

APEC CD GHS Implementation Convergence Questionnaire 2019

Progress Report

Table of Contents

Background	1
Introduction	2
Response summary	3
Respondent details	3
General Information	3
Economies adopt later editions of GHS	4
Economies adopt common building blocks to facilitate trade	5
Category 1 or Categories 1A and 1B?	5
Mixture cut-off of $\geq 0.1\%$ or $\geq 1.0\%$ (or $\geq 0.1\%$ or $\geq 0.2\%$)?	6
Regulators work with each other to find possible ways to deliver a convergent implementation of GHS	6
Conclusion	8
Economies adopt later revisions of GHS	8
Economies adopt common building blocks to facilitate trade	8
Regulators work with each other to find possible ways to deliver a convergent implementation of GHS	9
Recommendations	10

Background

Since the 7th CD meeting in Peru in 2008 where the report of the Virtual Working Group on GHS (VWGGHS), “*Developing Clarity and Consistency in the Implementation of the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*” was endorsed, the participating APEC Economies provided GHS implementation Reports detailing the progress of GHS implementation in their respective Economies on an annual or biennial basis.

Over the past decade, these reports identified that foreshadowed trade benefits from GHS implementation were not fully realized due to divergent implementation of GHS across the regions. The divergences in GHS implementation include:

- Adoption of different revisions of GHS,
- Adoption of different building blocks,
- Adoption of different classification cut-offs for building blocks, and
- Imposition of specific local requirements.

At the 21st Chemical Dialogue (CD) meeting in Papua New Guinea in 2018, the CD agreed to a new reporting mechanism on GHS implementation, focused on identifying strategies to improve GHS convergence by Member Economies, noting that the GHS Implementation Report template developed in 2008 was not intended to tease out the reasons behind the divergence, and therefore not an ideal tool for the task. The CD also supported trialing the new reporting form, the GHS Implementation Questionnaire (the Questionnaire), out of session, with a view to providing a new report to the Ministers Responsible for Trade (MRT) in 2019 (APEC CD 21 Agenda Item 3.c.ii).

The Questionnaire, in the form of a SurveyMonkey survey (https://www.surveymonkey.com/r/APEC_CD_GHS_Convergence) was circulated at the 22nd CD meeting in Santiago. The pdf file of the survey was also circulated at the same time and is provided with this report as Attachment 1. The CD encouraged delegates to respond to the Questionnaire by March 15, 2019 to facilitate development of the annual report by April 11, 2019.

This Report summarises the CD delegates’ input into the Questionnaire.

Introduction

The Questionnaire is focused on identifying any information that may assist in convergent implementation of GHS across the region.

The Questionnaire is structured in five sections and aims to reflect the recommendations in the 20th APEC CD report endorsed by Ministers regarding addressing GHS implementation divergence¹. The five sections are:

1. Respondent details
2. General Information
3. Economies adopt later editions of GHS
4. Economies adopt common building blocks to facilitate trade
5. Regulators work with each other to find possible ways to deliver a convergent implementation of GHS

It is noted that no questions in relation to the second dot point of the 20th APEC CD report recommendations (see footnote 1) were included in the Questionnaire as the issue is already clearly identified and actionable by individual Economies.

All responses to the Questionnaire are attached to this report as Attachment 2. The contact details of the respondents (in section 1) have been redacted as they were only requested for follow up if and as required. Following information have not been redacted to ensure transparency of responses:

- Economy,
- Whether responding as Regulator, industry or “other”, and
- Name of Organisation/Agency.

In addition to the Economies' input into the Questionnaire, this report draws on the Economies input into the GHSVWG GHS Implementation Rationale Questions. The summary of responses to the GHSVWG GHS Implementation Rationale Questions is provided with this report as Attachment 3.

¹ 3 *To address divergences in GHS, the CD recommends that:*

- *APEC CD regulators work with each other to find possible ways to deliver a convergent implementation of GHS over time.*
- *Each APEC CD economy considers and amends elements of its own local rules for GHS implementation that may impede convergent implementation of GHS within the APEC region.*
- *Economies adopt common building blocks to facilitate trade.*
- *Economies adopt later editions of GHS.*

Response summary

Respondent details

Total responses received: 15

Total number of responding APEC Economies: 11

Respondent economies:

- Australia,
- Canada,
- Malaysia,
- Mexico,
- The Republic of the Philippines,
- The Russian Federation,
- Singapore,
- Chinese Taipei,
- Thailand,
- United States of America, and
- Viet Nam.

Responses from regulators: 9 (from seven Economies)²

Responses received from industry: 7

Additionally, six Economies provided responded for the GHS Implementation Rationale Questions. They are:

- Australia
- China
- Japan
- Chinese Taipei
- The Russian Federation
- United States of America

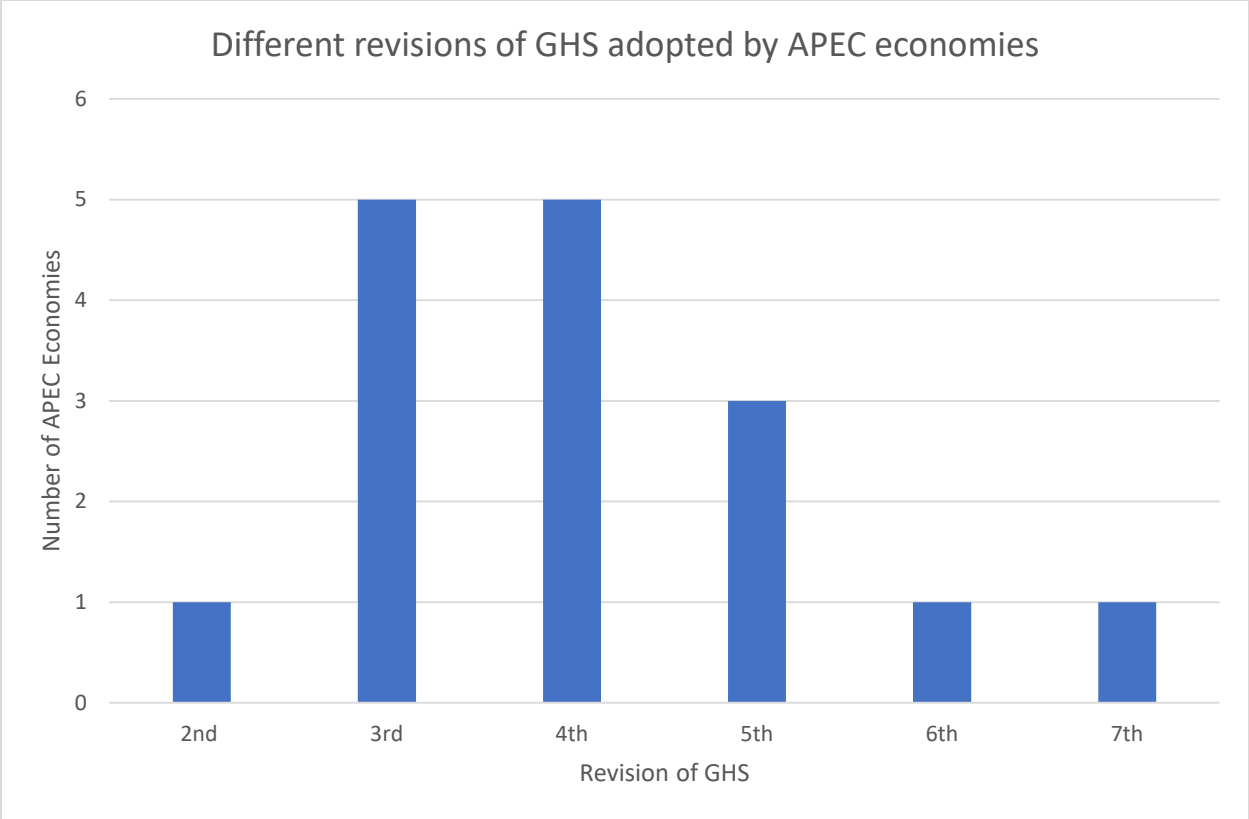
General Information

All respondents (13 Economies, including China and Japan through the GHS Implementation Rationale Questions) confirmed that GHS was implemented in their Economy.

The 3rd and 4th revisions of GHS were the most common GHS revisions adopted by the reporting Economies. One economy (Viet Nam) reported that the 2nd through to the 7th revisions of GHS were implemented. This information was included in Graph 1 and explains the seemingly larger total number of Economies shown in the graph than stated 11 reporting Economies.

Graph 1

² The Republic of the Philippines and Singapore provided a joint regulator and industry response and is counted as both regulator response and industry response. Chinese Taipei identified as neither regulator or industry (identified as the GHS focal point) and was not counted as either regulator or industry.



Five Economies (Mexico, Singapore, Chinese Taipei, Thailand, and The Republic of Philippines) responded that they accept later revisions of GHS than the implemented revision. Canada noted that they accept anything that meets or exceeds, and does not contravene their legislation. United States of America stated that they accept precautionary statements from later revisions of GHS.

Economies adopt later editions of GHS

Six Economies responded that they have plans to move to the 7th revision of GHS, with three Economies identifying 2020 as the likely adoption year, two Economies identifying 2021 and one Economy did not identify a year. No other revisions were identified for potential future adoption.

Of the remaining five Economies, two Economies did not provide a response and three were unsure whether the adoption of a later revision was likely within the next five years.

While some Economies identified formal mechanisms to trigger the adoption of later revisions of GHS such as legislated 5 yearly reviews, some Economies appeared to have less formal mechanisms, such as established GHS focal points that can review the need for update, while other Economies noted that the review would have to be “manually” triggered, usually by the regulator.

The review trigger mechanisms that were identified by the Economies are listed below:

- Legislated 5 yearly reviews,

- Established GHS task force of regulator, industry and training organisations to assess the need for the adoption of a new revision on an on-going basis,
- Review with every second revision of GHS (it is unclear whether this is a legislated or less formal administrative practice), and
- “manual” trigger by the regulator.

One Economy identified that later revisions of GHS than that formally adopted by the Economy were already recognized.

Some Economies also identified that a full law making/update process would need to be followed to update to the newer revision of GHS, including cost/benefit analysis, regulation impact analysis and public consultations.

Economies adopt common building blocks to facilitate trade

At the 2017 SOM3 Chemical Dialogue meeting in Ho Chi Minh City, the VWG-GHS shared a document comparing the implementation of GHS amongst APEC Economies, *Comparison of Implementing Globally Harmonised System of Classification and Labelling Regulations Amongst the APEC Economies* (agenda item 2017/SOM3/CD/012) for review and discussion.

The comparison document highlighted the divergent implementation of GHS building blocks across the APEC region. While some of these divergences are likely to be due to the differences that exist in the legislative/regulatory structure of each economy and/or careful regulation impact consideration e.g. decision by Australia, Canada and the USA not to adopt environmental building blocks, some divergences may be due to the lack of availability of information on GHS implementation by close trading partners during the Economy’s implementation consideration.

As an initial study to explore potential convergence of regulatory approach for GHS implementation, two hazard classes, skin sensitisation and respiratory sensitisation were identified as divergent building blocks implemented with trade impact where a more convergent approach has the potential to reduce the trade impact with minimal impact on the protection of human health or the environment.

Category 1 or Categories 1A and 1B?

The main benefit identified for using a single category was that often there was not enough data to allow classification to sub-categories 1A and 1B. The use of a single category has the potential to reduce additional and/or animal testing. Additionally, there are no differences in label elements for the two sub-categories, and therefore there are no additional hazard communication benefits, just an additional burden on industry.

The benefit identified for using two sub-categories was that it provided a choice to the Competent Authorities, particularly where the Economy had previously had two tiers of sensitization categories. The option also provides the most precise classification.

The largest number of benefits were identified for the flexible option where either a single category or sub-categorisation may be used. The benefits identified are:

- More reliable and accurate classification – sub-categorisation is only possible where there is sufficient data.
- Allows regulatory acceptance of both approaches that may be used by different regulatory jurisdictions.
- Flexibility gives industry a more practical method of compliance.
- Allows businesses with more data the option to use the less hazardous sub-category.

One respondent noted that the flexible option would be preferable but only if mutually agreed by all parties.

Mixture cut-off of $\geq 0.1\%$ or $\geq 1.0\%$ (or $\geq 0.1\%$ or $\geq 0.2\%$)?

Respondents identified that the main benefit of the lower concentration cut-off is the protection of end users, particularly those that are already sensitized or highly sensitive. The main criticism for this approach was that it is an additional burden on industry and the protection of highly sensitive individuals was theoretical - it is not known what proportion of the population is affected (presumably compared to the higher concentration cut-off), and may lead to over-warning for less severe skin sensitizers.

For higher concentration cut-off, the benefit identified was that it was a more practical option for industry. One respondent also noted that for some Economies the 1% mixture cut-off was the default prior to GHS implementation (and therefore no increase in the risk to the population). The same respondent noted that in some other Economies 0.1% may have been the default mixture cut-off prior to GHS implementation. The main drawback identified was that it may lead to under-warning for products containing severe skin sensitizers. Products containing concentration between 0.1 and 1% of the sensitizer would not be identified as sensitizers which may affect highly sensitive or already sensitized individuals.

Respondents appeared quite strongly for or against the option of allowing a flexible adoption of mixture cut-off concentration. Those that were for the flexibility noted that the flexibility allowed for better harmonization. Those against noted that it may cause more confusion and divergence.

Potential for application across other GHS building blocks and mixture cut-off concentrations

The reasons for the responding Economies' choice of building blocks (single category or two sub-categories) did not appear to be specific to the hazard categories. This may allow the findings of this Questionnaire to be applied more broadly to other GHS classification categories where the option for sub-categorisation exists.

However, some of the reasons provided for the mixture classification cut-off appear specific to sensitizers i.e. consideration of induction and elicitation concentration levels of chemicals in individuals, and may not be appropriate for broader application to other GHS mixture classifications.

Regulators work with each other to find possible ways to deliver a convergent implementation of GHS

Economies were asked to identify any forum for regulators that are dedicated to GHS implementation convergence.

The following fora were identified.

- APEC Chemical Dialogue
- UN GHS Sub-Committee (UNSCEGHS)
- United Nations Institute for Training and Research
- USA/Canada Regulatory Cooperation Council initiative on GHS (Workplace Hazards)
- ASEAN Chemical Industry Regulatory Co-operation Workshop platform
- ASEAN OSHNet

Interestingly, some Economies identified that there is no forum for regulators that are dedicated to GHS implementation convergence. This may be due to the varying interpretation of “dedicated” used in the survey – it is noted that the primary function of the identified fora is not regulatory convergence of GHS across multiple Economies e.g. APEC CD has a much broader purpose.

Conclusion

Based on the responses to the Questionnaire, the APEC Economies are working towards some aspects of convergent implementation of GHS. However, collaboration across the APEC region is required to achieve better alignment.

Economies adopt later revisions of GHS

All Economies that are planning to adopt a later revision of GHS have identified the 7th revision as the revision to adopt. The implementation timings also appear closely aligned with the Economies identifying 2020 or 2021 as the planned implementation years. We note that the difference of up to two years in implementation time may be managed with appropriate transition time to achieve harmonized implementation of the 7th revision of GHS across the Economies.

However, the mechanism for adopting later revisions of GHS do not appear to be present in some Economies that are required to “manually trigger” the process. Further those Economies that have mechanisms in place differ in the timing of the review process e.g. legislated five yearly review in some Economies, every second revision for one Economy, and a continuing review process in another.

This leads to the conclusion that the potential near future alignment with the adoption of the 7th revision of GHS is by good fortune rather than good design. To ensure continued convergent implementation of the GHS revisions, APEC Economies should consider mechanisms to regularly update their adoption of GHS

Economies adopt common building blocks to facilitate trade

It is noted that the conclusions drawn regarding convergent adoption of GHS classification building blocks is solely based on the responses to the Questionnaire, which in turn only considered two building blocks in detail.

The two building blocks and their mixture concentration cut-offs were deliberately chosen as they demonstrate significant divergences across the Economies.

The reasons for and against each of the options that are available for the building block implementation approaches lead to the conclusion that the flexible option (allow the choice of either the single Category 1, or two sub-categories 1A and 1B for classification) had the most benefit.

The commentary around mixture concentration cut-off appeared to need more in-depth exploration and consideration. While protection of vulnerable population was raised as a key factor for lower concentration cut-off, it was also noted that there was no data on what percentage of population would be impacted. This is a risk consideration, which highlights the challenges of implementing GHS, a hazard-based system, into an Economy’s rules, which may require risk assessment and risk management considerations.

Regulators work with each other to find possible ways to deliver a convergent implementation of GHS

While there are several fora where GHS implementation convergence could be discussed, it appears that there are none with the sole purpose of promoting convergent implementation of GHS and that include many countries. This is a potential work for the APEC CD Regulator's Forum, where an inclusive and open workshops on risk assessment and risk management specific to individual hazard categories and concentration cut-off could be considered, noting that while GHS is a hazard-based system, Economies may need to consider risk before GHS can be adopted into an Economy's rules.

Recommendations

The CD recommends that:

- Economies consider adoption of the 7th revision of GHS by 2021,
- Economies consider implementing automatic or legislated review processes to continually update to the newer revisions of GHS,
- Economies consider allowing flexibility for classification for building blocks where sub-categorisation options exist in GHS, and
- Economies consider whether the Regulator's Forum should convene workshops where detailed risk assessment and risk management specific to individual hazard categories and concentration cut-off could be considered.