Globally Harmonized System for Classification and Labeling (GHS)

Informal working group on non-animal testing

Joanna Matheson, Ph.D.

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GHS Background

- Began with the premise that existing systems should be harmonized in order to develop a single, globally harmonized system to address classification of chemicals, labels, and safety data sheets (1992).
- Sub-committee of experts on GHS was created (1999)
- The first version of the GHS was adopted in December 2002 .
  - Addresses classification of chemicals by types of hazard (physical, health, environmental) and proposes harmonized hazard communication elements
  - Subcommittee meets biannually
  - GHS is revised every two years as needs arise and experience is gained in its implementation

Non-animal testing working group

- Netherlands and UK submitted a paper proposing the establishment of an informal working group on facilitating the use of non-animal test methods (approaches) in GHS classification (2015).

- Proposed several activities to be included in the programme of work; these activities are regarding the use of non-animal approaches (in silico, in vitro, in chemico) for classifying substances and mixtures.

Non-animal testing working group (cont)

- Proposed consistent application for the use of read-across as stand-alone criterion for all health hazards (for respiratory and skin sensitization, read-across is permitted only in a weight-of-evidence evaluation).
- US, Germany, Canada, Sweden and ECHA provided comments
- Follow a step-wise approach by selecting a selecting a single hazard class to start with
  - Skin corrosion/irritation

Non-animal testing working group (cont)

- Working areas to address:
  - In vitro and in chemico approaches
  - In silico approaches
  - Weight of evidence approaches
- Netherlands drafted the first proposal
  - Chapter 1.3 – general considerations
    - Section 1.3.2 - created a specific section that described non-test methods (non-experimental method or approach)
  - Chapter 3.2 – new subchapter for in vitro data and non-test methods (minimal details

Chapter 3.2 options on details (cont)

- Chapter 3.2 – new subchapter for in vitro data and non-test methods; 3 options under consideration
  - Minimal details
  - Classification criteria (TER, EpiSkin, EpiDerm, SkinEthic RHE, epiCS, Corrositex)
  - Applicability domain

Working Group Participants

- Tialda Bouwman (RIVM) is the chair
- ECHA
- EU countries
- Industry, trade associations
- Health Canada
- United States

US Stakeholders

- Maureen Ruskin, OSHA, head of US delegation, Chair of GHS sub-committee
- Information on public meetings are posted:
  - https://www.osha.gov/dsg/hazcom/index.html
  - Federal Register notice
- GHS: 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!