

# Classification of hazardous chemicals according to the GHS

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**UNECE**

# Basic concepts

## Substance

**chemical elements and their compounds** in the natural state or obtained by any production process,

**including**

- any **additive** necessary to preserve the stability of the product and
- any **impurities** deriving from the process used,

but **excluding**

- **any solvent** which may be separated without affecting the stability of the substance or changing its composition

## Mixture

mixture or a solution composed of two or more substances in which they do not react

## Alloy

metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. In the GHS, alloys  $\approx$  mixtures

# Who classifies?



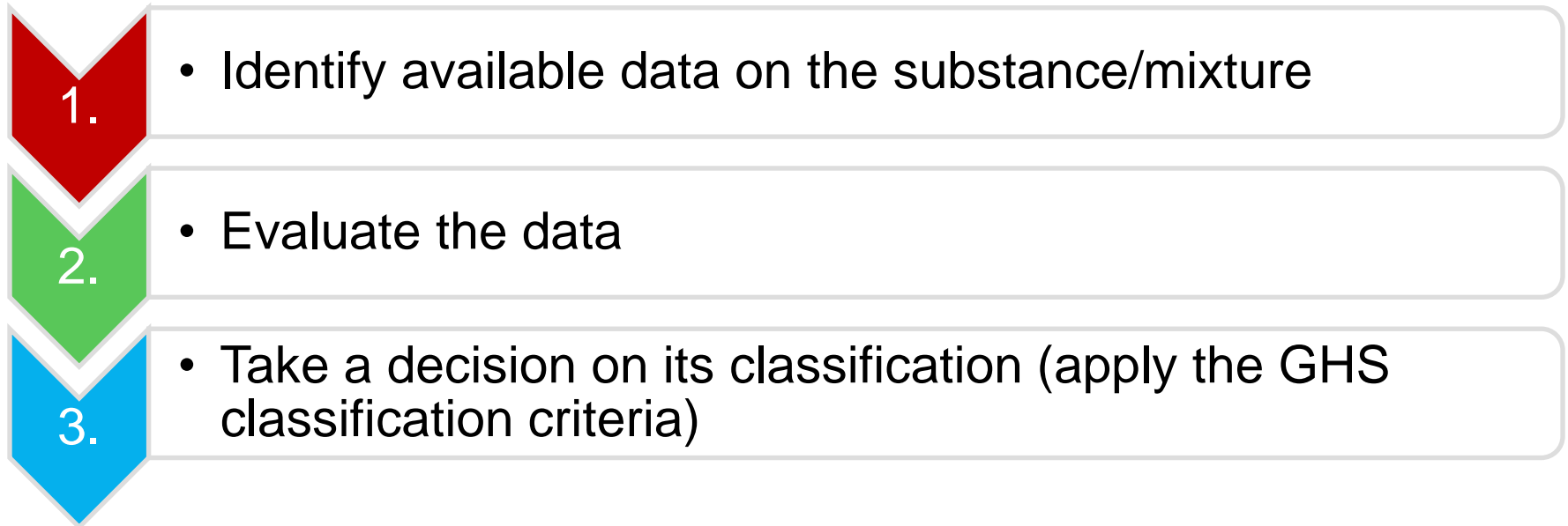
Manufacturers



Competent authorities  
(mandatory/voluntary classification)

# Classification process

3 steps



# Data identification

- Existing validated data:
  - From the manufacturer
  - From tests: *in vivo/in vitro*
  - Accidental exposure, clinical/epidemiologic studies...
  - Derived data:
    - Quantitative structure-activity relationships (QSAR) studies (e.g: “OECD Qsar toolbox for grouping chemicals”)
    - Bridging principles
    - Calculation methods
    - ...
- IF no validated and reliable data available, tests:
  - For physical hazards: those specified in the GHS
  - For health and environmental hazards: “test method neutral”



# Data identification


## Information sources

- GHS Sub-Committee secretariat (general information on GHS implementation worldwide with links to existing national/international databases)
- List of dangerous goods for transport
  - Part 3 United Nations Recommendations on the Transport of Dangerous Goods
- WHO recommended classification of pesticides by hazard
- International Programme on Chemical Safety
- OECD ChemPortal (links to more than 25 national/international databases)
- National/Regional databases:
  - European Union: Classification and labelling inventory (ECHA)
  - Japan: auto-classification tool
  - New Zealand: Chemical classification and information database
  - Republic of Korea: classification and labelling list of toxic chemicals
  - Australia: GHS hazardous chemical information list

# Data identification

## Information sources

### The Global Portal to Information on Chemical Substances

 **eChemPortal**

**eChemPortal** ▾

- > Home
- > Substance Search
- > Property Search
- > GHS Search
- > What's new?
- > General Information
- > Participating Databases**
- > Roles & Responsibilities
- > Linking to eChemPortal
- > Schedules of Assessments
- > Structure Search
- > GHS Classifications
- > Useful links
- > FAQ
- > How to search for information
- > Contact us
- > Disclaimer

### Participating Databases

- Databases currently participating in eChemPortal
- Data sources which can be found through a search by Property
- Data sources which can be found through a search by GHS classification
- Number of substance identity and endpoint records per participating source searchable through eChemPortal\*

### *Databases currently participating in eChemPortal*

- **ACToR**  
U.S. EPA Aggregated Computational Toxicology Resource
- **AGRITOX**  
AGRITOX - Base de données sur les substances actives phytopharmaceutiques
- **APVMA-CR**  
The Australian Pesticides and Veterinary Medicines Authority (APVMA) database of completed chemical reviews
- **CCR**  
Canadian Categorization Results
- **CESAR**  
Canada's Existing Substances Assessment Repository
- **Combined Exposures**  
Collection of Case Studies on Risk Assessments of Combined Exposures to Multiple Chemicals
- **ECHA C&L inventory**  
Public Classification and Labelling (C&L) Inventory according to the European Union (EU) CLP Regulation (EC) No 1272/2008
- **ECHA CHEM**  
European Chemicals Agency's Dissemination portal with information on chemical substances registered under REACH.
- **EFSA Open Food Tox**  
Chemical Hazards Database of the European Food Safety Authority
- **EnviChem**  
Data Bank of Environmental Properties of Chemicals
- **EPA HHBP**

# Data evaluation

Consider





# Data evaluation

## Quality

### Reliable?

- Was the data generated through validated and internationally recognized tests?
- Following Good Laboratory Practices? (GLP)

### Pertinent?

- Applicable to the subst./mixture in question?
- Referring to the form/state of the subst./mixture in question?

### Coherent?

- Is there contradictory information about the test results when coming from different sources?

### Enough?

- Are there enough data to classify the subst./mixture in question?

# Data evaluation

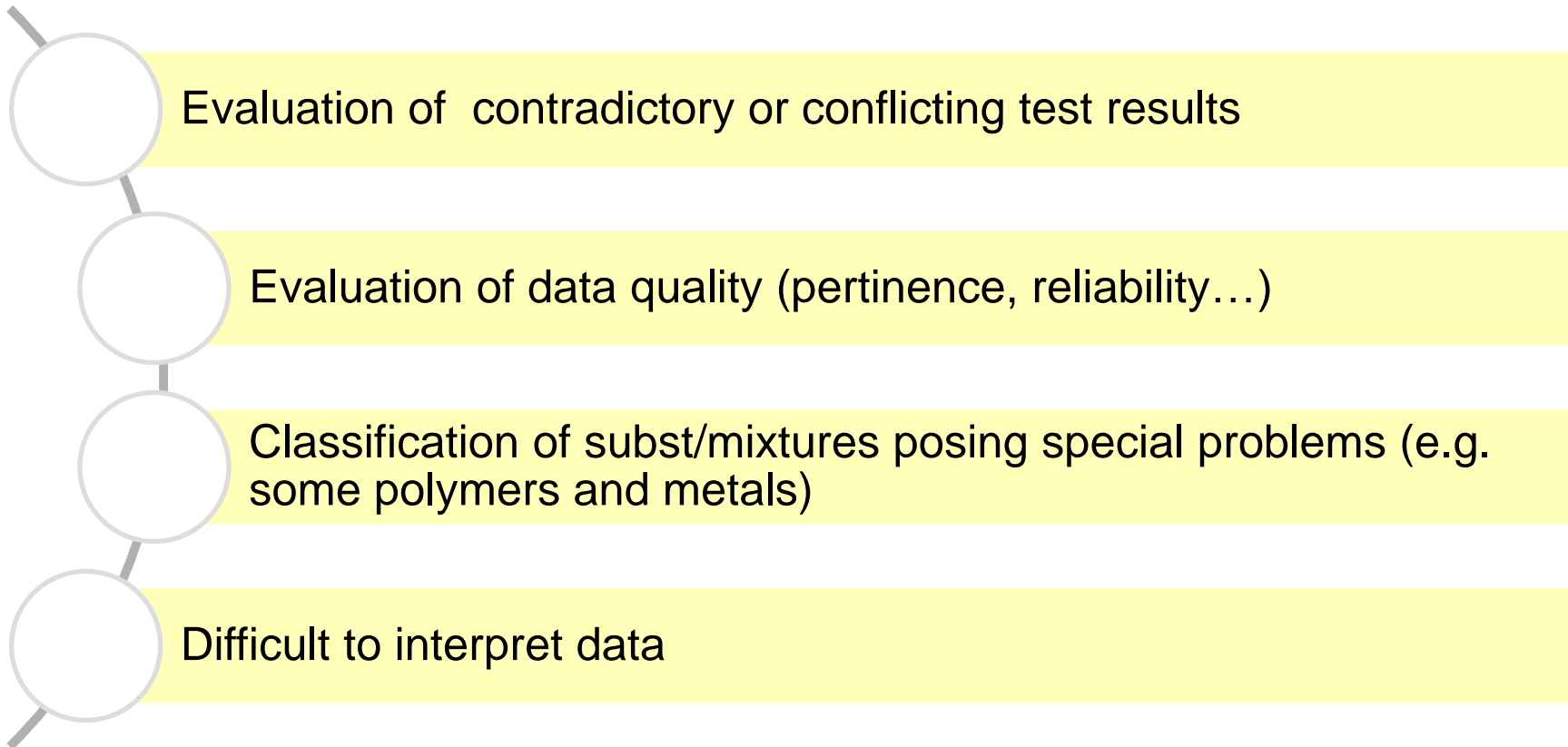
Weight of evidence

Consider all available information together

- Results of valid *in vivo/in vitro* tests
- Human experience
- Epidemiological/clinical studies
- Well-documented case reports and observations
- Relevant animal data
- Route of exposure
- Mechanistic information and metabolism studies
- Quality and consistency of data
- Test results (both positive and negative)

# Data evaluation

Expert judgement



# Classification

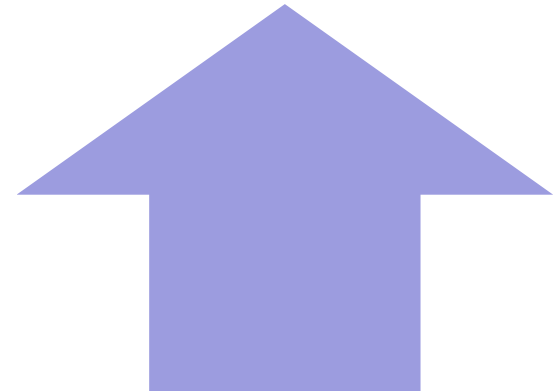


## Possible

Reliable data justify classification  
(hazard class? Hazard category?)  
Reliable data justify non-classification  
(Non-hazardous subst/mixture)



**Not possible**  
No data available  
Data not reliable



# Classification of mixtures: tiered approach

## 1. Data on the mixture as a whole?

- YES: apply classification criteria
- NO: go to the next step

## 2. Data on similar mixtures and individual ingredients of the mixture?

- YES: Apply bridging principles (dilution, batching, interpolation...)
- NO (or bridging principles not applicable): go the next step

## 3. Data on all or some of the ingredients of the mixture?

- YES: Classify based on cut-off values/concentration limits, additivity principle, calculation methods..., as specified in GHS for the relevant hazard class
- NO: Classification is not possible with the available data  
*Further information on the mixtures or its ingredients is needed*

# Decision on classification and labelling

Does the subs/mixture meet the GHS classification criteria?

- Assign hazard class/category accordingly

Hazard communication elements

- Assign in accordance with the identified hazards
- Respect precedence rules (e.g. signal words )
- Ensure compatibility with labelling for transport of dangerous goods





# Revision of classification and labelling

- When new information on the subst/mixture is available
- When the manufacturer/provider modifies the composition
  - Changes in concentration
  - Replacement or addition of ingredients
  - Significant variations between production batches

# Thank you!



<http://www.unece.org/trans/danger/danger.htm>