The UN GHS and non-animal testing workgroup

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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

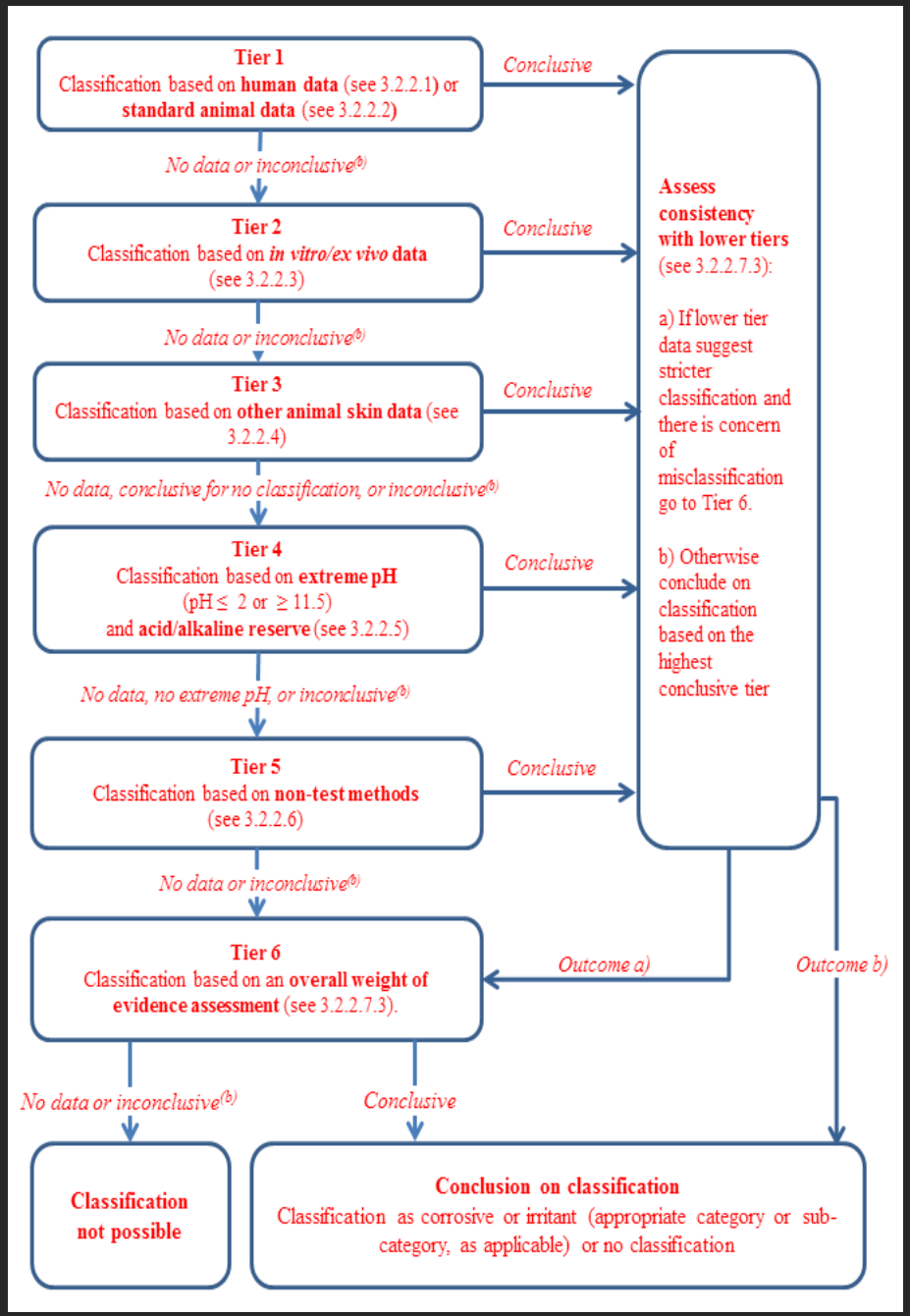
- Proposed several activities in the program of work related to the use of non-animal data (*in silico, in vitro, in chemico*) for classifying substances and mixtures.

UN GHS Non-animal WG

- 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

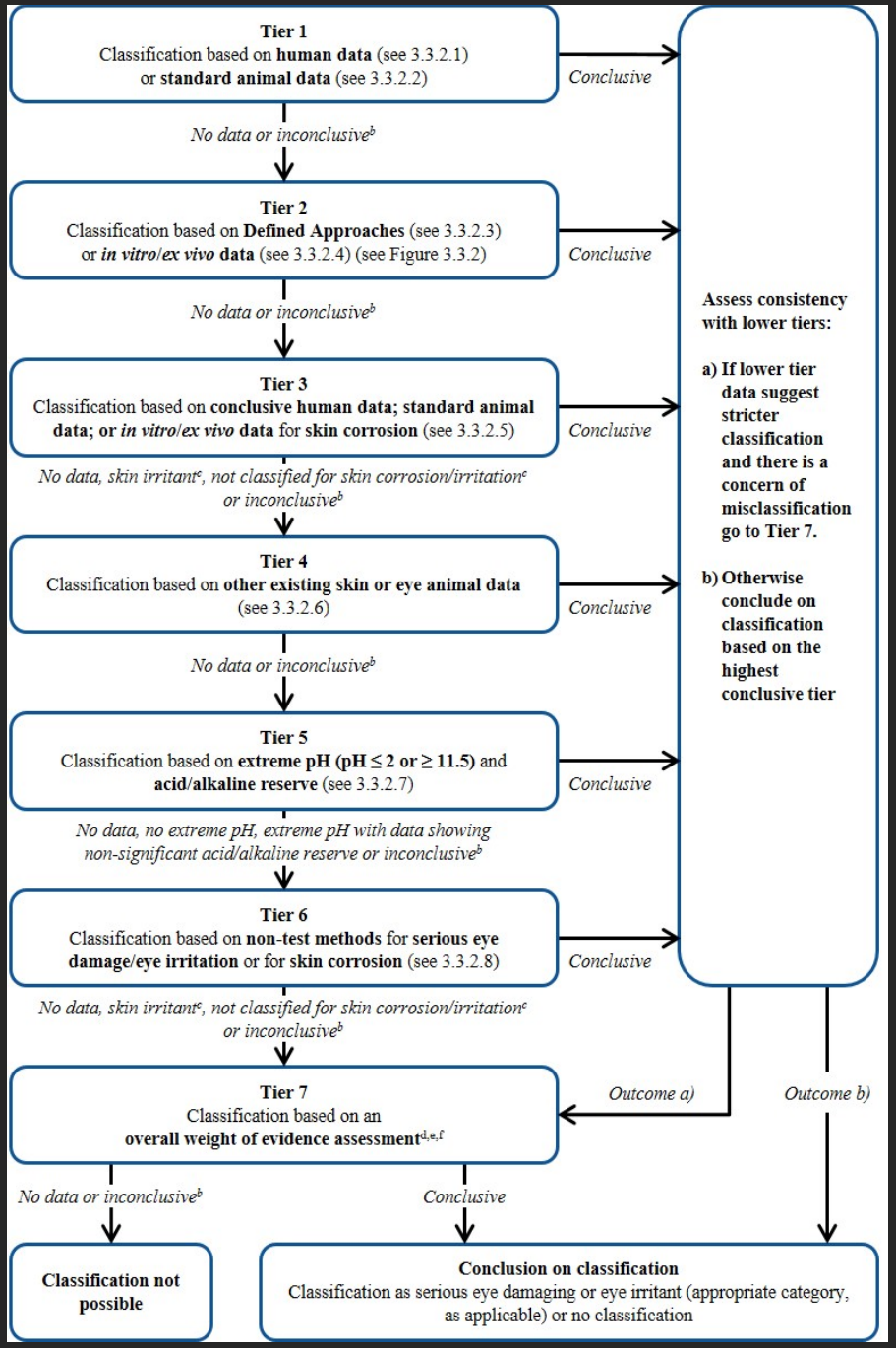
- Updated guidance on use of non-animal test data
- *In vitro* data was elevated to tier 2



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:
  - https://www.osha.gov/dsg/hazcom/index.html
  - 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!

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