

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 ≈ mixtures

Who classifies?



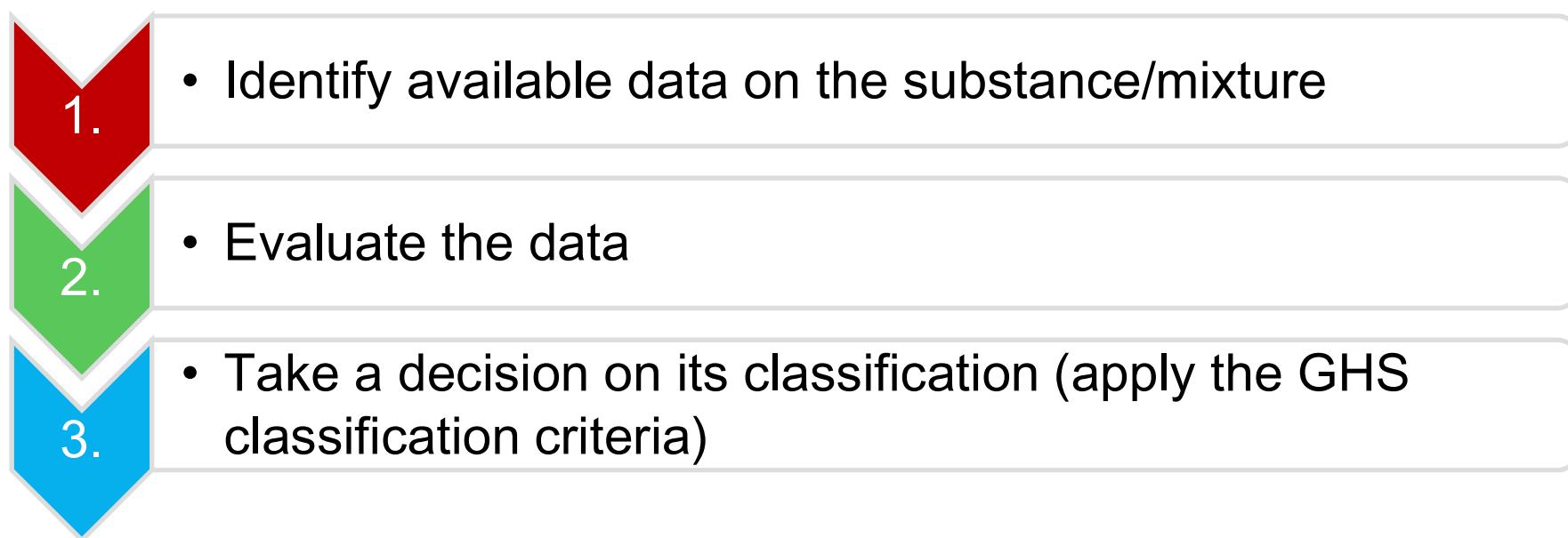
Manufacturers



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 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

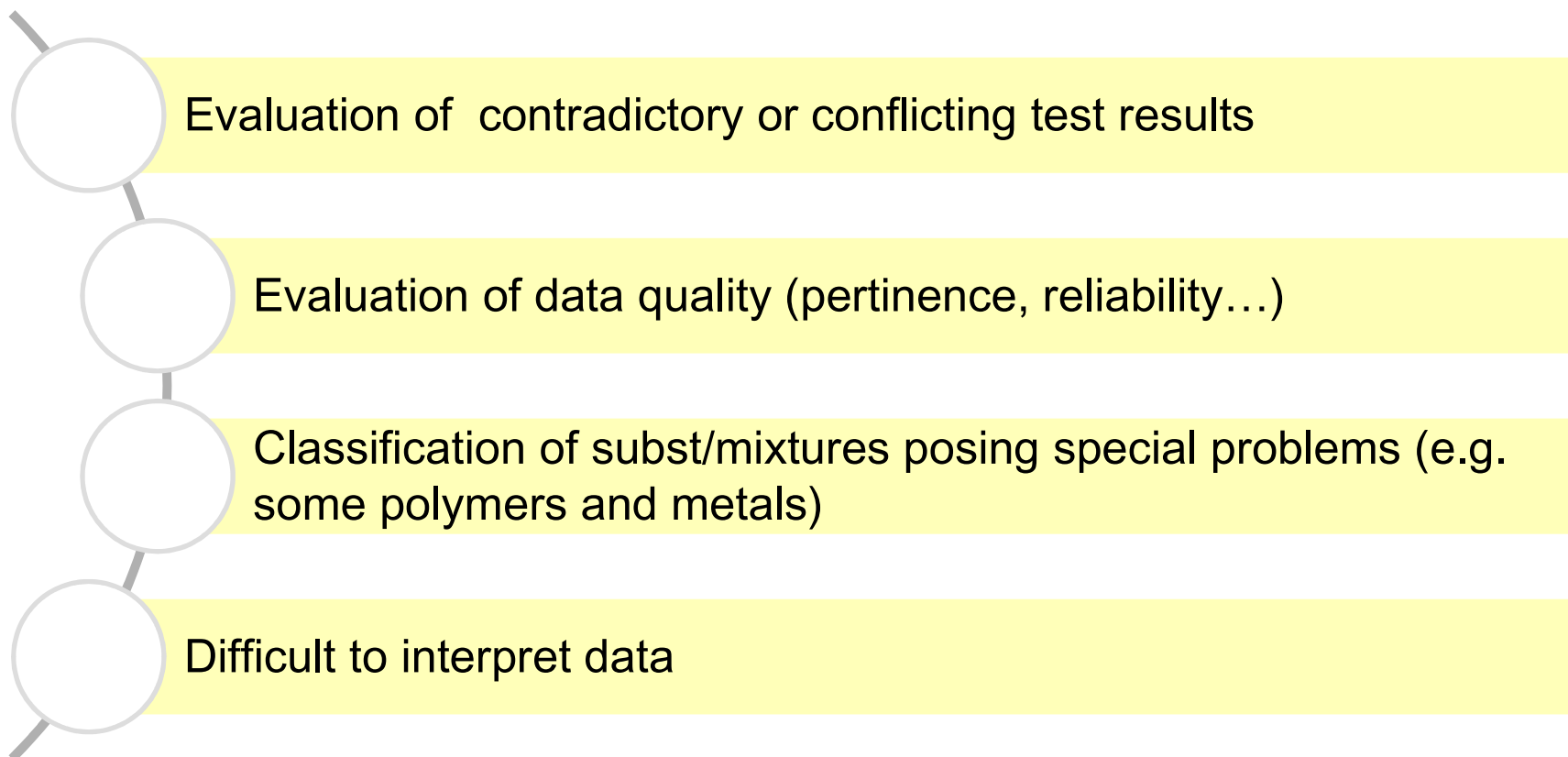
Weight of evidence

Consider all available information together

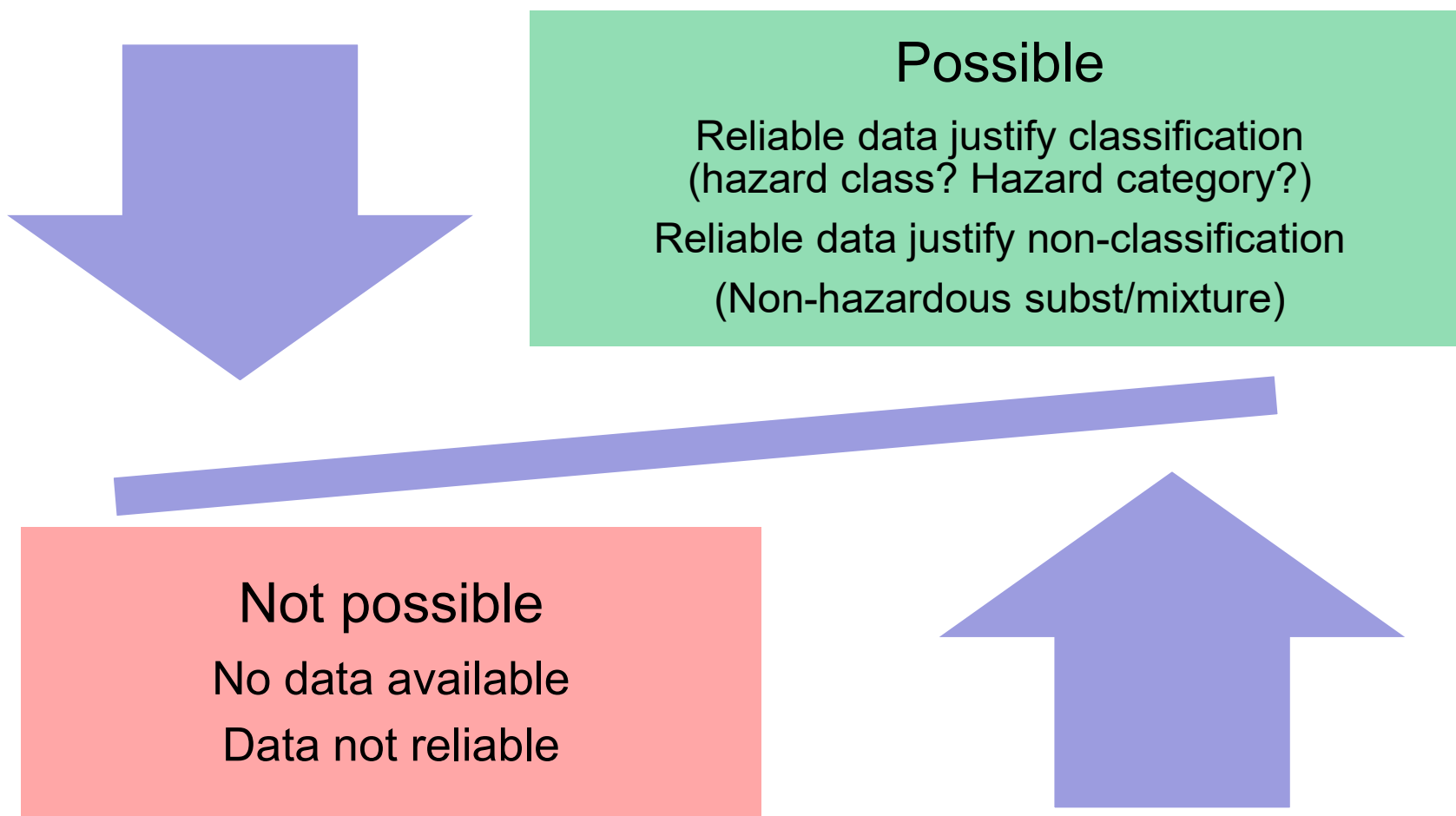
- Results of valid *in vivo/in vitro* tests
- Human experience
- Epidemiological/clinical studies
- Well-documented case reports and observations
- Relevant animal data
- Route of exposure
- Mechanistic information and metabolism studies
- Quality and consistency of data
- Test results (both positive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

Classification of mixtures

Example of application of the additivity principle

Serious eye damage

Sum of ingredients classified as	Concentration triggering classification of a mixture as	
	Serious eye damage	Eye irritation
	Category 1	Category 2/2A
Skin Category 1 + Eye Category 1 ^a	≥ 3%	≥ 1% but < 3%
Eye Category 2		≥ 10% ^b
10 × (skin Category 1 + eye Category 1) ^a + eye Category 2		≥ 10%

^a If an ingredient is classified as both skin Category 1 and eye Category 1 its concentration is considered only once in the calculation;

^b A mixture may be classified as eye Category 2B when all relevant ingredients are classified as eye Category 2B.

If the sum of the ingredients classified in Cat.2 (eyes) ≥ 10%, the mixture is classified as Cat.2 (eyes)

Classification of mixtures

classification when the additivity principle is NOT applicable

Carcinogenicity

Ingredient classified as:	Cut-off/concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	$\geq 0.1\%$	--	--
Category 1B carcinogen	--	$\geq 0.1\%$	
Category 2 carcinogen	--	--	$\geq 0.1\%$ (note 1)
			$\geq 1.0\%$ (note 2)

If at least one of the ingredients of the mixture classified as Cat.1A or Cat. 1B is present in the mixture at a concentration $\geq 0.1\%$, the whole mixture is classified as Cat.1

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



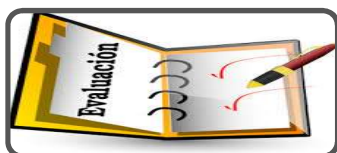
Revision of classification and labelling

- 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

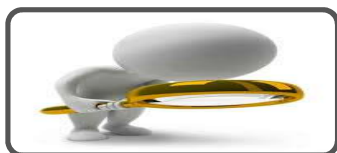
Classification procedure (summary)



Compile data



Evaluate/examine data



Apply classification criteria



Take a decision on classification



Revise and validate classification result

Thank you!



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