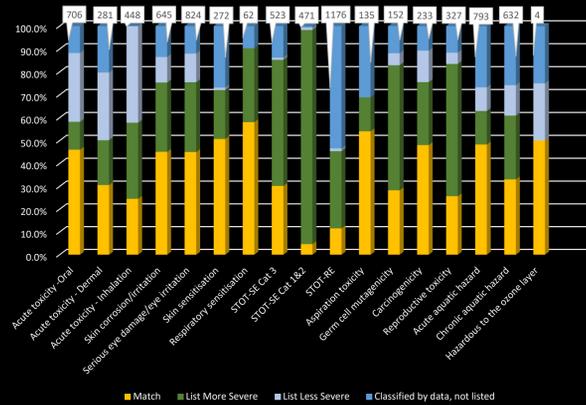


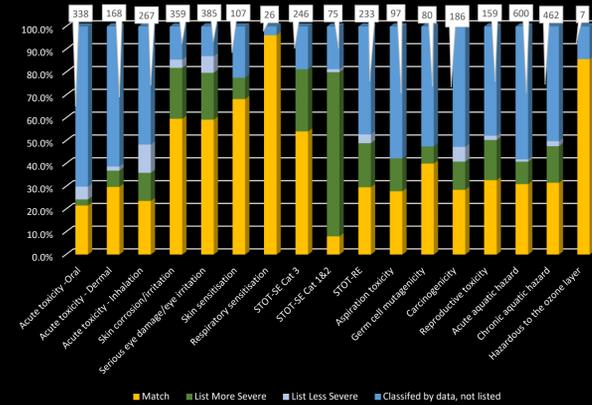
Regulatory list classifications vs. classification based on reliable published data and implications for global SDS authoring

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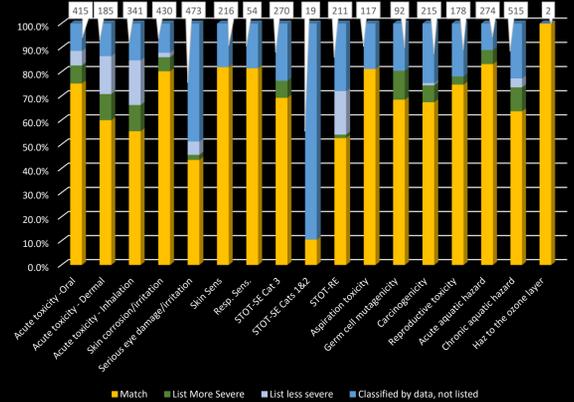
JP Chemicals Classification Program vs. Best Available Data Classification



CN Catalog of Hazardous Chemicals vs. Best Available Data Classification



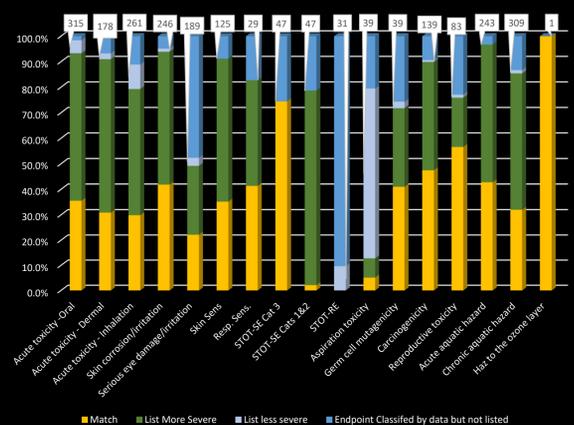
EU CLP Annex VI vs. Best Available Data Classification



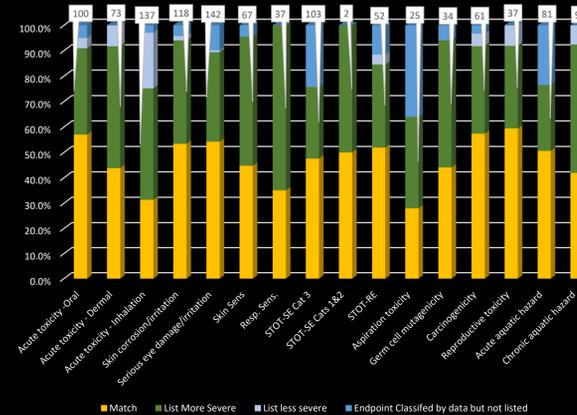
Background

The European Union, Turkey, Japan, China, Korea and Malaysia have published GHS-based classification lists. Publication of REACH registration dossiers and increased availability of a number of national hazard information databases has led to a rapid expansion of previously unpublished studies becoming readily available on the dissemination websites. Experienced hazard communication experts and toxicologists, self-classified 600+ substances that were found on at least one classification list using reliable published data, and compared the list-based classification data to self classifications. Environmental and human health endpoints were compared to see if they matched, or were more or less severely classified.

KR GHS MOE Classification vs. Best Available Data Classification



MY Industry Code of Practice vs. Best Available Data Classification



Possible Causes of different classifications

Difficult to assess due to lack of transparency for most list based classifications.

- Recent data not considered
- Unpublished studies not available
- Read-across studies differ or were not considered
- Weight given to human studies may be different, quality of study may be a factor
- Data interpretation differences

Choosing List Data vs. Best Available Data Classification

- Is regulation mandatory, mandatory minimum? Could it compromise worker or environmental protection?
- EU and Turkey– Lists intended to focus on CMRs and sensitizers, some published classifications are mandatory, some are minimum classifications, classification based on best available data required if endpoint is not listed. Turkey list is very similar to EU, but slightly behind the EU in implementation timeline. Rationale for classifications readily accessible.
- China – Classifications are mandatory minimum classifications, rationale for classification not transparent.
- Japan – Classifications are not mandatory, some rationale for classifications included in NITE database.
- Korea – Both the Ministry of the Environment and Ministry of Labor have classification lists. Only the Ministry of the Environment has mandatory classifications based on product level concentrations.
- Malaysia – Very Small list of mandatory classifications.

Preferred Option for Classification

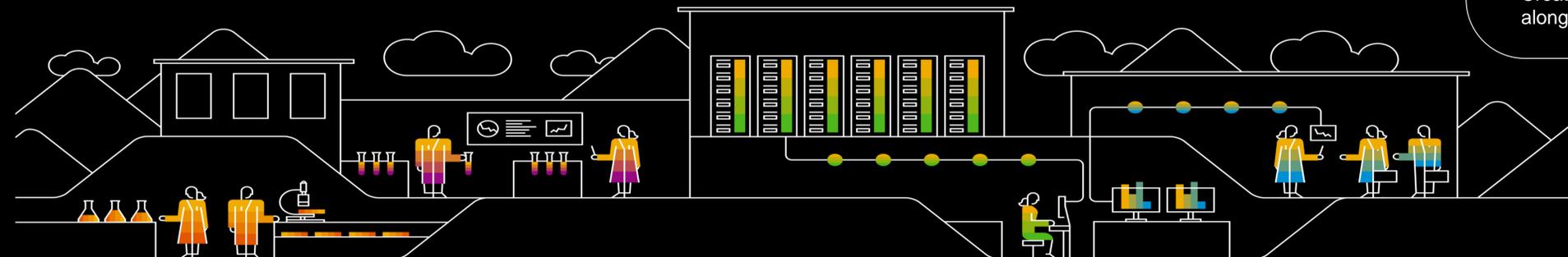
- Primary goal must be to ensure worker and environmental protections and also compliance with local regulatory requirements.
- Do not use non-mandatory classification data, where required and possible, treat list data as a minimum classification, and apply self classification when it is more stringent, where mandatory, use list-based classification only for required endpoints
- Data shows that many self classifications are more severe than list-based classifications. Under-classifying hazards could put workers at risk.
- Data shows that in all regions a significant number of self-classifications are missed by the lists.
- Most regions acknowledge that newer data may be available justifying a more severe classification and encourage self classification in these cases (mandatory minimum classifications)
- Some countries specify classification is mandatory, for some countries this is a gray area.
- Downstream users sometimes question why regulatory list data is not used when available.

Strategies to manage conflicts in mandatory classification vs. available data

Although the data in sections 11 and 12 should support the classification, it is possible to display both the data which supports the classification as well as the additional data supporting the self classification. Qualifying phrases such as, classification according to Annex VI or Mechanism of Action is not relevant for humans may help explain the differences.

Recommendations for first aid, fire-fighting, handling, storage, exposure controls and spills should be based on the best available scientific information.

- Create a local classification as required in the local regulations, based best available science, substituting only the mandatory or mandatory minimum classification when required.
- Create a global classification, covering all endpoints, using the lowest cut-offs for classification, and use this, along with phys chem data to develop precautions listed in sections 4, 5, 6, 7, 8 and 10 of the SDS.



THE BEST RUN

