REACH

Chemical Safety Assessment (CSA)

Dinant Kroese

TNO Quality of Life
Zeist, The Netherlands

CONTENTS

1. Registration requirements:

1. A Technical Dossier ≥ 1 tonne/y
2. A Chemical Safety Report ≥ 10 tonnes/y

Format of the Technical Dossier

- identity of the Manufacturer / Importer
- identity of the substance
- information on its manufacture and use
- the classification and labeling of the substance
- guidance on its safe use
- (robust) study summaries of the information on the intrinsic properties of the substance derived from applying *Annexes VII* to *XI*
- an indication as to whether the above issues and/or, if relevant, the Chemical Safety Report (→) has been reviewed by an assessor
- proposals for further testing, if relevant
- between 1 and 10 tonnes, the Techical Dossier shall also contain exposure related information for the substance (main use categories, type of uses, significant routes of exposure).

Simplified format of the Chemical Safety Report

Part A Summary of risk management measures

Declaration that risk management measures are implemented

Declaration that risk management measures are communicated

Part B Identity of the substance and physical and chemical properties

Manufacture and uses

Classification and labelling

Environmental fate properties

Human health hazard assessment

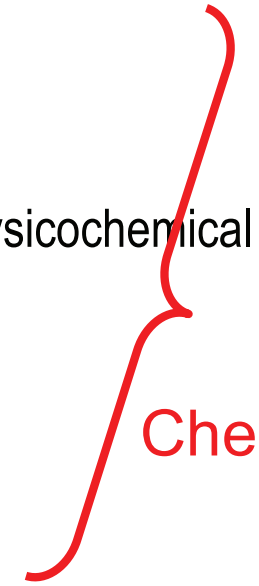
Human health hazard assessment of physicochemical properties

Environmental hazard assessment

PBT and vPvB assessment

Exposure assessment

Risk characterization



Chemical Safety Assessment

2. Core tools under REACH

- The Chemical Safety Assessment is the tool used to ***determine*** the safety of the chemical
- The Chemical Safety Report is the tool used to ***record/document*** the assessment to EChA
- The Safety Data Sheet is the tool used to ***communicate*** safe use to downstream users (DU)

Aim of the Chemical Safety Assessment:

To establish the safe conditions of manufacture and use of a substance for all life-cycle[1] stages.

Manufacturers/Importers/Downstream Users:

have to ensure that the manufacture and use is in such a way that human health and the environment are not adversely affected.

[1] on their own or in preparations or in articles

Chemical Safety Assessment should describe:

1. The intrinsic properties of the substance
   - Human Health (Physico-chemical) hazards
   - Environmental Health hazards
   - PBT & vPvB properties
2. All manufacturing and use scenarios

PBT = Persistent, Bioaccumulating and Toxic,
vPvB = very Persistent, and very Bioaccumulating

Note:

If

the substance meets the criteria for classification as dangerous[1] or is assessed to be PBT or vPvB,

then

the Chemical Safety Assessment has to include an exposure assessment for one or more exposure scenario(s), exposure estimation and risk characterization.

[1] i.e. labeled with any R sentence

Chemical Safety Assessment should describe:

1. The intrinsic properties of the substance

   HH (PC) hazards

   ENV hazards

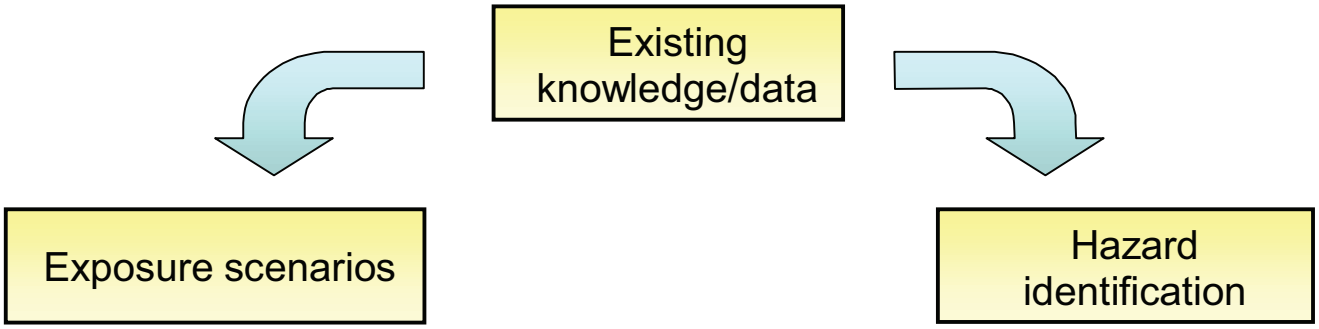
   PBT & vPvB properties

2. All manufacturing and use scenarios

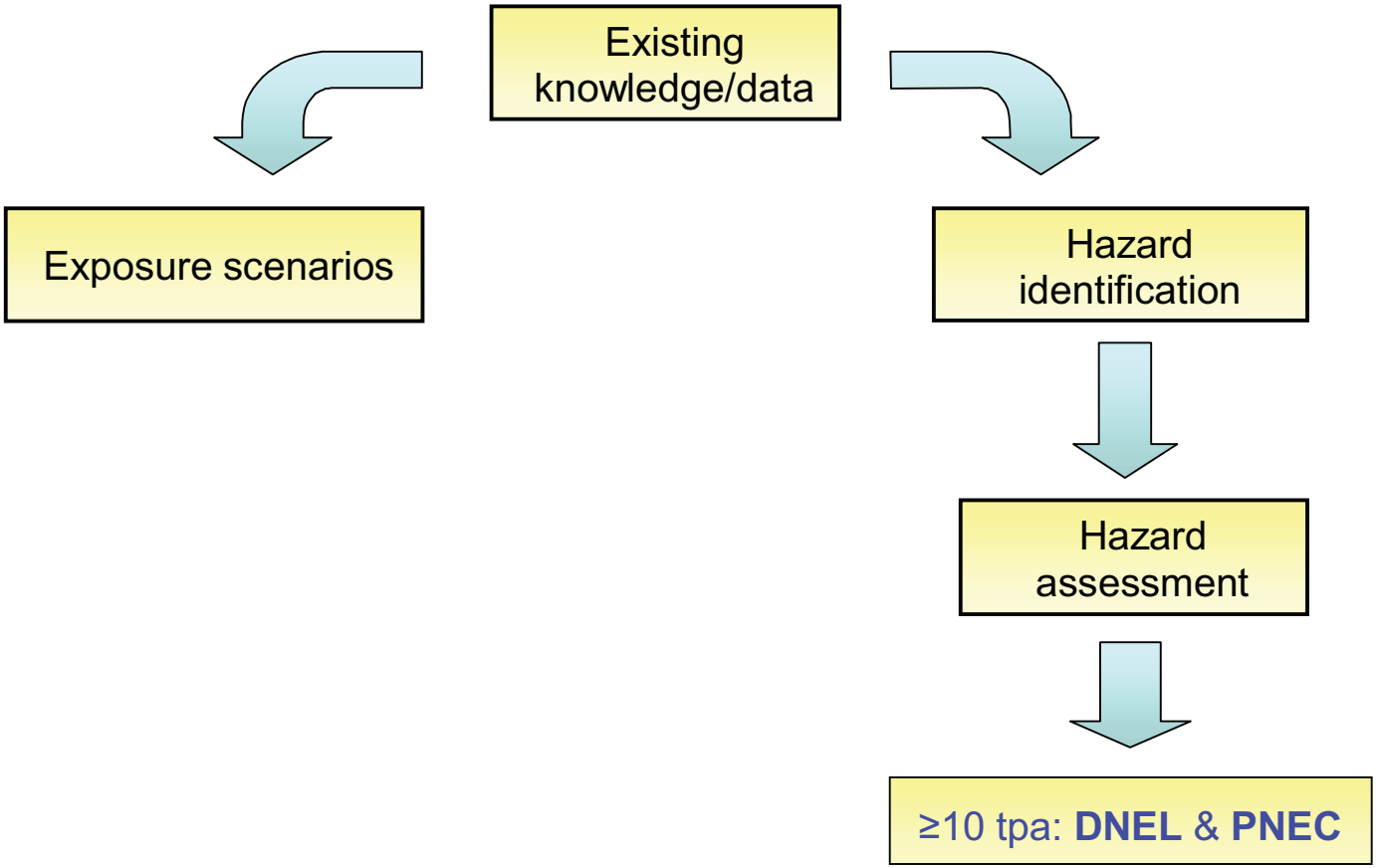
3. Risk Characterisation:

   comparison of *ad 1.* with exposures of *ad 2.* (of scenarios, including RMM),
   showing safe manufacture & safe use

CSA:

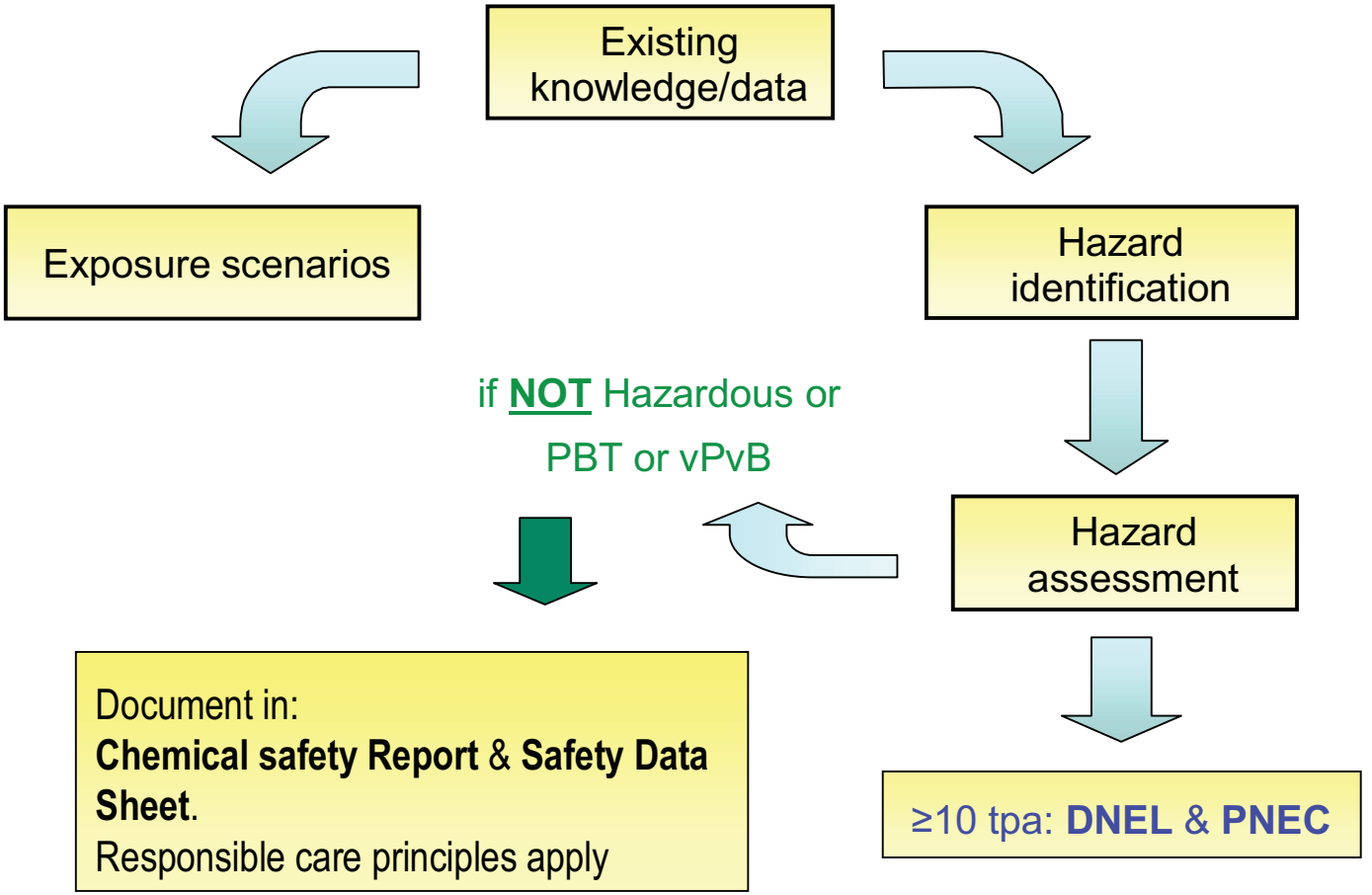

Existing knowledge/data
Exposure scenarios
Hazard identification

CSA:

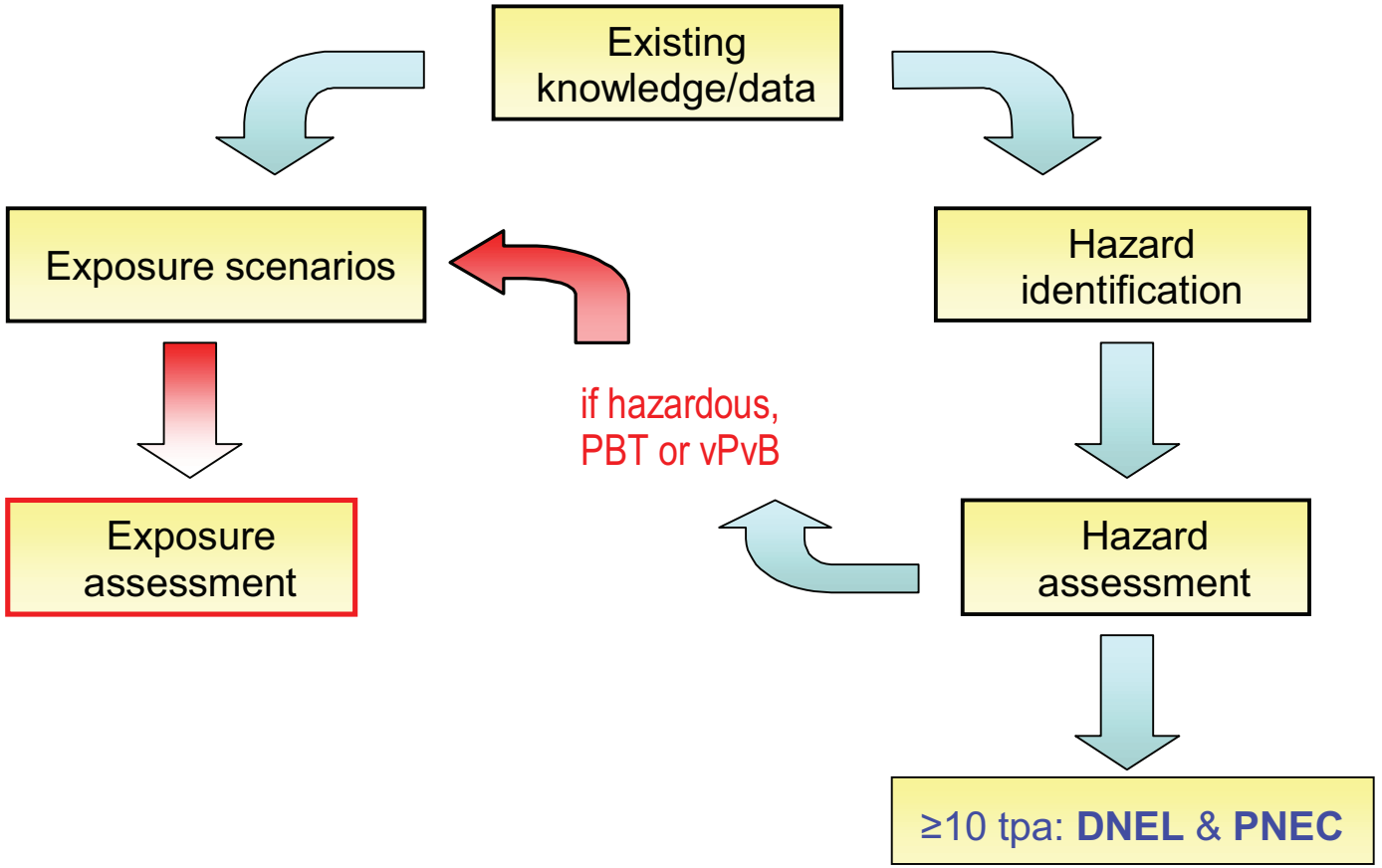


DNEL: Derived No Effect Level; **PNEC**: Predicted No Effect Concentration

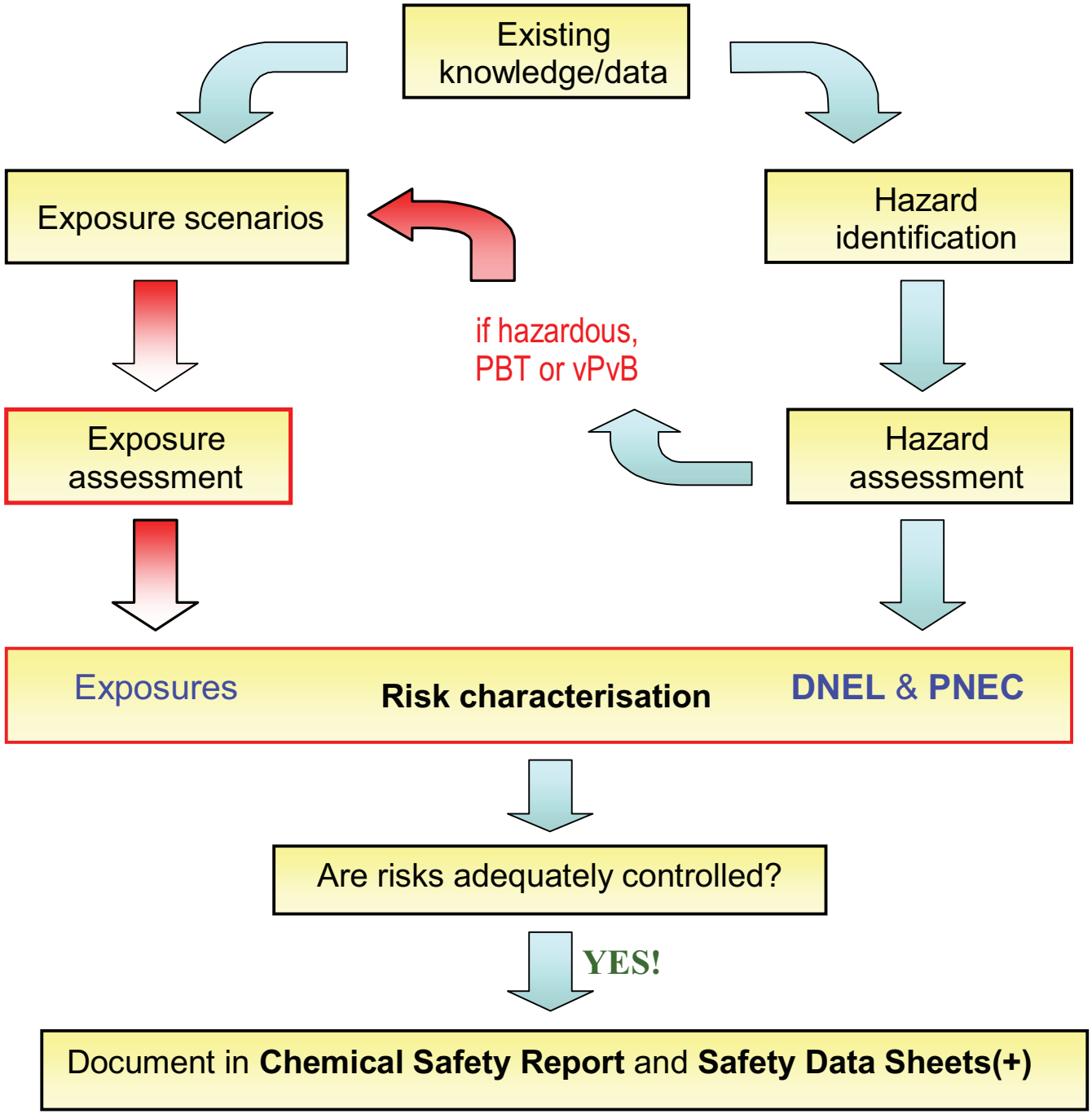
CSA:


Existing knowledge/data
Exposure scenarios
Hazard identification
if **NOT** Hazardous or PBT or vPvB
Hazard assessment
Document in:
Chemical safety Report & **Safety Data Sheet**.
Responsible care principles apply
≥10 tpa: **DNEL** & **PNEC**

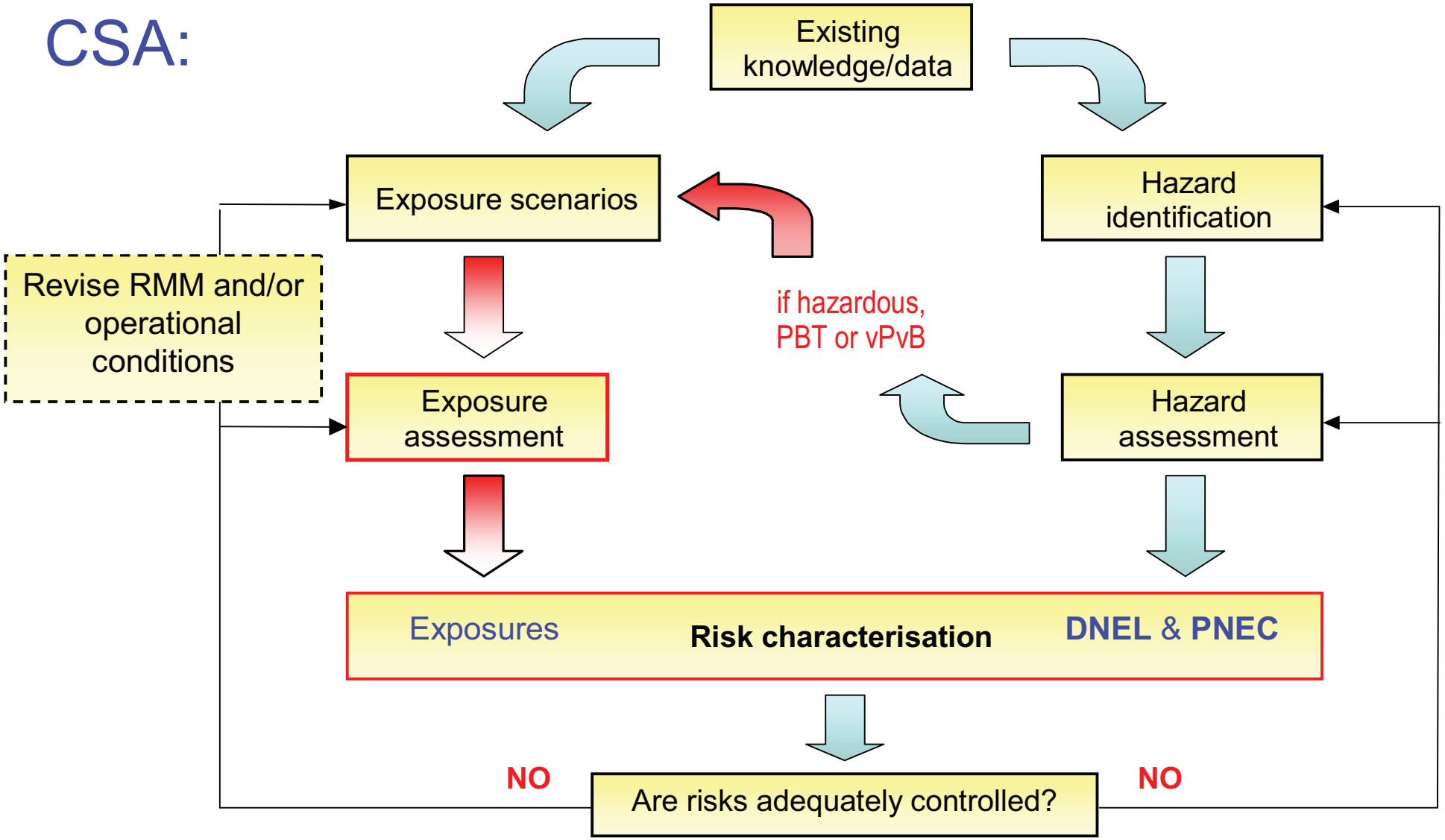
CSA:


Existing knowledge/data
Exposure scenarios
Hazard identification
if hazardous, PBT or vPvB
Exposure assessment
Hazard assessment
≥10 tpa: DNEL & PNEC

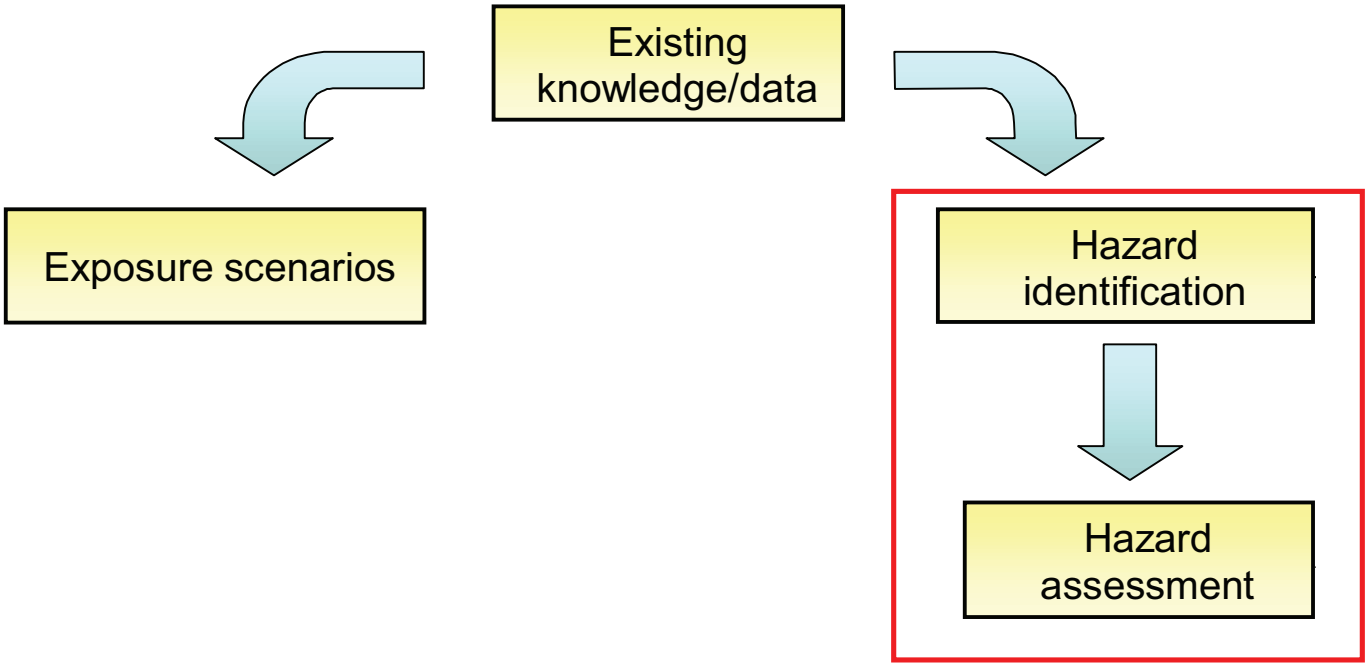
CSA:


Existing knowledge/data
Exposure scenarios
Hazard identification
if hazardous, PBT or vPvB
Exposure assessment
Hazard assessment
Exposures
Risk characterisation
DNEL & PNEC
Are risks adequately controlled?
YES!
Document in Chemical Safety Report and Safety Data Sheets(+)

CSA:


Existing knowledge/data
Exposure scenarios
Hazard identification
Revise RMM and/or operational conditions
if hazardous, PBT or vPvB
Exposure assessment
Hazard assessment
Exposures
Risk characterisation
DNEL & PNEC
NO
Are risks adequately controlled?
NO

CSA:


Existing knowledge/data
Exposure scenarios
Hazard identification
Hazard assessment

CSA / **describe** intrinsic properties

of the substance

1. Human health hazard assessment
2. Human health hazard assessment of phys-chem properties
3. Environmental hazard assessment
4. PBT and vPvB assessment

CSA / describe intrinsic properties

Objectives:

1. Human health hazard assessment
    1. determine Classification & Labeling in accordance with 67/548/EEC
    2. derive Derived No Effect Level (DNEL)
2. Human health hazard assessment of phys-chem properties
3. Environmental hazard assessment
4. PBT and vPvB assessment

CSA / describe intrinsic properties

Objectives:

1. Human health hazard assessment
2. Human health hazard assessment of phys-chem properties
    1. determine Classification & Labeling in accordance with 67/548/EEC
3. Environmental hazard assessment
4. PBT and vPvB assessment

CSA / describe intrinsic properties

Objectives:

1. Human health hazard assessment
2. Human health hazard assessment of phys-chem properties
3. Environmental hazard assessment
    1. determine Classification & Labeling in accordance with 67/548/EEC
    2. derive Predicted No Effect Concentration (PNEC)
4. PBT and vPvB assessment

CSA / describe intrinsic properties

Objectives:

1. Human health hazard assessment
2. Human health hazard assessment of phys-chem properties
3. Environmental hazard assessment
4. PBT and vPvB assessment
    1. determine if criteria Annex XIII are fulfilled
    2. if yes: characterize emission potential

CSA / **evaluate** intrinsic properties

1. Human health hazard assessment
2. Human health hazard assessment of phys-chem properties
3. Environmental hazard assessment
4. PBT and vPvB assessment

Same basic approach for all 4 assessments:

CSA / evaluate intrinsic properties

(Annex VI)

1. Gather and share available information
2. Consider information needs
3. Identify information gaps
4. Generate new data / propose testing strategy

CSA / evaluate intrinsic properties

1. Gather and share available information

All Available Health & Environmental Information:

- physico-chemical data

- human data

- *in vitro* / *in vivo* data

-read-across, SAR, QSAR

&

Exposure characteristics

CSA / evaluate intrinsic properties

1. Gather and share available information
2. Consider information needs

- ≥ 1 tpa : Annex VII
- ≥ 10 tpa : Annex VIII:
- ≥ 100 tpa : Annex IX:
- ≥ 1000 tpa : Annex X:

} Annex XI

CSA / evaluate intrinsic properties

1. Gather and share available information
2. Consider information needs
3. Identify information gaps

Conclude on whether information is adequate to:

Assess:

Classification & Labeling,

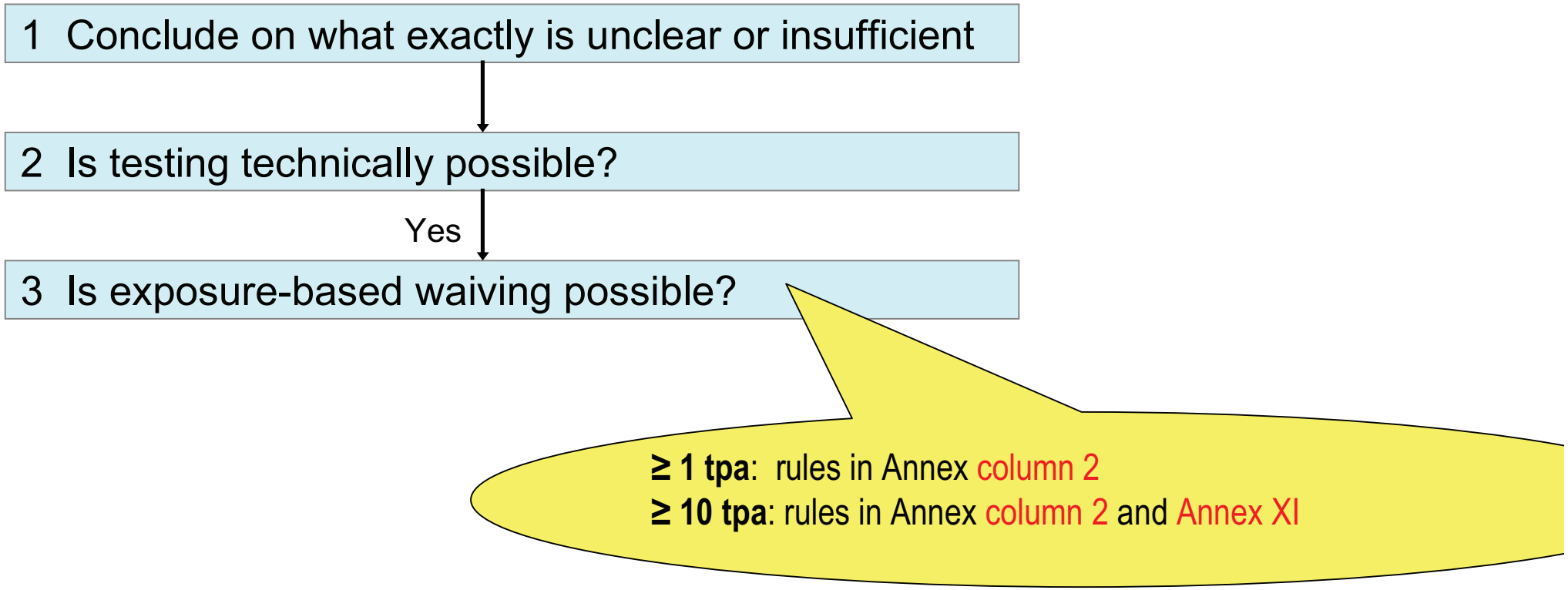
PBT, vPvB

Allow the derivation of:

DNEL and PNEC

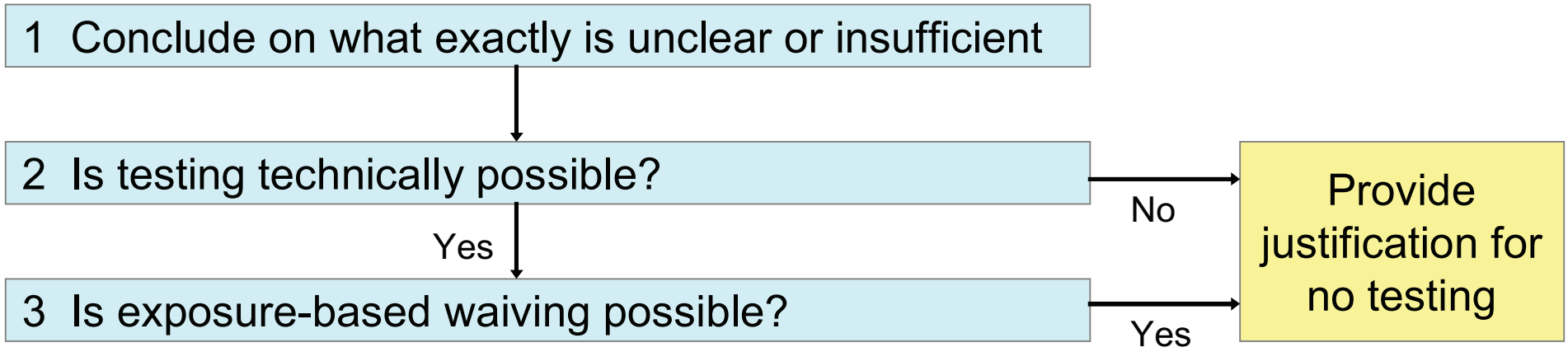
CSA / evaluate intrinsic properties

1. Gather and share available information
2. Consider information needs
3. Identify information gaps
4. Generate new data / propose testing strategy



CSA / evaluate intrinsic properties

1. Gather and share available information
2. Consider information needs
3. Identify information gaps
4. **Generate new data / propose testing strategy**



CSA / evaluate intrinsic properties

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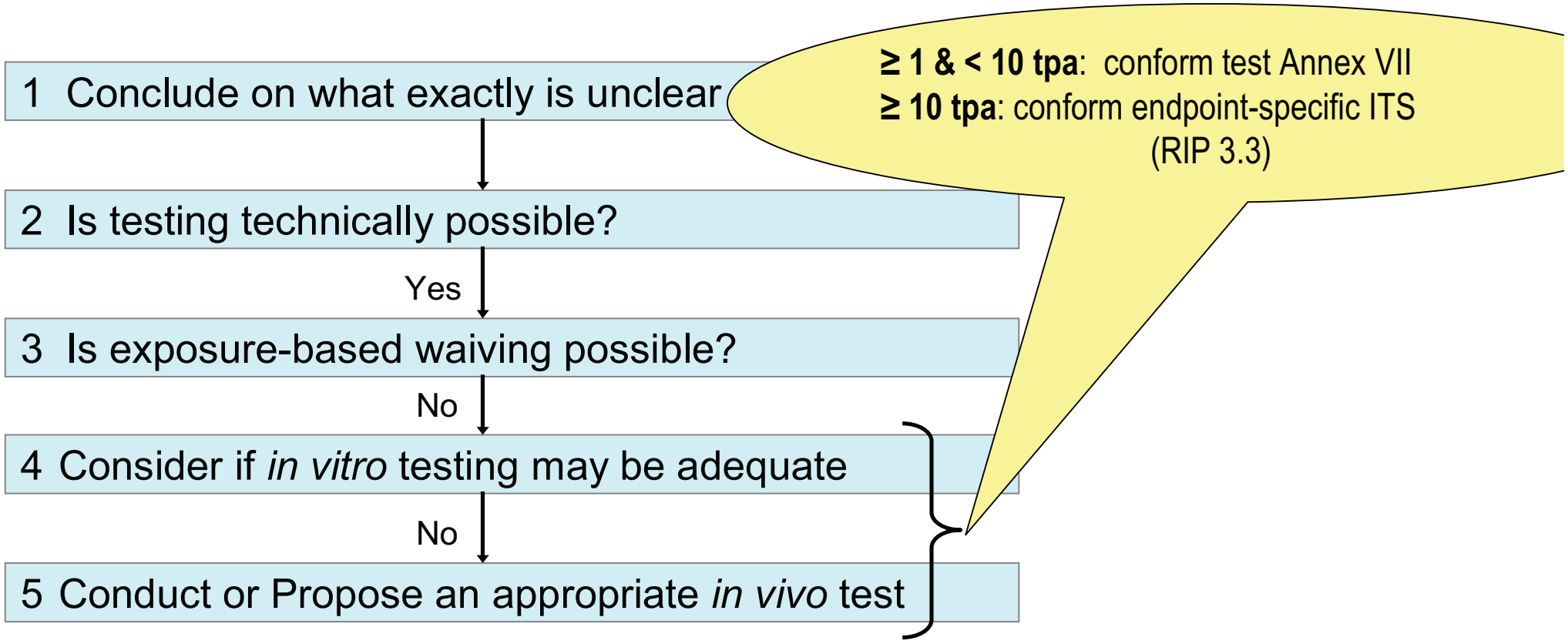
4. Generate new data / propose testing strategy



CSA / evaluate intrinsic properties

1. Gather and share available information
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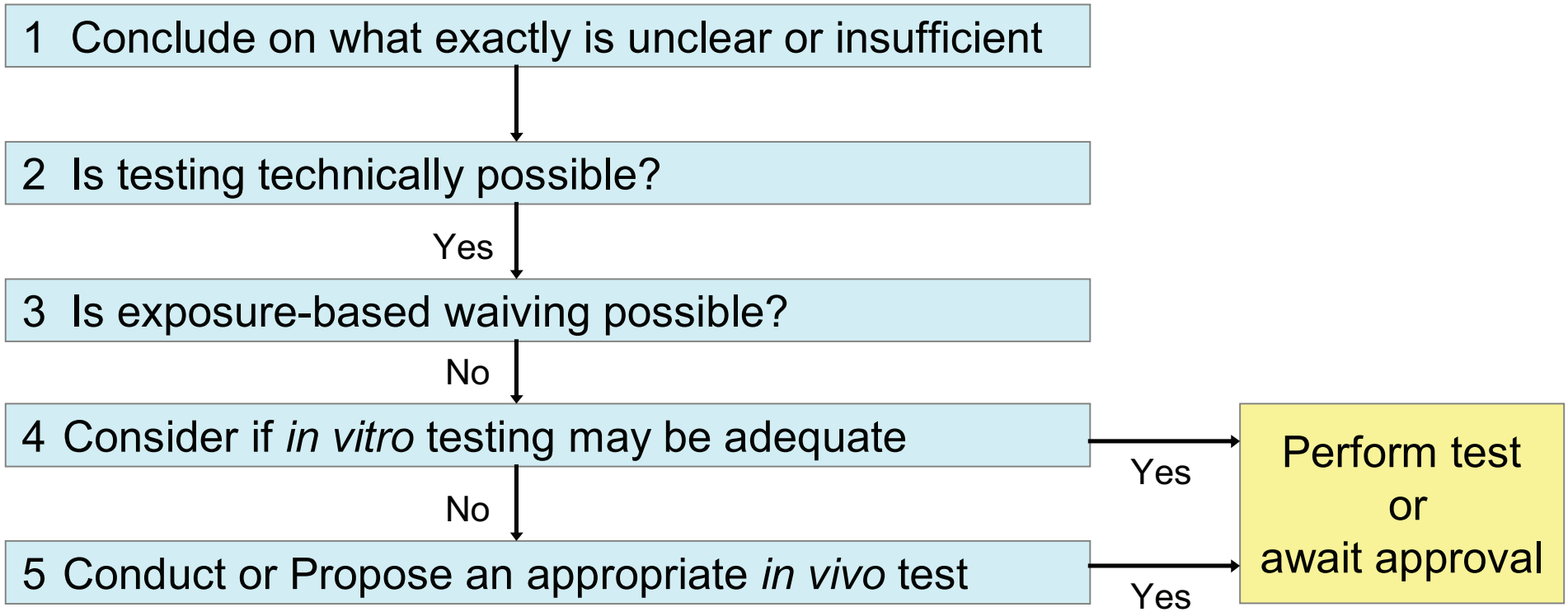
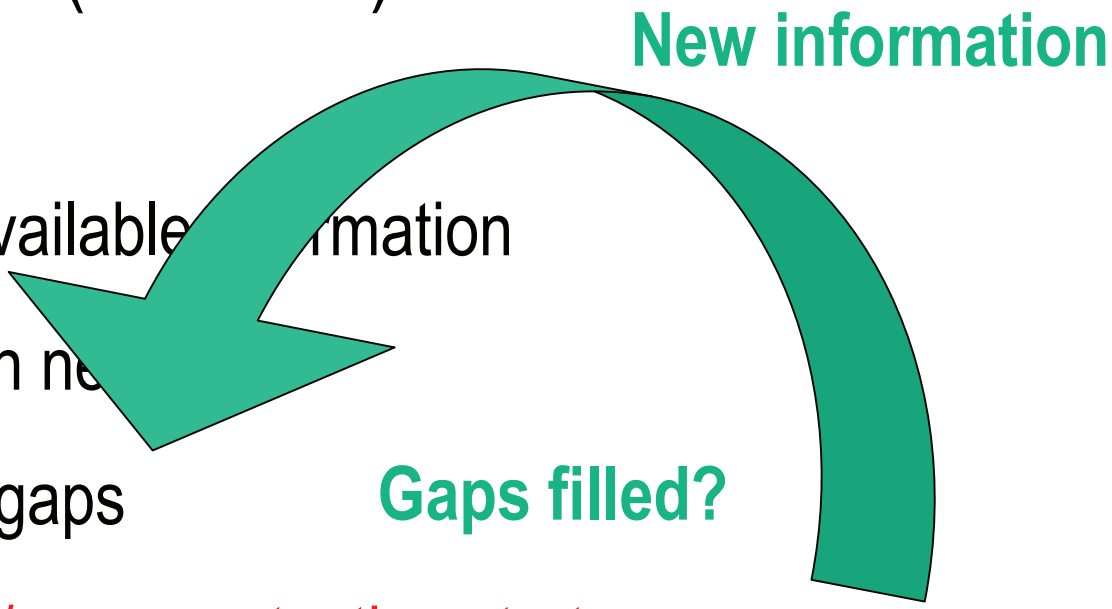
4. Generate new data / propose testing strategy



CSA / evaluate intrinsic properties

(Annex VI)



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2. Consider information ne
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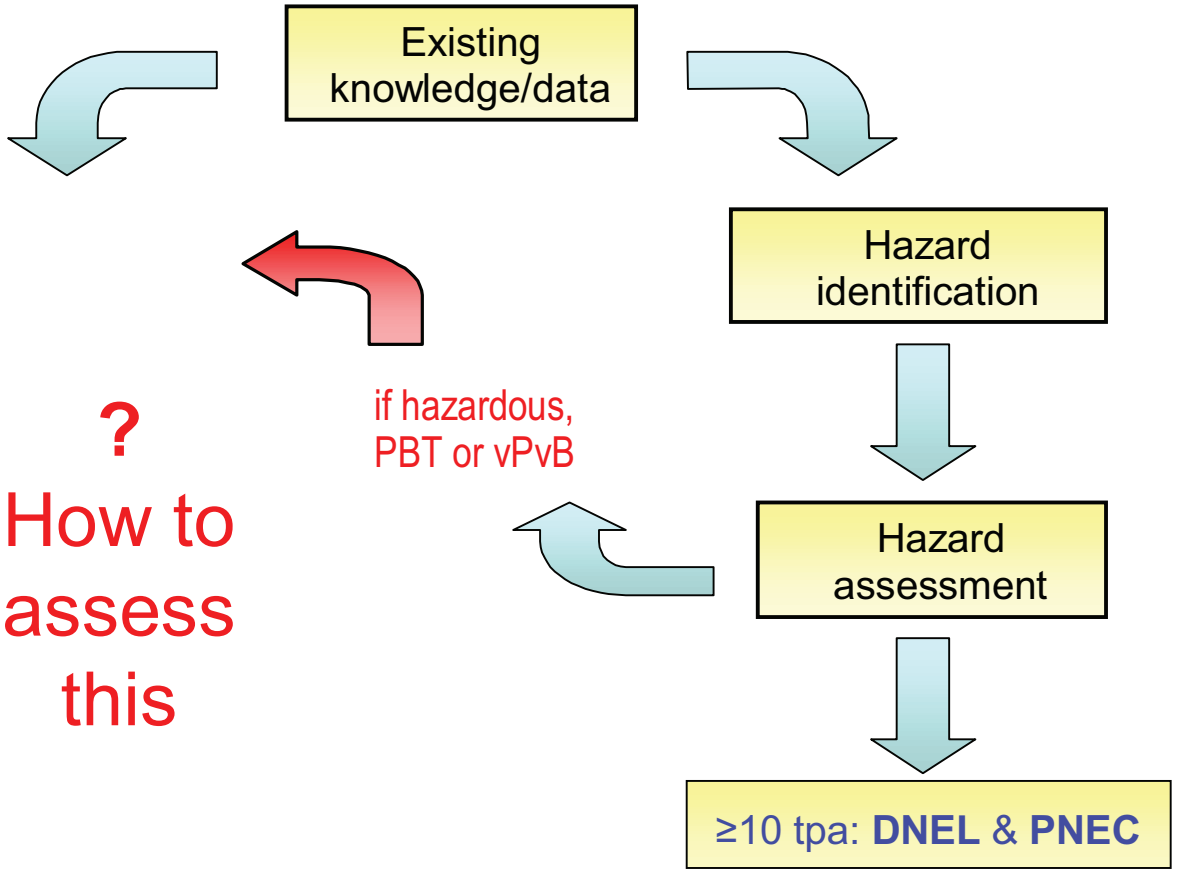
CSA:


Existing knowledge/data
Hazard identification
Hazard assessment
≥10 tpa: DNEL & PNEC
if hazardous, PBT or vPvB
?
How to assess this

Hazardous?

Apply Classification & Labeling Criteria

in accordance with Dir 67/548/EEC

REACH  RIP 3.6 [1]

Globally Harmonised System

of Classification and Labeling of Chemicals

(GHS)

(reclassification deadline December 1st 2010)

[1] **not yet started**

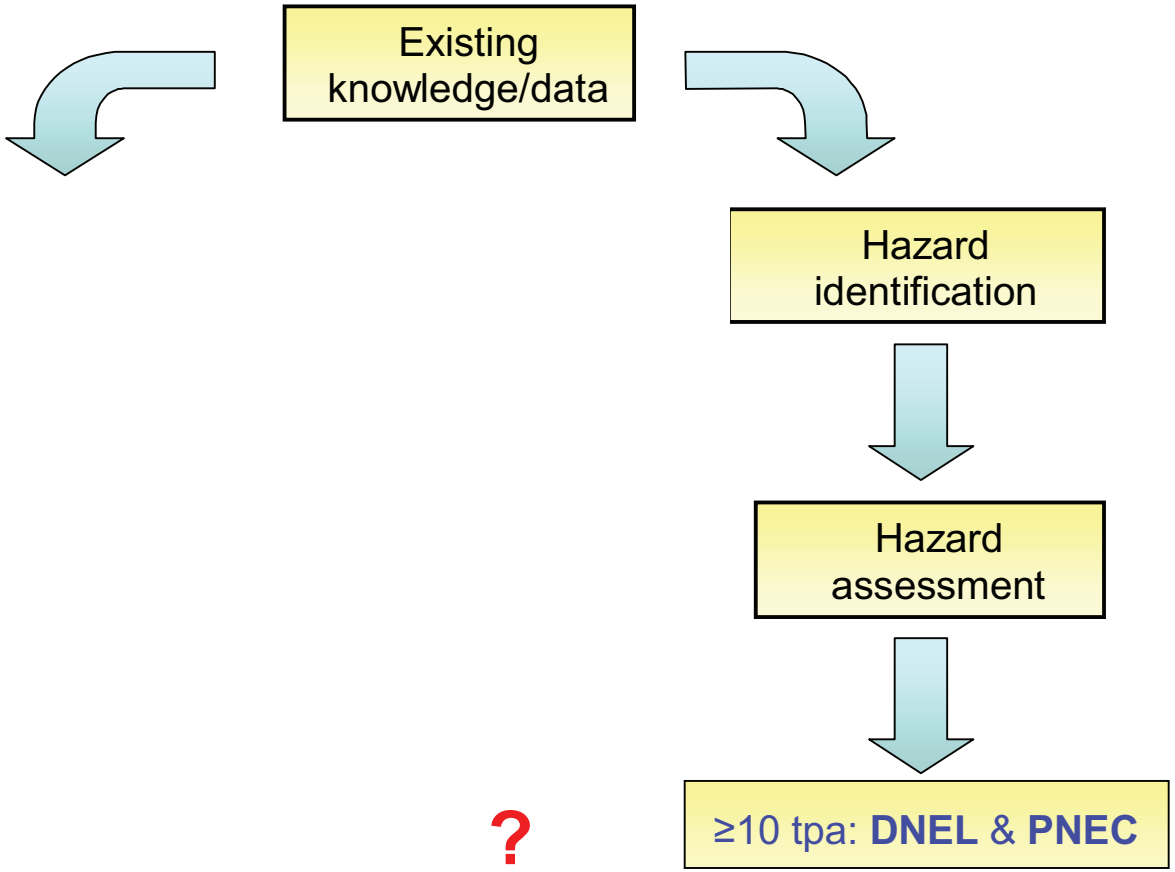
PBT or vPvB ?

Apply assessment criteria: [1]

Parameter	PBT criteria	vPvB criteria
P	Half-life: > 60 d in marine water, or > 40 d in fresh- or estuarine water, or > 180 d in marine sediment or > 120 d in fresh- or est. sediment, or > 120 d in soil	Half-life: > 60 d in marine, fresh- or estuarine water, or >180 d in marine, fresh- or estuarine sediment > 180 d in soil
B	BCF > 2000	BCF >5000
T	Chronic NOEC < 0.01 mg/l or **C** (cat. 1, 2) **M** (cat. 1, 2) **R** (cat. 1-3) or ED-effects T-R48 or Xn-R48	*Not applicable*

[1] developed by TGD RIP 3.2

CSA:



?

How to assess these

DNEL derivation

$$\text{DNEL} = \frac{\text{NOAEL}}{\text{Overall}^{1}\text{Assessment factor}} \quad \textit{(lowest)}$$

NOAEL (**N**o **O**bserved **A**dverse **E**ffect **L**evel) from Repeated Dose Toxicity studies (28-day, 90-day, 2-year) or Reproductive Toxicity studies

Assessment Factor (AF) are to address various uncertainties in extrapolation from animals to humans

		value
AF_1	interspecies	'10'
AF_2	intraspecies	*5 (worker)*
		10 (general population)
AF_3	duration	*2 to 6*
AF_n	dose-response (e.g. LOAEL only)	*1 to about 3*
AF_m	database quality	≥1

[1] **Overall** Assessment Factor = AF1 • AF2 • AF3 • .....

PNEC derivation (water)

$$\text{PNEC} = \frac{\text{L(E)C50}}{\text{Assessment Factor}} \quad \textit{or} \quad \frac{\text{NOEC}}{\text{AF}} \quad \textit{or} \quad \frac{\text{HC}_5}{\text{AF}} \qquad \textit{(lowest)}$$

L(E)C50 (**Lethal E**ffect **Concentration to 50% of population**) from appropriate studies
NOEL (**N**o **O**bserved **E**ffect **Concentration**) from appropriate studies

	Assessment factor value
Short-term **L(E)C$_{50}$** from each of three trophic levels of the base-set (fish, daphnia, algae)	1000
Additional	
One long-term **NOEC** (either fish or Daphnia)	100
Two long-term **NOECs** from species representing two trophic levels (fish and/or Daphnia and/or algae)	50
Species sensitivity distribution: **HC$_5$**	5-1
Field data or model ecosystems	case by case

6. REACH guidance and tools

- RIP 1: Process description
- RIP 2: Development of REACH-IT
- RIP 3: Guidance documents for Industry
  - 3.1 TGD on preparing the Technical Dossier
  - 3.2 TGD on preparing the Chemical Safety Report [1]
  - 3.3 TGD on Information requirements on Intrinsic properties
  - 3.6 GD on Classification & Labeling under Global Harmonised System [2]
- RIP 4: Guidance documents for Authorities
- RIP 5/6: Setting up the Agency

[1] not yet finalized

[2] not yet started

Thank you for your attention!