

10th Meeting of the Chemical Dialogue
September 13, 2011
San Francisco, United States

EXPLANATORY NOTES AND SUMMARY OF ACTION ITEMS

Representatives from government and/or industry of Australia, Canada (industry), China, Indonesia, Japan, Korea, Mexico, Malaysia, Russia, Singapore (industry), Chinese Taipei, Thailand, and the United States participated in the 10th Chemical Dialogue (CD10). The following are summary action items and deadlines agreed at CD10. A full report will be prepared for intersessional review by September 30. The briefing by the CTI Chair also is included as an attachment to this note for ease of reference in project preparation. In that regard, Ministers' instructions from the MRT in Big Sky Montana in May 2011 are of significance. *"We welcome the continued active commitment to regulatory cooperation for chemicals through a strategic framework that contributes to regional economic integration and regulatory convergence priorities, including progressing, the Globally Harmonized System of Classification and Labeling of Chemicals."* The results of the CD10 meeting showed that the Dialogue has a robust work program that aligns closely with the three APEC 2011 priorities of regional economic integration, green growth and regulatory cooperation and convergence.

ACTION ITEMS AND BRIEF DESCRIPTION

The Strategic Framework 2011/SOM3/CD/014 and 2011/SOM3/CD/018

The Strategic Framework was updated to include actions for the period 2011-2013 and endorsed by Ministers at their meeting in May 2011 in Big Sky, Montana. As an evergreen document, the Strategic Framework needs to be updated to reflect the status of project implementation under the 3 shared goals and to include agreed new projects. While this is a collective responsibility, the APCIC Secretariat and ACCORD will take responsibility for updating the document for review at CDSG1 in 2012. ACCORD will provide a first draft to the APCIC Secretariat by October 14, 2011.

Shared Goal 1: Expand and support cooperation and mutual recognition among chemical regulators in the region to facilitate trade

GHS Implementation

GHS Implementation and consumer products (2011/SOM3/CD/010)

The report of the Consumer Products, which included the principles document "Approaches for Consideration by APEC economies in Applying GHS Principles to the Classification and Labeling of Consumer Products", was endorsed by the CD for submission to the CTI and SOM and transmission to Ministers. In endorsing the document, CD10 noted that "in referring to the principles document, competent authorities should be aware of situations where consumer goods may have more than one use". Next steps include the establishment of a Virtual Working Group (VWG) Co-chaired by Australia and New Zealand for work going forward on the development of case studies of different approaches taken by APEC economies in implementing, or in consideration of implementing GHS for consumer products. The principles document may be revised in the future to reflect learnings from those case studies. CD members interested in participating in the VWG should send their expression of interest to the Program Director by September 30.

GHS Implementation – Report from Virtual Working Group (2011/SOM3/CD/003)

The GHS implementation status report to Ministers was endorsed pending additional updates by member economies. Economies are requested to submit updates to the Program Director by September 26 to allow time for intersessional approvals by the CTI and SOM. Updates submitted after September 26 will be included in the 2012 status report. Consideration will be given to reviewing the template format so that the report and attachments can be posted on the G.R.E.A.T. website in a user friendly format. Chinese Taipei and the Virtual Working Group will work on this project and report at CDSG1 in 2012. CD10 also agreed to integrate the status report into the project on alignment of the Strategic Framework with SAICM core objectives with a view to including in a possible APEC

submission to ICCM3 in 2012. Economies also are urged to submit progress reports on SAICM implementation.

Status of G.R.E.A.T. Project (2011/SOM3/CD/009)

The G.R.E.A.T. portal is being well used. More than 18,000 visits have been made since its launch in 2010. 23 additional EU languages have been added. The site now offers GHS elements in 32 languages from 9 economies and the EU (Thailand, Chinese Taipei, Australia, Chile, Japan, Korea, Malaysia, the Philippines, and the Russian Federation). Updates recently were received from China, Indonesia and Mexico. Regulators and industry representatives in member economies are encouraged to provide additional GHS labeling elements and implementation update/timelines through their GHS focal points.

Discussion with the SCCP on GHS Implementation and Single Window System

The SCCP Chair was invited to brief the CD on the status of APEC work on the single window, with a view to assessing prospects for the inclusion of GHS elements on an economy's single window portal. The SCCP Chair was unable to attend. The CD government Co-Chair noted that the SCCP convenor's report to CTI indicated that work on the single window is being done under chokepoint 4 of the APEC supply chain connectivity framework. The goal is to improve the efficiency of clearance of goods at the border, especially regulated goods. Japan is the lead economy. Japan and Chinese Taipei are coordinating work going forward. Current focus is on interoperability. There will be a regional workshop funded by APEC in Chinese Taipei in October.

CD10 agreed to encourage economies to provide information on their own single window efforts intersessionally with a view to having a broader discussion at CDSG1, 2012. The SCCP Chair will be invited to present at that meeting.

REACH and other regulatory systems

EU and SVHC Thresholds/ REACH Article XIII Revisions

SVHC – 2011/SOM3/CD/005. There remain inconsistencies in the implementation of thresholds for Substances of Very High Concern (SVHC). France announced in its official gazette in June that if an article comprises one or more objects, Articles 7.2 and 33 of REACH would apply to each of them. The Commission intends to send a letter to France, which could form the basis of an infringement.

Annex XIII issues – 2011/SOM3/CD/015. There are questions over how the new amendment published in the March 2011 Official Journal will be applied. All available information will be based on "weight of evidence" using expert judgment. It is unclear how the Commission intends to apply the weight of evidence approach. For example, in examining the strength and weaknesses of certain data, it is not clear if that data still needs to comport with numeric criteria, leading to concerns that more products could be classified as persistent/ bio-accumulative.

In light of potential market effects, the CD agreed to draft with urgency a letter to ECHA on SVHC and on how the Commission intends to apply the weight of evidence approach, among other things asking for clarification of whether or not the Commission will follow criteria laid out in the annex with the weight of evidence, in looking at the quality and strength of data. Industry will provide a first draft by September 30.

The CD also agreed to invite a representative of ECHA to participate in the CDSG1 meeting in Russia in 2012. A letter of invitation will be drafted by the Government Co-Chair for review by the CD and transmission to ECHA by mid-October.

Chemicals in Articles (2011/SOM3/CD/013 and 2011/SOM3/CD/007)

The CD agreed to take forward the idea of an information sharing workshop in 2012. The Virtual Working Group will discuss whether to hold the workshop separately or include it as part of the 2012 Regulators Forum agenda. One issue would be how to ensure the best participation at the workshop. The VWG will consider whether supporting developing economy travel to the workshop would be

helpful, and if so, then the VWG would begin preparation of a draft concept note by December 2011 for submission to the expected January 2012 first budget cycle. The concept note should include identification of the audience (e.g. regulators); type of forum; where it would take place; how it would fit in with the regulators forum, and, the expected contribution to SAICM. The Program Director will work with the Virtual Working Group Chair on time-lines, how to craft a two part project (chemicals in articles workshop and regulators forum and training workshop). Economies interested in participating in the development of the concept note should send in names to the Program Director and Government Co-Chair by September 30.

The CD Government Co-Chair will discuss with the SCSC Chair plans for the SCSC Trade Facilitation Task Force (TFTF) dialogues in 2012. There is a prospect of a possible morning session on Chemicals in Articles if that would be of interest to the CD.

Regulators Forum and Workshop (2011/SOM3/CD/020, 2011/SOM3/CD/006,2011/SOM3/CD/021)

The CD affirmed the importance of the regulators forum and associated workshop(s) and agreed that bundling various regulatory projects is an efficient way of proceeding. A multi-party teleconference of relevant CD VWGs will be held. The CD further agreed to seek funding for a regulators forum and risk assessment workshop in 2012. The United States will circulate an email by September 23 soliciting topics for the regulators forum, feedback on the draft concept note for the risk assessment training workshop and propose dates/times for the multi-party VWG call.

Voluntary Industry Programs

The industry's commitment to sustainability through the Responsible Care™ program and its subset the Global Product Strategy, which focus on product stewardship, is being updated with a view to helping the associations around the world that are implementing Responsible Care™ do so in a way that is timely and effective. Work will be done principally in the APEC region and in India. ACC also is undergoing a strategic review of ACC Responsible Care™ program, looking at potential new metrics for measuring sustainability. The results will be shared with the CD.

Capacity building is underway in all regions, helping SMEs to prioritize chemicals for conducting safety assessments under the global product strategy and helping to share information throughout the value chain. A "GPS for dummies" guidance document is available on the ICCA website - http://www.icca-chem.org/ICCADocs/ICCA_GPS%20July2011_LowResWEB.pdf

Malaysia agreed to circulate to the CD via the Program Director the proceedings of the upcoming IchemE Hazards Symposium in Kuala Lumpur September 27-29. Conference information can be found on: <http://www.icheme.org/events/conferences/hazards%20asia%20pacific/programme.aspx>
Transparency and Innovation (2011/SOM3/CD/019)

Given the tensions that are emerging between the need to protect confidential business information and provide transparency to stakeholders, CD10 agreed to form a VWG to elaborate on Transparency and Innovation, and develop a short paper that includes how CBI is being dealt with in member economies and; how they provide for transparency. Australia, the United States and JCIA volunteered to be on the VWG. Others interested should send their contacts to the Program Director. USCIB will provide the first draft by October 14. The discussion paper would be reviewed at CDSG 1 in 2012.

Shared Goal 2: Enhance understanding of the chemical industry's role as an innovative solutions industry (2011/SOM3/CD/022)

In preparation for Rio+20, the CD will gather examples of innovative regulatory programs or technologies/business models that involve chemistry to help promote sustainable growth. Canada provided examples of work being done by contractors on oil sands projects on a for profit basis to use chemistry to generate useful water reduction savings, regenerate settling ponds, and deal with sulfa emissions. Industry will gather information. All economies are requested to submit examples by November 30. Examples should include a brief paragraph describing the program/technology/business model and how it contributes to sustainable growth. Consideration will be given by the CD at CDSG1 in 2012 to attaching the examples to a contribution to Rio+20.

Shared Goal 3: Encourage chemical product stewardship, safe use and sustainability

CD / SAICM Alignment (2011/SOM3/CD/008)

CD10 agreed to move forward with the alignment of CD's work with SAICM's core objectives risk reduction, knowledge and information, governance, capacity building and technical cooperation and illegal international traffic as an APEC contribution to ICCM3 in 2012. The document reviewed by CD10 will be expanded to start the process of assessing work under the Strategic Framework against the SAICM core objectives. CD10 agreed that feedback on the paper 2011/SOM3/CD/008 should be provided by September 30 and that the mandate of the VWG would be extended to turn the document into a submission to ICCM3. The submission would be reviewed at CDSG1 in 2012.

Emergency Response (2011/SOM3/CD/004)

ACC has offered to build and host a website that would provide industry first responders with resource information in APEC economies for addressing chemical incidents. Resource information would include contact points, visa and other requirements for getting critical equipment across borders, available resources and deployment capabilities. Canada suggested that weather and time zone information also would be useful. The site is intended to be operating by January 2012. CD10 agreed to support this project. Members are requested to forward information to the Program Director on contact points, emergency response organizations in their economy, studies and white papers that would be useful in developing response and preparedness plans and where there are level 3 response capabilities.

ACC will send out a message to the CD with the information request by September 30. Responses are requested by October 21.

Consideration will be given to informing the Senior Disaster Management Group in APEC of this work.

CD and UN CSD/Rio+20 Conference

It was agreed at CDSG SOM1 to form a Virtual Working Group (VWG) to consider developing a new project that would show the importance of chemistry to the green economy and how to facilitate new technologies. The group was unable to find useful case studies of barriers to the deployment of innovative solutions. Instead, CD10 agreed to share information on what economies might be submitting in the chemicals sector in the context of the November 1 deadline for submission of comments to the Rio+20 process, including views on the EU paper on an overarching framework. The "zero" draft of the Rio document is expected in January 2012, with text emerging in May 2012. Chemicals could feature in either of the two main themes: the green economy in the context of poverty reduction and institutional processes. The EU paper includes a section on chemicals calling for a more robust chemicals management regime such as a framework convention, which would be a significant departure from existing environmental governance of environmental waste.

The CD has a potential contribution in the examples collected of progress over the last 20 years in using chemistry as a sustainable solution and in the context of the strategic framework. ICCA will submit a paper on the importance of chemistry in promoting innovation and sustainable development.

CD10 agreed that it would be helpful also if economies shared their November 1 submissions or comments and economies are encouraged to forward these to the Program Director for distribution to members of the CD as they are completed. CD10 also agreed to investigate side events to the June 4-6, 2012 Rio+20 summit that could be of interest to members. A list will be forwarded to the Program Director for circulation as these are developed.

New project proposals (2011/SOM3/CD/016)

The Russian Federation described a new project proposal to develop a portal that would allow searches across multiple databases to inform how chemicals are classified in terms of hazards. Currently, differences or discrepancies in data result in different classifications for the same chemicals in different economies, which can constitute a barrier to trade. There is a need for information exchange on the safe handling of chemicals. Consistency in the implementation of GHS requires agreement on key concepts and terms for the classification of a chemical as hazardous. The objective

of the project is to consolidate content to avoid discrepancies in data and create a global information backbone for hazardous properties. The portal would take account of the OECD eChem portal in its development and perhaps create a model to correct discrepancies. It was noted that the issue of data discrepancies and classification problems had been raised in the 2006 GHS expert workshop. As APEC economies were moving to GHS implementation, it would be important to address the issue in a timely manner. The workshop would help define the parameters of the portal and search criteria.

CD10 agreed to support the workshop to further explore aspects and details of the project proposal. A project concept note will be developed by a small group for consideration at CDSG1, 2012. The United States volunteered to work with the Russian Federation on the concept note. Singapore and Japan will consult in capitals and revert to the Program Director as to their involvement in the small group

CTI Chair's Report

The CTI Chair observed that the work of CD is outstanding, and that it is regarded as one of the best groups. She explained progress with the APEC 2011 priorities as follows.

1. Strengthening regional economic integration and expanding trade. The CTI is examining what FTAs of this century should contain. The MRT endorsed three areas: and work began in Singapore in mid-August on the content. The areas are:
 - a. Facilitating global supply chains – customs procedures and electronic commerce
 - b. Enhancing participation of SMEs in global production chains – looking to foster participation of SMEs in international trade in an indirect way as supporting industries by helping them to integrate into global production chains within their economies.
 - c. Promoting effective and non discriminatory, market driven policies related to innovation

Content development will be approached holistically. In terms of supply chain and next generation issues, there will be three trade policy dialogues in San Francisco:

- A workshop on performance measurement in supply chain
- Submarine cable protection
- Advanced rulings – particularly on valuation – establish de minimis value on imports -- \$2000

SME barriers to integration into supply chains are being examined. Nine barriers were identified, work is proceeding on five of these in the CTI. The SMEWG will cover the other four. CTI work will be on high transportation costs; customs clearance delays; intellectual property rights; electronic commerce; and, difficulties that SMEs face to take advantage of FTA preferential rates. The SMEWG will cover: lack of access to financing; foreign business opportunities; corruption; and, navigating regulatory and technical requirements

2. A green growth proposal under consideration is centered on reducing tariffs on environmental goods to no more than 5% and eliminating inconsistencies in requirements by 2012. The MAG is working on a pathfinder on ways of facilitating re-manufactured products as a contributor to green growth. The Auto Dialogue is working on streamlining import procedures for alternative fuel demonstration vehicles.
3. The contribution of the CD is considered really important on regulatory issues. The work is recognized as outstanding. The CD is encouraged to work on drafting the right messages to convey the work that is being done, including to Ministers. She noted that the CD already had significant Ministerial attention since its first meeting in 2002.

In the area of advancing regulatory convergence and cooperation, work is proceeding on Good Regulatory Practices involving internal coordination of rule making, impact assessments, and public consultations. The CTI is developing recommendations to promote standards and conformance and ensure that new regulations do not constitute barriers to trade. The public-private component of the CD gives strength to the overall work on regulatory convergence and cooperation.

Report of the Consumer Products Working Group

Background

At the 7th APEC Chemical Dialogue (CD) in Peru, the Consumer Products Working Group (CPWG) was formed as a sub-group of the APEC CD in recognition of the challenges faced by those APEC CD Economies contemplating GHS implementation for the consumer products sector.

The aim of the Consumer Products Working Group was to distil the information in GHS that is relevant for consumer products and to share this with the APEC CD Member Economies, particularly those Economies contemplating GHS implementation for the Consumer Products sector. The United Nations document *Globally Harmonized System of Classification and Labelling of Chemicals* (GHS) contains a small section on consumer products with the main focus of the GHS is on hazard communication for workplace chemicals.

At the 9th APEC CD held in Sendai Japan, the CPWG reviewed the background to the Draft Discussion Document *Approaches for Consideration by APEC Economies in Applying GHS Principles to Classification & Labelling of Consumer Products*. It was observed that concerns had been raised over previous versions of this tool that had been submitted to the CD. The terminology "guidance" was no longer used as that could imply regulation and the document had been revised to illustrate its non-binding nature. The Consumer Products Working Group commended the document under discussion to the CD for finalization.

The APCIC observed that at the industry pre-meeting there was consensus on commending the document to the CD for review and approval. The Government Co-Chair noted that not all CD government were in the room and suggested that the CD welcome the document in-principle as a tool for industry pending indication from the government representatives that they were comfortable with the approach as outlined in the document. Japan indicated that it supported the document as did Australia. A Thai industry representative urged the CD to move forward and finalize the document as industry needed this tool because GHS implementation had begun.

The Government Co-Chair suggested that as the document in various forms had been in front of the CD for almost a year, the CD should welcome the document in-principle pending review by governments that they were comfortable with this approach. The Government members of the CD were requested to respond by 13 October 2010 with confirmation of the approach.

The CPWG received several responses from the APEC CD Economies by 13 October 2010. Most of these responses were in support of the document with one Economy, Canada, requesting an amendment to the document. The request was to include a quote from the UN GHS text (or the Purple Book) in the CPWG Discussion document.

The Washington CDSG meeting of 2 March 2011 made a recommendation on moving forward to finalise the paper on *Approaches for Consideration by APEC Economies in Applying GHS Principles to Classification & Labelling of Consumer Products*. It was agreed that the document would be revised by Accord to take Canada's comments into consideration, and some minor technical corrections provided by the United States. It was noted that as CD9 had agreed to the document in-principle subject to government sign off, the revised document was to be circulated intersessionally for finalization and submitted to Trade Ministers in May. (2011/SOM1/CDSG/014). The document was circulated for intersessional agreement on 7 June 2011.

The document has now been finalised and is ready to be submitted to Ministers and Leaders. The final document is attached.

Issues

The CPWG Discussion Document is intended as a basis for dialogue between the APEC Economies on the implementation of GHS for the consumer products sector. It does not stipulate any mandatory

requirements, nor does it suggest a single method of implementation. APEC Economies are encouraged to explore options for the implementation of GHS for the consumer products sector, and consider GHS implementation that will provide maximum benefit for their Economy, and the APEC region as a whole.

It is the intent of the CPWG to compile case studies of different approaches taken by APEC Economies in implementing, or in consideration of implementing GHS for the consumer products sector. We believe that lessons can be learnt through implementation and that these can be shared by Member Economies as a learning experience. We hope that this will aid the APEC Economies in their consideration of GHS implementation for this sector. Now that the CD Discussion Document is finalised, the CPWG will start the work of developing a number of case studies on implementation of GHS for consumer products as illustrative examples on how Member Economies have gone about implementing GHS for consumer goods for their particular economy. The Discussion Document may need to be revised in light of Member Economies experiences with implementation of the GHS over time.

The CPWG would like to thank the assistance of the CD in the development of this document and for the support it has received in its work.

Recommendations

That the CD 10

1. Notes the above report
2. Notes the finalisation of the Discussion Document and agrees that it be submitted to Trade Ministers and Leaders
3. Supports the ongoing work of the CPWG to develop case studies on implementation of the GHS for the consumer products sector; and
4. Agrees to review the functionality of the Discussion Document at a future date as the implementation of GHS progresses in APEC CD Economies.

Approaches for Consideration by APEC Economies in Applying GHS Principles to Classification & Labelling of Consumer Products

APEC Chemical Dialogue

Revised: May, 2011

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1. Purpose

Numerous APEC economies are implementing the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)¹ 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 sectors have more sources of information than the label, such as Safety Data Sheets and/or workplace training.

¹ 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

- 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.”² 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.”³

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

3.6 Precedence of human experience over other information

² 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).]

³ Section 1.1.4.1

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.”⁴

“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.”⁵

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.”⁶

3.8 Protection of Confidential Business Information

“The competent authority should protect the confidentiality of the information in accordance with applicable law and practice.”⁷

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.”⁸

⁴ Section 1.3.2.4.9.3

⁵ Section 1.3.2.4.9.3

⁶ Section 1.3.2.4.9.1

⁷ Section 1.4.8.3(c)

⁸ 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.

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