

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?



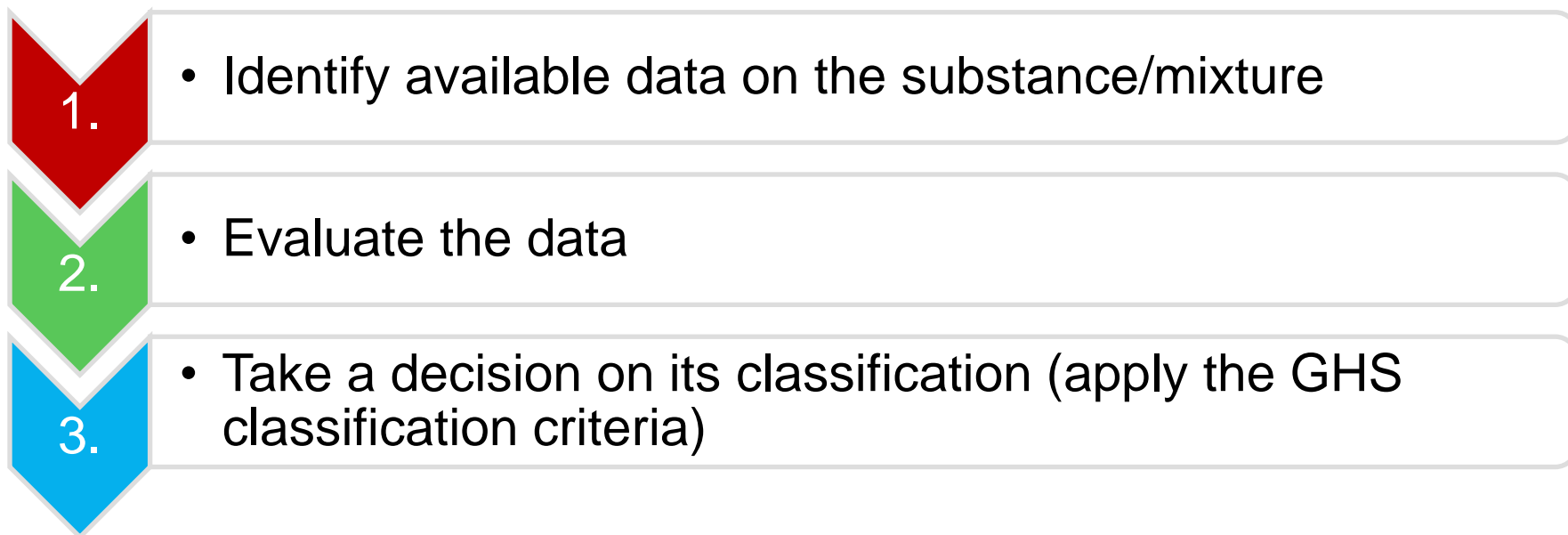
Manufacturers



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

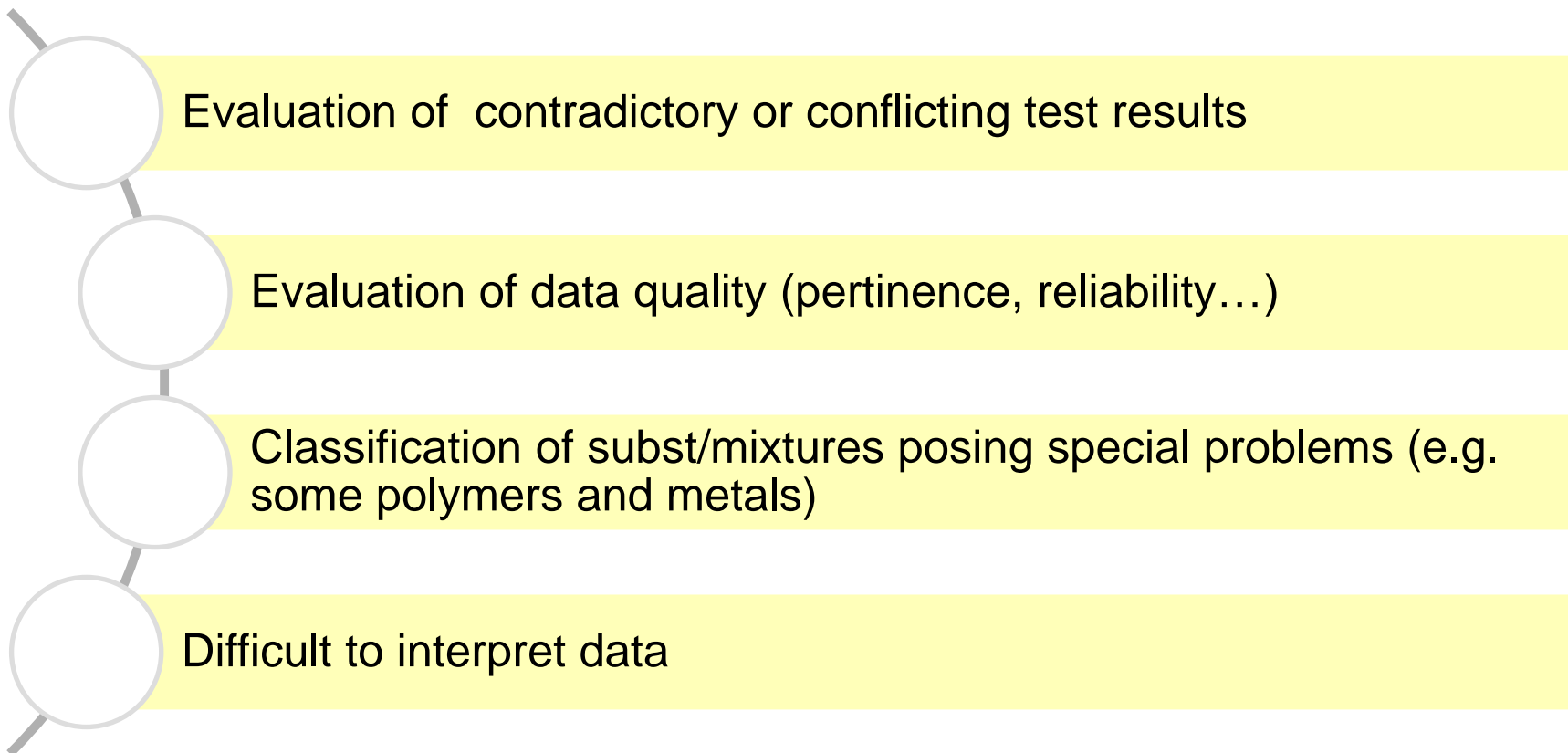
Weight of evidence

Consider all available information together

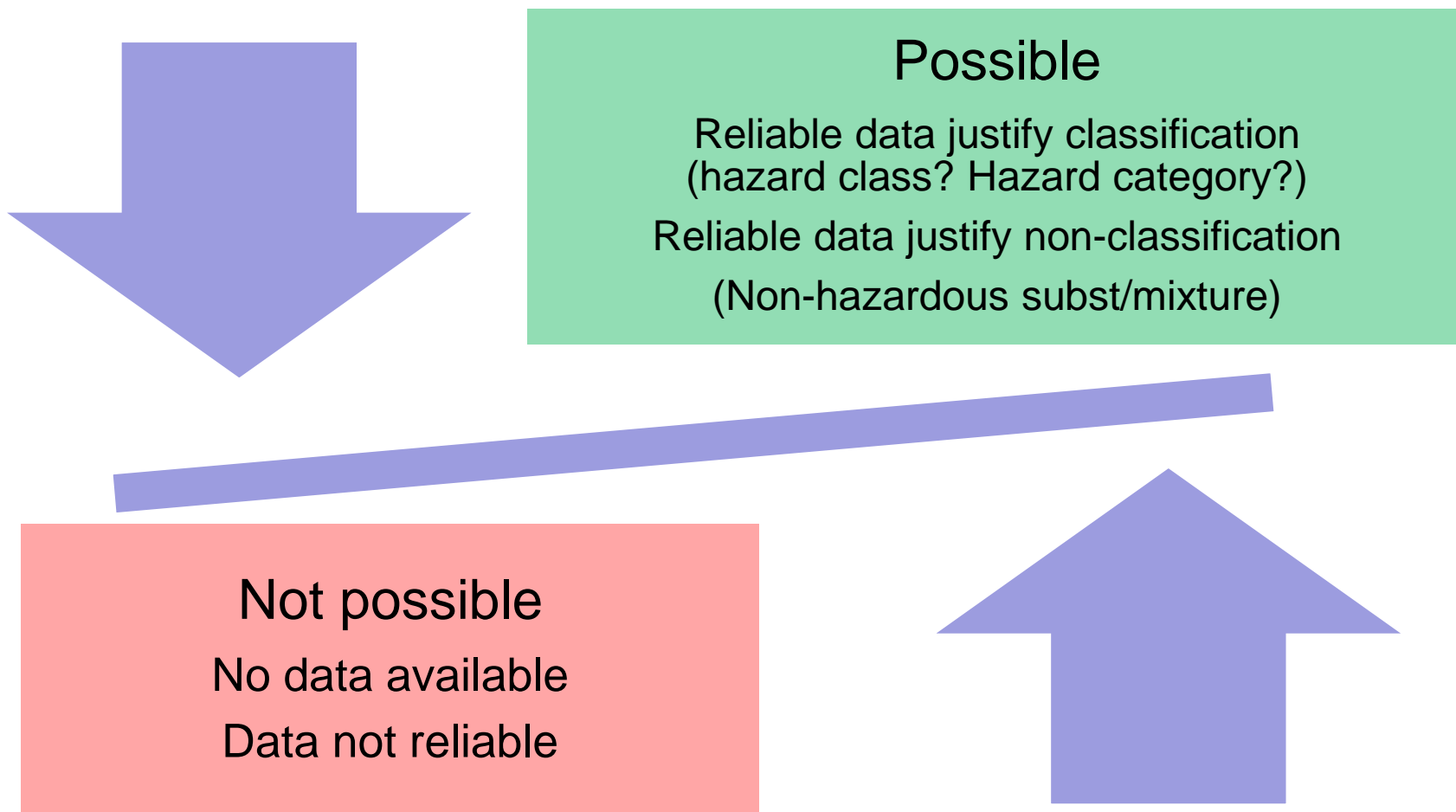
- Results of valid *in vivo/in vitro* tests
- Human experience
- Epidemiological/clinical studies
- Well-documented case reports and observations
- Relevant animal data
- Route of exposure
- Mechanistic information and metabolism studies
- Quality and consistency of data
- Test results (both positive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

Data evaluation

Expert judgement



Classification



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>