml to 1000 ml.

Several APEC economies do not have comprehensive policies or regulations for consumer products. Other economies do not have regulations to distinguish between consumer and industrial chemical products. Even when consumer legislation exists, approach to GHS varies.

Australia has indicated that for consumer products, it will adopt certain elements of GHS, such as the GHS classification (but not all building blocks), and some labelling elements. However, Australia has also indicated that it would be preferable to work within its existing regulatory framework and adapt GHS to fit the framework.

Japan has indicated that adoption of GHS consumer products will be voluntary, relying on industry Code of Practice. The Japanese Government does not intend to implement GHS for consumer products as a mandatory requirement. A guidance document for GHS risk-based labelling has been prepared and is available on-line.

Russia indicated that there has been no decision yet, but the risk-based labelling approach in their current risk assessment framework has the capacity to incorporate elements of the GHS.

Unlike the Industrial Workplace sector, the consumer sector appears unable to clearly identify benefits from GHS implementation. This may explain the reported difficulties in formulating policies for GHS implementation for this sector. Another factor identified that may be impacting on the implementation of GHS for consumer products is the lack of participation by non-government organizations.

These divergent methods may however still deliver benefits for economies if some level of harmonization can be reached between close trading partners.

**AGRICULTURE:**

Similar to the Consumer Products sector, the GHS implementation for the Agricultural sector also appears uncertain. Economies indicated that a) they will not adopt GHS for the sector, b) the decision has not yet been made to implement GHS, or c) the decision has been taken but there are no details available on how and when the implementation will occur.

The implementation of GHS in the Agricultural sector appears to be awaiting the latest version of "FAO/WHO Guidelines on Good Labeling Practice for Pesticide" which are currently being updated by FAO/WHO to incorporate GHS elements. Malaysia noted that the amendment to their Pesticide (Labelling) Regulation under the Pesticides Act 1974 will be made based on recommendations of the latest version of FAO/WHO Guidelines.

**TRANSPORT:**

The Transport sector regulations in most economies appear to be based on the *United Nations Recommendation on the Transport of Dangerous Goods* (UNRTDG, or the “Orange Book”). There are some similarities between the pictograms used by the Orange Book and the Purple Book, although there are a number of important differences. The work at the UN level to improve harmonization of criteria and classification cut-off limits between the Orange Book and the UN GHS (the “Purple

Book”) will continue to improve the interface between transport regulations with GHS-based regulations in those economies that are planning to adopt GHS.

Australia, Chinese Taipei and Japan have transport sector regulations based on the UNRTDG. Russia indicated that their transport legislation is based on an older version of the UN “Orange Book.” This is true in several APEC economies so transport regulations must be updated as well as align with GHS.

Chile indicated that they currently use the Orange Book for the transport sector regulations, and that the Purple Book may be integrated into the transport regulations.

Hong Kong, China will base their requirements for transport classification and labelling on the IMDG Code, which is based on the Orange Book.

#### **RECOMMENDATIONS FOR FUTURE REPORTING**

The Virtual Working Group urges all APEC CD Members to complete and return the GHS Implementation progress template to the Virtual Working Group. Increased number of responding economies will aid in identification of common issues and potential future work by the APEC CD to benefit all APEC CD Economies.

The Virtual Working Group requests that where the APEC Economy has previously provided input and has no further comments to add, to contact the Virtual Working Group so that the information from 2008/09 report can be carried forward.

**APPENDIX 16 - ATTACHMENT****APPROACHES FOR CONSIDERATION BY APEC ECONOMIES IN APPLYING GHS PRINCIPLES  
TO CLASSIFICATION & LABELLING OF CONSUMER PRODUCTS****APEC Chemical Dialogue****Revised: May, 2011****Contents**

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## 1. Purpose

Numerous APEC economies are implementing the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)<sup>2</sup> or developing plans to implement the GHS, but the focus has largely been on GHS implementation for transport and workplace situations. As some APEC economies turn to expand implementation to other sectors, there is less experience within APEC related to implementation for consumer situations to draw upon. The purpose of this document is to respond to this regional need and provide for APEC economies an overview of those elements of the GHS critical to understanding application of the GHS principles to classification and labelling of consumer products.

Recognizing that APEC economies are in various states of implementation or development of plans for implementation of the GHS, this document was developed in the APEC Chemical Dialogue, with input from industry and government participants, as information for governments and others to consider as they move toward implementation of the GHS for consumer products. The Chemical Dialogue serves as a forum for regulatory officials and industry representatives to find solutions to challenges facing the chemical industry and users of chemicals in the Asia-Pacific region. An important role of the Chemical Dialogue is to encourage a harmonized approach in addressing those issues in order to limit trade barriers and encourage regulatory and business efficiency.

Users of this document are reminded that competent authorities in each APEC economy will decide how to apply the various elements of the GHS to consumer products within their jurisdiction, based on the needs of their economies and their target audiences. Therefore, it will be important for producers of consumer products to consult the relevant laws, regulations and policies that are in place in each economy before making final decisions on GHS classification and labelling of their products.

## 2. The specific needs of consumers

The primary objective of GHS is to enhance the protection of human health and the environment through harmonized classification and communication of hazard information for chemicals and mixtures and to facilitate international trade.

To achieve this goal, the information related to the characteristics of chemicals and mixtures, identified using an internationally agreed set of classification criteria, should be communicated in a form that is comprehensible and relevant to the target audiences, i.e. consumers, workers, transport workers and emergency responders. This is so that the target audiences in their local settings can take safety measures that are appropriate for the use situation.

Some characteristics of consumers relevant to the implementation of the GHS are listed below:

- Consumers usually do not have any systematic opportunity to learn how to interpret chemical hazard information in order to be able to determine on their own appropriate measures in emergencies and/or accidents involving chemicals and mixtures.
- Consumer education is more difficult and less efficient than education for other audiences.
- The label is likely to be the sole source of information readily available to the consumer, and consumers want clear, concise, easy-to-read information. Chemical users in the other

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<sup>2</sup> Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition (2009), [http://www.unece.org/trans/danger/publi/ghs/ghs\\_rev03/03files\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html)

sectors have more sources of information than the label, such as Safety Data Sheets and/or workplace training.

- It is reported that excessive hazard warnings on consumer product labels lead to a decrease in effectiveness of warnings that truly enhance protection (Viscusi, 1991; Frantz et al., 1999)

Given the unique circumstances around communication to consumers listed above, the implementation of the GHS for consumer products, including any guidance developed to support that purpose, must take into account:

- the accessibility and comprehensibility of product labels for consumers so that consumers can take appropriate safety measures in their use of consumer products, and
- international harmonisation.

### **3. Application of GHS Principles to consumer products**

#### **3.1 Consumer product labelling based on the likelihood of injury**

Both risk-based and hazard-based labelling approaches for consumer products are consistent with GHS. Labelling of consumer products based on the likelihood of injury (risk-based labelling) is included in the Annex 5 of the GHS official text. The GHS document, through Annex 5, recognizes that “some systems provide information about chronic health hazards in consumer products only after considering additional data regarding potential exposures to consumers under normal conditions of use or foreseeable misuse.” A competent authority may decide to allow risk-based labelling in certain circumstances. Under GHS, risk-based labelling can only be applied to chronic health hazards of chemicals in the consumer products setting. All acute health, environmental and physical hazards should be labelled on intrinsic hazards.

Several consumer research studies clearly demonstrate (summarized in the paper submitted by industry to the ILO Working Group for the Harmonization of Chemical Hazard Communication, ILO/HC6/00.13, 21 September 2000);

- More benefits can be expected if the labelling system is changed to be more consumer and consumer risk oriented (Dutch consumer institute, Venema et al., 1997).
- Consumers want clear, concise, easy-to-read information that connects consequences to actions (The US EPA Consumer Labelling Initiative, Abt Associates, Inc., 1999).

There have been reports to suggest that focusing on those specific and relevant hazards that are likely to cause injury to man or the environment as a result of consumer product handling or use when providing information on the label increases the effectiveness of communication and leads to enhanced consumer and environmental protection (ILO/HC6/00.13 21.09.2000).

Thus, some systems communicate appropriate and relevant information on the label based on the evaluation of both the intrinsic hazards of the product and possible exposure through use, including relevant human experience. In systems such as these, the likelihood of injury is used to determine the hazard information that is communicated to the consumer in a form that is accessible to the consumer; i.e. risk-based labelling.

Maintenance of existing or creation of new risk-based labelling systems for consumer products in APEC economies is therefore consistent with the intent of Annex 5 to recognize such systems under the GHS.

### **3.2 Focus on providing information that meets the differing information needs of users to ensure comprehensibility**

The GHS includes approaches to take into account the information needs of different target audiences. It is reported that cluttered, difficult to read labels, containing superfluous warnings that are outside the experience of consumers reduces the likelihood of consumers' understanding of and adherence to warranted labels (ILO/HC6/00.13 21.09.2000).

Competent authorities should focus on implementing GHS in a way that provides information on consumer product labels that meets the information needs of the consumer to ensure comprehensibility.

### **3.3 Application of the "Building Block Approach"**

GHS provides the flexibility to meet specific user needs through the Building Block Approach.

When considering building blocks for implementation for consumer products classification and labelling, competent authorities should take into account the needs of different target audiences, in this case consumers.

### **3.4 Classification based on existing data**

One of the central objectives of the GHS is to "reduce the need for testing and evaluation of chemicals."<sup>3</sup> It does not require additional testing of chemical substances or mixtures but is "based on currently available data." When data from scientifically robust, non-animal test approaches (e.g., human experience, bridging data, *in vitro* tests, SAR/QSAR, *in silico* approaches) are available, this information may be used for classification.

Competent authorities should implement GHS for consumer products in a manner that relies on existing data and makes no demands for new data. Further, with regard to classification based on existing data, all such data should be considered, including data from non-animal tests and approaches.

### **3.5 Self-Classification**

For many industries and government organizations implementing the GHS, the process of implementation will be resource-intensive and create requirements for evaluating information on chemicals in ways not previously established. As economies consider approaches for facilitating implementation of the GHS, they should remain committed to maintaining the fundamental principle of self-classification articulated in the GHS: "The GHS is designed to permit self-classification."<sup>4</sup>

As economies move forward with GHS implementation, the objective of self-classification stated in the GHS framework should be maintained for consumer products.

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<sup>3</sup> Section 1.1.1.4 [The sections given in the footnotes identify where the quoted information appears in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition (2009).]

<sup>4</sup> Section 1.1.4.1



### 3.6 Precedence of human experience over other information

Precedence of human experience over other information is a key concept within GHS. “Generally, data of good quality and reliability in humans will have precedence over other data.”<sup>5</sup>

“However, even well-designed and conducted epidemiological studies may lack sufficient numbers of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness and quality of both the human and animal data relative to the expected frequency of occurrence of effects and the impact of potentially confounding factors.”<sup>6</sup>

Existing human experience information should be considered in determining appropriate labelling for consumer products.

### 3.7 Use of a weight-of-evidence approach in classification decision

It is important to consider the weight and quality of the evidence used in a classification decision, taking into account the reliability and consistency of data of all available information. This is one of the key classification principles within GHS.

“For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a substance or a mixture is made on the basis of the total weight of evidence. This means that all available information bearing on the determination of toxicity is considered together, including the results of valid *in vitro* tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.”<sup>7</sup>

### 3.8 Protection of Confidential Business Information

“The competent authority should protect the confidentiality of the information in accordance with applicable law and practice.”<sup>8</sup>

Competent authorities should ensure that Confidential Business Information related to consumer products is not compromised in implementing GHS.

## 4. Summary

In discussing consumer product labelling based on the likelihood of injury, Annex 5 states that “the work on the GHS has not addressed harmonization of this type of approach. Therefore, specific procedures to apply this approach would have to be developed and applied by the competent authority.”<sup>9</sup>

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<sup>5</sup> Section 1.3.2.4.9.3

<sup>6</sup> Section 1.3.2.4.9.3

<sup>7</sup> Section 1.3.2.4.9.1

<sup>8</sup> Section 1.4.8.3(c)

<sup>9</sup> Section A5.1.2

In an attempt to provide the starting point for the discussion of this harmonized approach to the implementation of GHS for the consumer products sector, this document has drawn out the key principles of GHS while being mindful of the needs of the target audience, the general public.

While international harmonization is encouraged, it is imperative that the competent authorities be mindful of the needs and understanding of the consumer when implementing GHS for consumer products in each economy.

The key principles for GHS implementation for consumer products discussed in this paper are summarized as below:

- All chemicals and mixtures within the scope of the GHS should be classified based on GHS classification criteria
- Labels should focus on providing information that meets the information needs of the consumer to ensure comprehensibility
- When considering building blocks for implementation for consumer products, competent authorities should take into account the needs and understanding of the general public
- Competent authorities should strive to implement GHS for consumer products in a manner that minimizes animal testing, and investigate the acceptance of non-animal tests
- The fundamental principle of self-classification articulated in the GHS official document should be upheld for consumer products
- Competent authorities should provide the framework for the evaluation of both the intrinsic hazards of the product and possible exposure through use where:
  - Human experience generally takes precedence over other information
  - Weight of evidence approach is used
- Competent authorities should ensure that confidential business information is not compromised in implementing GHS for consumer products.

## References

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