



Derek D. Swick, PHD, MPP  
Manager

Regulatory and Scientific Affairs

1220 L Street, NW  
Washington, DC 20005-4070  
USA  
Telephone 202-682-8341  
Email [swickd@api.org](mailto:swickd@api.org)  
[www.api.org](http://www.api.org)

**VIA EMAIL**

June 19, 2019

Maureen Ruskin  
Deputy Director Standards and Guidance  
Office of Chemicals Hazards-Metals  
DOL - Occupational Safety and Health Administration  
200 Constitution Avenue, NW  
Washington, DC 20210

RE: U.S. Positions at the 37<sup>th</sup> Session of UNSCEGHS

Dear Ms. Ruskin:

The American Petroleum Institute (API) is writing to provide comments on issues and papers that will be discussed at the upcoming 37<sup>th</sup> Session of the United Nations (UN) Sub-Committee of Experts on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) (UNSCEGHS or Sub-Committee) to be held July 8 through 10, 2019, in Geneva, Switzerland. API is a national trade association representing over 600 companies involved in all aspects of the oil and natural gas industry. API's members include producers, refiners, suppliers, pipeline operators, and marine transporters, as well as service and supply companies that support all segments of the industry. API member companies are leaders of a technology-driven industry that supplies most of America's energy, supports more than 10.3 million jobs and nearly 8 percent of the U.S. economy, and since 2000, has invested more than \$3 trillion in U.S. capital projects.

API members are regulated under existing U.S. hazard communication programs, and implementation of the GHS directly affects API members.<sup>1</sup> Further, many API members transport petroleum substances and products around the globe and support the global harmonization of hazard communication requirements. This includes support for consistent adoption of the GHS by regulatory entities in the U.S. and other competent authorities around the world.

---

<sup>1</sup> API member companies comply with U.S. Occupational Safety and Health Administration (OSHA) standards related to hazard communication (e.g., OSHA's Hazard Communication Standard (HCS)), and support the efforts of OSHA and the U.S. Environmental Protection Agency (EPA) to provide workers with the right-to-know about hazards and identities of the chemicals they are exposed to in the workplace. Specifically, API's members evaluate the hazards of the chemicals they produce or import, provide information about them through labels on shipped containers and safety data sheets (SDSs), and prepare and implement written hazard communication programs, ensuring that all containers are labeled, employees are provided access to SDSs, and an effective training program is conducted for all potentially exposed employees.

API appreciates that OSHA is granting stakeholders the opportunity to communicate with OSHA prior to the upcoming UNSCEGHS meeting. We respectfully contribute the ideas below for consideration by the U.S. Interagency GHS Coordinating Group, in preparation for the upcoming UNSCEGHS meeting.

First and foremost, API would like to highlight the IPIECA document *Guidance on the Application of Globally Harmonized System (GHS) criteria to Petroleum Substances*. This document should be considered and referenced at appropriate points in the Sub-Committee discussions.

The most recent version of the IPIECA GHS guidance refers to the seventh revised edition of the GHS (2017) and includes new research on the hazards of petroleum-related substances and constituents. The IPIECA GHS guidance suggests arranging petroleum substances logically in groups of “similar” substances (product groups), which facilitates read-across for purposes of consistent classification and minimizes unnecessary testing. The IPIECA guidance also informs the user that there are certain hazardous constituents that should be considered in classification decisions when there is limited data on the complete substance.

The IPIECA GHS guidance focuses on human health hazards and includes a detailed discussion of a Weight-of-Evidence (WoE) approach. A classification flowchart utilizes a three-tiered approach in which substance-specific toxicity data are considered first, followed by read-across data and then data for hazardous constituents. The Technical Support Document portion of the guidance provides substance-specific and toxicological information for petroleum substance hazardous constituents and includes two case studies that highlight the importance of evaluating and prioritizing substance-specific data when performing WoE-based hazard classifications of UVCB substances.

In addition to ensuring that the most recent version of this guidance document is considered at all appropriate points of Sub-Committee discussions, API strongly encourages OSHA to consider the document in its planned update to the U.S. Hazard Communication Standard (HCS), particularly as any aspects relate to UVCBs or petroleum substances. Regarding the forthcoming revision of the HCS, API also encourages OSHA to align its HCS with the most recent version of the GHS that is available when the U.S. notice and comment rulemaking process commences.

The remainder of our comments are organized according to the documents that are under consideration.

**ST/SG/AC.10/C.4/2019/5 - ST/SG/AC.10/C.3/2019/32**

**Development of a new Chapter 2.1 for the GHS (explosives)**

In this paper, Sweden provides an overview of the potential new GHS classification system for explosives and its relation to transport classification. The program of work aims to develop a

new Chapter 2.1 in the 2019-20 biennium, and describes the route to this goal in terms of four work items. API supports the ongoing work on GHS Chapter 2.1 (explosives).

**ST/SG/AC.10/C.4/2019/4 - ST/SG/AC.10/C.3/2019/20**

**Tests for oxidizing liquids and oxidizing solids improvement regarding consideration for particle size, friable or coated materials**

This program of work includes the tests for oxidizing liquids and oxidizing solids. It will focus on improvements concerning the testing of materials of different particle sizes or coated materials, as well as improvements to the testing methods for the Tests O.1, O.2, and O.3. API supports this work on the tests for oxidizing liquids and oxidizing solids.

**ST/SG/AC.10/C.4/2019/3**

**Proposed changes to the presentation of flammable gas categories and sub-categories in Annex 3**

The Annexes 1-3 informal working group identified two areas where amendments about precautionary statements presentation should be made to improve clarity and consistency of the sub-categories of Flammable Gases Category 1A presented in Table A3.2.2 of Annex 3 in line with Table 2.2.1 and the matrix tables in section 3 of Annex 3. API supports the changes, and also supports providing future informal papers that show full text changes.

**ST/SG/AC.10/C.4/2019/2**

**Proposed changes to Annex 1**

The purpose of this work item was to review the pictograms and notes in Annex 1 to remove inconsistencies, provide greater clarity, and improve the readability and presentation of the tables in Annex 1. Annex 1 is very useful in demonstrating the relationship between GHS and TDG, and the revisions would make it even better. API supports the changes, and also supports providing future informal papers that show full text changes.

**ST/SG/AC.10/C.3/2018/61–ST/SG/AC.10/C.4/2018/15**

**Thought starter on digitalization of hazard information for chemical products**

The Practical Labelling Issues Work Group will address how to consider the opportunities that digitalization may bring to convey hazard information. This paper calls for additional data and opens discussion of benefits, concerns, backup options, digital labels, parallel use, complementary use, alternative use, information layout, label definition, and sector differences. API's comments on some of these issues include the following:

- Sector differences may be a primary issue with digital labeling/information. Because industrial workplaces often do not allow mobile phones and other electronic devices in work areas, digital labeling in the industrial workplace sector would need careful consideration.
- Proposing any additional documents or information beyond a traditional container label and SDS would warrant serious consideration. Requiring, recommending, or mandating digital hazard information would be a substantial change to the GHS. It would impose additional costs, but potential benefits are not clear. For the workplace industrial setting, there is not a demonstrated need for material beyond the SDS (which already can be electronic and electronically searchable) and container label.
- Discussion of parallel use, complementary use, or alternative use should take into account sector differences. Using digital hazard information in the transport phase could be helpful for products in transit; however, developing an appropriate approach would require collaboration with the UN Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG).
- Any digital label or digital hazard information would need to be consistent with the GHS container label content. It should have signal word, hazard statement(s), precautionary statement(s), and pictograms.
- Information layout was a discussion in the initial GHS and then was only addressed at a general level of detail. Standardizing or mandating label information layout is challenging and could have cultural and regulatory implications. Even for SDSs, only a high-level outline of sections/information is in the GHS.
- Any change to the GHS definition of *label* would be problematic. It might be better to add additional definitions such as for labeling, digital label(ing), parallel label(ing), complementary label(ing), alternative label(ing), container label, digital hazard information, etc.
- Any digitalization effort should not aim to substantially change the existing GHS labeling elements and philosophy, but rather should complement the existing GHS.

#### **UN/SCEGHS/37/INF.4**

##### **Proposed changes to the presentation of flammable gas hazard category 1A in Annex 3**

The United Kingdom has provided a document that sets out the changes proposed for Annex 1 in working document ST/SG/AC.10/C.4/2019/2. API supports the changes, and seeing detailed proposed changes is very helpful. In general, the practice of informal papers showing the actual changes (strikethroughs and additions) should be strongly encouraged.

#### **UN/SCEGHS/37/INF.10**

##### **Potential path forward for global list project**

This paper does a good job of summarizing how the Sub-Committee has studied the possibility of developing a global list of chemicals classified in accordance with the GHS. Most recently, the Global List Informal Correspondence Group discussed the potential paths forward during a February 2018 teleconference, but did not meet at the thirty-fifth or thirty-sixth session. API's suggestions on the global list work reflect the concern that there are many obstacles to developing a global list of harmonized GHS-classified substances, and that attempting to do so would require substantial resources. It has been demonstrated that there is a significant and substantial lack of identical classifications on existing lists. This in itself should raise the issue about the credibility of existing lists and prospects for a global list.

So far, work on a global list has been a multi-year effort, including many discussions over time and a pilot exercise that was time-consuming and challenging. API believes that the Sub-Committee is at a critical juncture and that a decision should be made to either commit to develop a global list or decide not to. The U.S. government already has expended substantial resources on this work stream, and future resources could be better used to address practical classification issues and to promote more consistent adoption of the GHS globally. The Sub-Committee should focus on maintaining a sound framework and promoting consistent GHS implementation, rather than wading into the detailed work of developing a global list of classifications. Efforts to harmonize classifications are best accomplished on a sector-specific basis by experts on the particular substances—the IPIECA GHS guidance effort is a good example.

The paper discusses three potential work streams (A – C). If work moves forward on a global list, there are pros and cons for each of the workstreams. Some thoughts on specific work streams that are under discussion follow.

##### **Work Stream A: Continue to research and analyze the existing classification lists**

While further analysis is theoretically interesting, care should be taken that this workstream not fall into “analysis paralysis.” There are already several existing studies that have examined GHS classifications and the reasons for the differences in classifications, including:

- OECD Classification and Labelling of Chemicals According to the UN GHS: Outcome of

the Analysis of Classification of Selected Chemicals Listed in Annex III of the Rotterdam Convention (2010);

- OECD Report of the Pilot Exercise on Classifications for Selected Chemicals Assessed at COCAM (2014);
- Report on the Pilot Project on Assessing the Potential Development of a Global List of Classified Chemicals, UN/SCEGHS/32/INF.4 (2016 OECD); and
- Observations: UN Global List Pilot Project vs. Published GHS Classifications (SCHC/ChemADVISOR 2017).

Additional analysis would not necessarily add new useful information. It would be more productive to review the above reports, several of which concluded that the difference in datasets used is the main reason for divergent classifications. Also, data interpretation has been cited as a reason for different classifications. The above reports should be reviewed to determine if clarification of certain areas of the GHS criteria, or further guidance on how to apply the criteria, would assist in promoting more harmonized GHS classification.

#### **Work Stream B: Further explore possibilities to develop a global list**

As explained above, API suggests that the Sub-Committee not do more work on developing a global list. Rather than aiming for an extensive list of harmonized classifications, the Sub-Committee might approach the problem as a trouble-shooter, addressing particular classifications of concern that are brought to its attention.

Unfortunately, there is no existing list that meets all of the relevant guiding principles<sup>2</sup> for the development of a global list of chemicals. Regarding **WHO/ILO International Chemical Safety Cards (ICSCs)**, there was not enough opportunity provided for stakeholders to provide input on the ICSCs. Also, on the ICSCs, the GHS classification is provided by pictograms and hazard statements. There is no GHS hazard class or hazard category explicitly stated on the cards.

The **UN Dangerous Goods List (“TDG list”)** has over 2,000 entries, and although the TDG list is widely used, it has not been systematically updated to align with the GHS in many respects (e.g., acute toxicity categories, flammable aerosols, environmentally hazardous materials).

---

<sup>2</sup> (1) Opportunities should be provided for stakeholders to provide input as well as mechanisms for expert review, conflict resolution and updating the list when new significant data or information become available.

(2) All GHS hazard categories and classes must be included in the global list of classified chemicals.

(3) Only substances, as defined by the GHS, will be included in the global list of classified chemicals.

(4) All substances must be accurately identifiable and described for each entry (e.g. including Chemical Abstracts Service Registry Numbers (CAS numbers), the UN numbers assigned under transport of dangerous goods regulations where assigned/applicable, and relevant impurities).

(5) The data sets forming the basis for the chemical classification must be referenced with the classification. The source of the information must also be electronically available, and publicly accessible. The data should be derived using test methods that are scientifically sound and validated according to international procedures.

(6) The global list of chemical classifications will be non-binding. As with the GHS itself, countries will have the option to make the list binding if they adopt it through their legislative and/or regulatory process. Furthermore, the development of a global list is compatible with the GHS principle of self-classification.

There is value in having all existing GHS classification lists readily accessible on the OECD's eChemPortal. It would be valuable to present the existing lists of classified chemicals, noting how each list does or does not align with the UNSCEGHS guiding principles.

### **Work Stream C: Develop a list limited to specific hazards or chemicals of concern**

To do this, the UNSCEGHS would have to start with some set of chemicals to develop a harmonized UN list of classified chemicals. Any existing GHS classification list went through a selection process. The pilot project, while a valuable lesson and learning opportunity, probably did not use the best method for selecting/prioritizing chemicals. If there were additional work on a limited list, considerations for selecting chemicals might include:

- Chemicals that are data rich;
- Chemicals that are data poor;
- Chemicals with “harmonized” GHS classifications in existing systems;
- Chemicals with “un-harmonized” GHS classifications in existing systems;
- Chemicals that raise serious health, physical, and/or environmental concerns; and/or
- Chemicals most commonly used and transported worldwide or high-volume chemicals.

### **Modifications on Chapter 3.3 SERIOUS EYE DAMAGE/EYE IRRITATION for the introduction of *in vitro*/*ex vivo* classification criteria**

API welcomes the ongoing work of the correspondence group on non-animal test methods. The U.S. government should remain involved in these discussions, and U.S. agencies (e.g., OSHA, EPA, DOT) should continue to coordinate on these issues. It is also important that the U.S. government continue to keep the regulated community and other stakeholders informed and provide opportunities for input on these issues. We expect that additional stakeholders will participate and provide input once they are aware of the work of the correspondence group and its potential impacts. OSHA should maximize transparency in order to facilitate this input.

As this work proceeds, it will be important to keep in mind that a fundamental principle of the GHS is that the GHS criteria for determining health and environmental hazards are test method neutral, allowing different approaches. Many *in vitro* tests have a domain of applicability and will likely not be suitable for all substances. It is critical to the continued widespread adoption and success of the GHS that animal testing, structure activity relationship analysis, etc. remain part of the GHS. Non-animal testing should be one part of the GHS classification criteria, but not become mandatory or a preferred method. Jurisdictions differ in non-animal testing policies and mandates, and not all substances (e.g., petroleum substances) will likely be compatible with non-animal methods. While the GHS should align with advancements in technology, the GHS Purple Book should allow validated/recognized testing and good quality data but remain **test method neutral**.

June 19, 2019

Page 8

API appreciates the opportunity to provide input as the U.S. government prepares for the upcoming UNSCEGHS meeting. Please contact me if you have any questions or would like additional information from API.

Sincerely,

A handwritten signature in black ink, appearing to read "Duane Pfund". The signature is written in a cursive style with a large initial "D".

cc:

Shane Kelly, U.S. DOT  
Deana Holmes, U.S. OSHA  
Anne Godoy, U.S. DOL  
Duane Pfund, U.S. DOT