The UN GHS and non-animal testing workgroup

Janet Carter

Sr. Health Scientist
U.S. Department of Labor
Occupational Safety and Health Administration

2 September 2020
What is the GHS?

• The GHS (Globally Harmonized System of Classification and Labeling of Chemicals)

• Completed in 2001 and adopted in 2002, the GHS had 3 basic areas of focus:
  – Classification of physical hazards
    • Focal point: TDG
  – Classification of health and environmental hazards
    • Focal point: EU, US, Canada, IARC, OECD
  – Hazard communication
    • Focal Point: ILO safety tools

• Updated every biennium (currently working on revision 9)
UN GHS

• GHS is a non-mandatory framework to be adopted by member countries

• GHS is intended to aid in identifying, classifying and communicating information on the hazards of chemicals or substances

• GHS is designed to provide hazard information for occupational, consumer, and environmental exposures
GHS Health Endpoints

• 10 Health endpoints
  – Each endpoint has criteria for classification as well as criteria to assess the degree of the hazard (e.g. carcinogenicity category 1A)

• Some endpoints have specific values or range of values
  – Acute toxicity, STOT (RE), STOT (SE)

• Most endpoints have more subjective values for categorizing
  – Tiered evaluations (Chapter 3.2 (skin corrosion/irritation), Chapter 3.3 (eye corrosion/irritation)), expert judgement, weight of evidence
GHS Classification

• Hazard classification indicates only intrinsic hazardous properties of the substance (or mixture)
• Three steps for classification
  – Identification of relevant data regarding the hazards of the substance
  – Subsequent review of the relevant data to ascertain the hazards associated with the substance
  – Decision on whether the substance will be classified, and the degree of the classification (category of the severity of the classification)
• Classification is generally based on existing information as there are no testing requirements
• Classification is based on the criteria and reliability of the test methods
• GHS is test method neutral
UN GHS Updates for expanding non-animal data for classification

• In 2015 Netherlands and UK submitted a paper proposing the establishment of an informal working group on facilitating the use of data from non-animal test methods in GHS classification

• Proposed several activities in the program of work related to the use of non-animal data (*in silico, in vitro, in chemico*) for classifying substances and mixtures.
• Following a step-wise approach by selecting a single hazard class to start with:
  – Skin corrosion/irritation (chapter 3.2) was completed in 2019 and published in revision 8
  – Eye corrosion/irritation (chapter 3.3) scheduled to be completed December 2020/January 2021
  – Skin sensitization (chapter 3.4) will be updated either for revision 9 or the following biennium
Skin Corrosion/Irritation

- Updated guidance on use of non-animal test data
- *In vitro* data was elevated to tier 2
Eye corrosion/irritation

• Using Chapter 3.2 as guideline for updating Chapter 3.3

• Update guidance on use of *in vitro* data for classifying hazards, use of pH data for classification

  – Eye chapter is introducing the concept of defined approaches
Serious Eye Damage/
Eye Irritation
Additional Information on UN GHS

- Maureen Ruskin, Acting Director, Directorate of Standards and Guidance, OSHA
  - Head of US delegation,
  - Chair of GHS sub-committee

- Information on public meetings are posted at:
  - Federal Register notice

- GHS information: https://www.unece.org/trans/danger/publi/ghs/ghs>Welcome_e.html
  - Meetings and Events
  - GHS Sub-committee
    - Agendas, Reports, Working documents, Informal documents
Thank you!

- OSHA ICCVAM contacts:
  - Deana Holmes, Health Scientist
    holmes.deana@dol.gov
  - Janet Carter, Sr. Health Scientist
    carter.janet@dol.gov