



SCHC Fall 2022

OSHA GHS/HCS Update

**Maureen Ruskin
Deputy Director
Directorate of Standards
and Guidance**



Overview

- UN Subcommittee Update
 - 2021/2022 Biennium Program of Work progress
 - Looking forward
- Brief HCS rulemaking update

UN Sub-Committee



2021/22 biennium Program of Work

- Non-animal testing methods for classification of health hazards
- Classification of skin sensitizers using the results of local lymph node assays (LLNA) test methods in accordance with OECD Test Guideline 442B
- Classification criteria for germ cell mutagenicity
- Practical classification issues
- Nanomaterials
- Simultaneous classification in physical hazard classes and precedence of hazards
- Practical labelling issues
- Improvement of Annexes 1 to 3 and further rationalization of precautionary statements
- Assessing the possible development of a list of chemicals classified in accordance with the GHS
- Alignment of guidance in Annex 9 (section A9.7) and Annex 10 of the GHS with the criteria in Chapter 4.1

Non- Animal Testing

- Workstream 1
 - To review and revise Chapter 3.3, Serious Eye Damage, Eye Irritation, following as appropriate the work already done on Chapter 3.2.
 - Specific issue of classification using pH
- Workstream 2
 - To review and revise Chapter 3.4 in regard to skin sensitisation.
- Workstream 3
 - To consider whether updates are needed in Chapter 1.3 as a result of the group's work.

Non Animal Testing

Chapter 3.3

- The Subcommittee Adopted the updated chapter in July 2021
- GHS updated the Tiered approach
 - Tier 1 - human data or standard animal data for serious eye damage/eye irritation
 - Tier 2 - defined approaches or in vitro/ex vivo data for serious eye damage/eye irritation
 - Tier 3 – conclusive human data; standard animal data; or in vitro/ex vivo data for skin corrosion leading to classification for serious eye damage
 - Tier 4 – other existing skin or eye animal data
 - Tier 5 – pH-based assessment
 - Tier 6 – non-test methods for serious eye damage/eye irritation or for skin corrosion leading to classification for serious eye damage
 - Tier 7 – consideration of the overall weight of evidence
- The Subcommittee also updated Chapter 1.2 and Chapter 3.2

Non Animal Testing pH resolution

- (a) Classification for substances based on chemical properties (3.3.2.7), including an amended text in the section heading; and
- (b) Inclusion of classification based on extreme pH and acid/alkaline reserve within Tier 5 on the application of the tiered approach for serious eye damage/eye irritation (Figure 3.3.1); and
- (c) Classification of mixtures when data are available for the complete mixture (3.3.3.1.3) including the introduction of an additional figure 3.3.2 to show the difference in the use of the pH rule between substances and mixtures; and
- (d) Guidance on the use of pH and acid/alkaline reserve for classification as serious eye damage (3.3.5.3.7).

Non Animal Testing

Chapter 3.4

- Will provide a formal proposal for the Sub-Committee for the December meeting. This will include:
 - Updated text for classification for substances
 - Updated guidance
- The working group will provide an informal paper for any remaining issues.
- Work on mixtures may continue into the 2023/24 biennium.

Germ Cell Mutagenicity

- Workstream 1 (a) Terminology (b) Update the chapter according to current state of science as described in (c). (c) Non-testing methods, read-across and consulting with the informal working group on NATM.
- Workstream 2: Review criteria (a) Review and revise, as needed, the criteria for category 1B (b) Review and revise, as needed, the criteria for category 2 (c) Review and revise, as needed, the criteria for category 1A (d) Engage the OECD for review of updated classification criteria
- Workstream 3: Explore the relevant sections in Chapter 3.5 with reference to the results of workstream 1 and 2 and propose additional or modifying text, if deemed necessary (a) Ensure that any revised criteria for the different categories are consistent with each other. (b) Decision logic and guidance. (c) Consult with the PCI informal working group on technical errors and/or editorial improvements. Workstream 4: Review and finalize draft chapter for submission to the Sub-Committee

Simultaneous classification in physical hazard classes

- Task 1: Analyze systematically all combinations of physical hazard classes with regard to their simultaneous assignment to a chemical.
- Task 2: Check the precedence of hazards of the Model Regulations as to whether it can be used for the purposes of the GHS and whether it is in line with the results according to Task 1.
- Task 3: 3.1 Taking into account the results of tasks 1 and 2, decide whether and how a systematic approach for combinations of physical hazards can be developed for the GHS. 3.2 Decide how provisions/information could or should be added to the GHS, e.g. as guidance and/or within the individual hazard classes and propose amendments to the GHS, as appropriate

Annex 1 to 3 Updates

- Continues to review Hazard/Precautionary statements to ensure accuracy and clarity.
 - The Sub-Committee Adopted additional examples of combinations of Hazard statements
 - Discussing potential updates to respiratory sensitizers precautionary statements
 - Updating P260 and P271 for clarity
- US has insisted that the changes made are to improve communication.



Looking Forward

What do we see for the next Biennium

Practical Labeling issues

- The working group reenergized – reviewing the benefits of digital labeling:
 - Digital information could be provided in addition to the traditional physical label;
 - Digital information can increase readability and understanding of hazard information;
 - Supplemental and additional information could be easily accommodated including special needs;
 - Swift and targeted updates of hazard information could be provided.

Potential new items on the Program of Work

- The EU submitted an informal proposal to add additional health endpoints to the GHS program of work.
 - (a) Entrusting the technical work to OECD as the Sub-Committee's focal point on environment and health hazards
 - (b) Entrusting the technical work to an informal group within the Sub-Committee. Under this option, involvement of the OECD would be vital
- The Sub-Committee expressed concerns over timing as well as the current workload of the Sub-Committee.

UN Sub-Committee

- Program of Work
 - December 2020 Report pages 20-22
 - https://unece.org/sites/default/files/2021-01/ST-SG-AC10-C4-78e_0.pdf
 - Link to UN website
 - https://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html
- Next UN meeting: December 7-9



HAZARD COMMINATION RULE UPDATE

Informal Hearing for the HCS Rulemaking

- OSHA held an informal hearing from September 21 thru September 23, 2021
 - OSHA received 33 requests of notice to appear (NOITA)
 - Twenty eight organizations or individuals presented comments at the hearing
 - Hearing was presided over by an Adjuvant Law Judge
 - Hearing was organized into 13 panels over the 3 days of hearing
 - Participants were given option to ask panelists questions
 - More than 230 individuals viewed the hearing on day 1

Next steps in the rulemaking process

- OSHA posted hearing transcripts to the docket
 - All materials are available for viewing in the docket (*copyrighted materials are viewable at docket office*)
- OSHA reopened the docket only for those who participated in the hearings and submitted a NOITA
 - Docket closed December 21, 2022

Comments Received to the Docket

- OSHA received more than 171 comments from individual and organizations
- Provisions receiving most comments:
 - Release for shipment
 - Shipment date
 - Small packages
 - Concentration ranges for trade secrets
 - Normal conditions of use
- Majority of provisions received at least one comment

Issues

Provision	Proposed changes	Issues raised
(a) Purpose	Align with GHS revision 7 with option include major changes to revision 8	Supportive of aligning to revision 7, most commenters supportive of including changes from revision 8 – non-animal test methods, medical/precautionary statements, include “chemicals under pressure” and updates to “aerosols”
(c) Definitions	Small changes to several existing definitions, 6 new definitions	Most commenters supportive of changes – few specific comments on technical issues
(d) Hazard classification	Update to “normal conditions of use” to include “hazards resulting from reactions with other chemicals under normal conditions of use”	Provision receiving most comments - Labor supported change, industry mostly against, mostly supportive from Public Health organizations and Gov’t agencies

Issues - continued

Provision	Proposed changes	Issues raised
(f) Labels and other forms of warning	Proposed to include date of released for shipment, bulk shipment labels, DOT and HCS pictograms, and release for shipment, new small packing requirements	Many comments - pro and con changes, mostly involving 'release for shipment'
(i) Trade secrets	Allowing for concentration ranges (as prescribed ranges) to align with Health Canada	Public Health and labor supported provision, mixed comments from industry – some wanted it to be optional

Issue - continued

Provision	Proposed changes	Issues raised
(j) Dates	Proposed 1 year for general manufacturers, 2 years for manufacturers of mixtures	Received lots of comments from industry that this was burdensome, especially to manufacturers of mixtures since they rely on upstream manufacturers for initial information
Appendix A	Proposed, in Options section, including expanded non-animal test methods in Appendix A.2.1 (skin corrosion/irritation) from Rev. 8	Received comments favoring and opposing inclusion. NIOSH, public health groups, PETA, and several from industry supported including expanded non-animal test methods
Appendix B.1 - explosives	Added Note 2 – explanation on wetted explosives reduce explosive properties and references new added B.17 (desensitized explosives) Added Note 3 – regarding testing under the Manual of Test Criteria	Department of Defense – wants changes to notes and an exemption B.1.3.4 chemical reaction calculation is incorrect – correcting the UN GHS subcommittee WG – will deal with in guidance once it has been finalized in GHS WG

Next Steps

There are still a few steps to go prior to finalization

- OSHA finalizes the updated rule considering the docket as a whole.
- The final rule goes through a series of reviews
 - OSHA review/ DOL review/OMB review
- Publication in the Federal Register



Questions?
