



ICCA GPS Risk Assessment and Guidance

GPS/REACH/CLP workshop

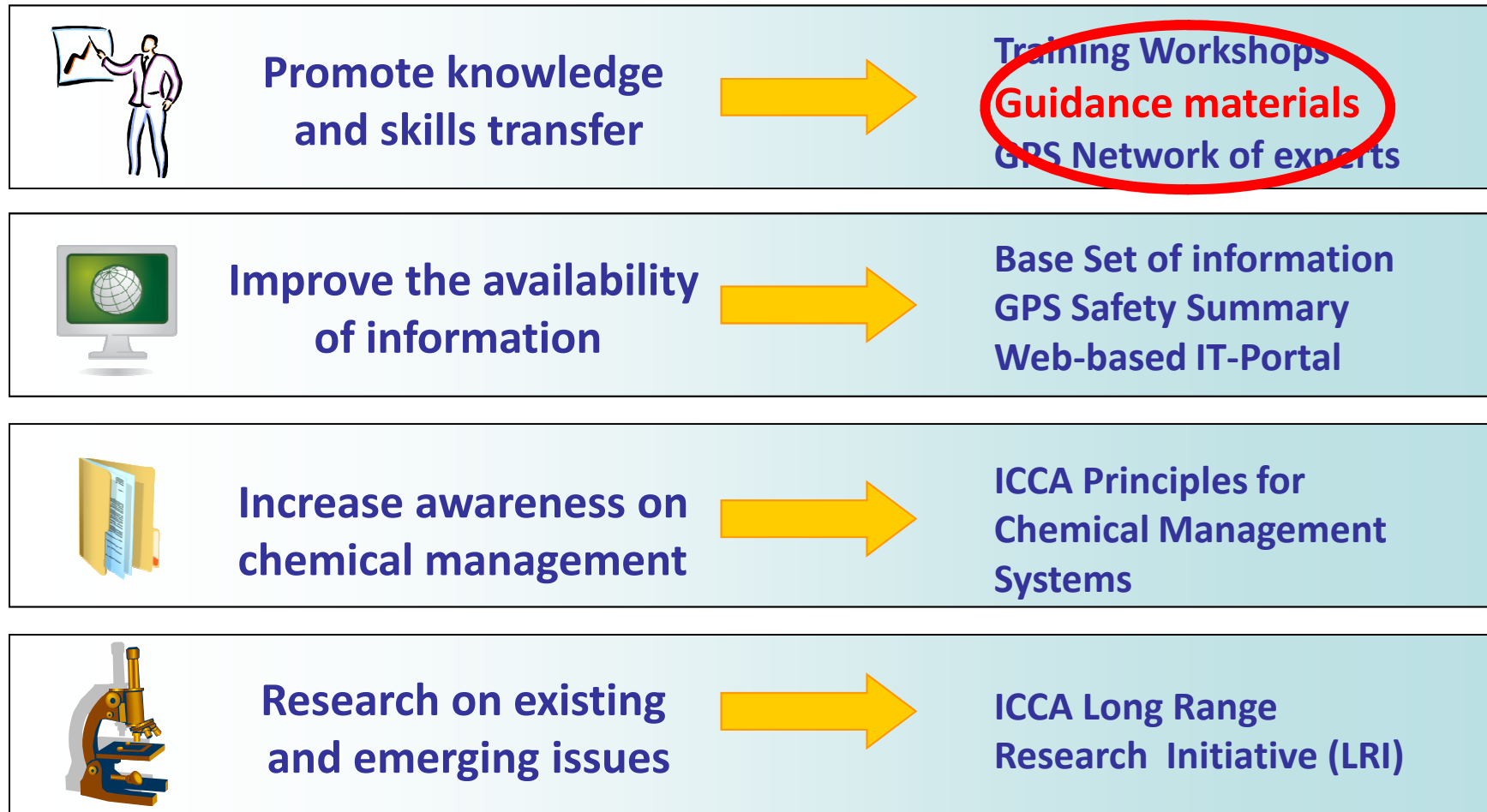
Bratislava

25 May 2011

By: L. Heezen



Global Product Strategy - Contribution to SAICM



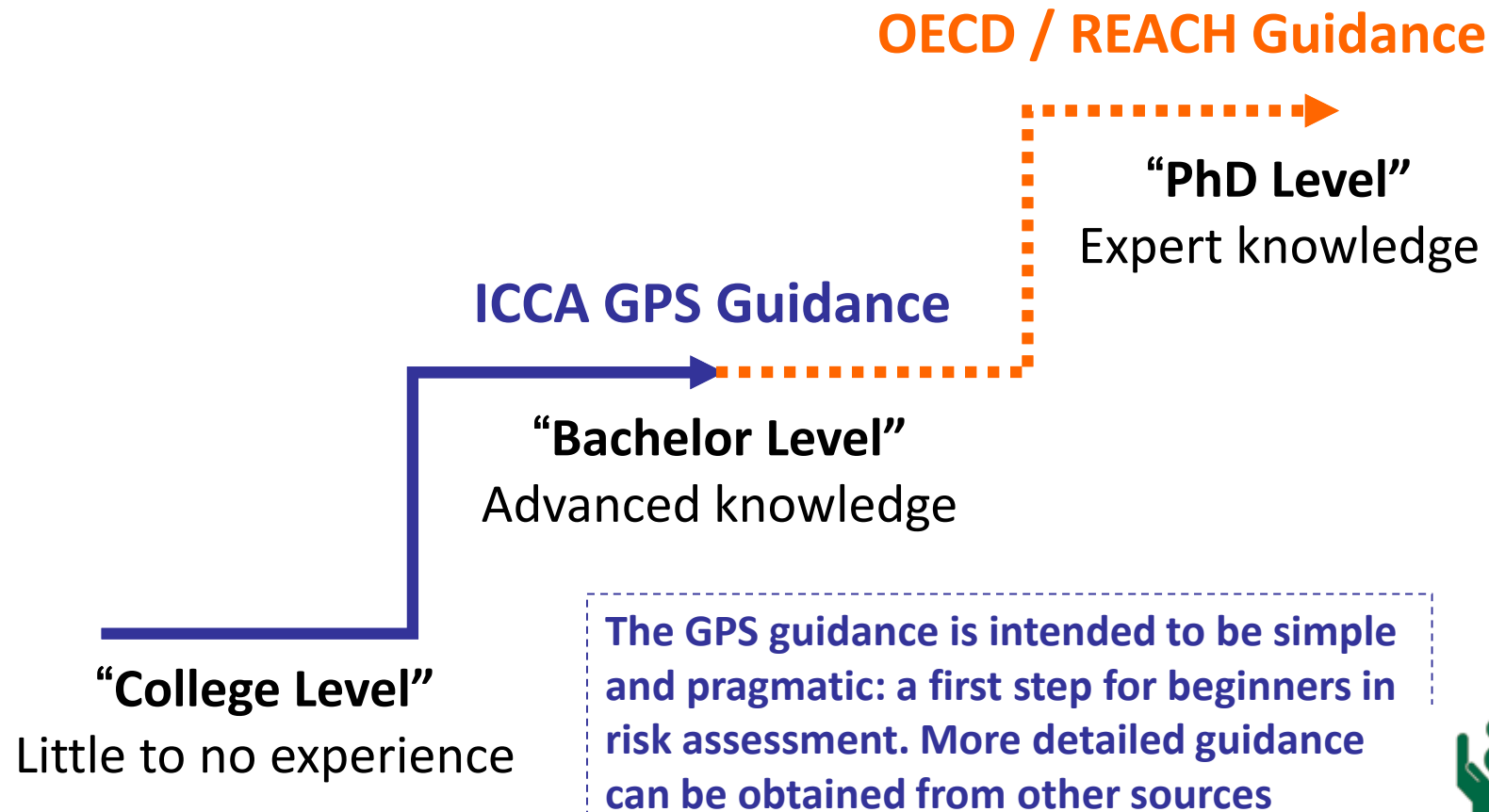


Improve performance – Risk Assessment Guidance

- The target audience are emerging economies and small and medium sized companies (SMEs) with no or very limited experience in risk assessment and related methodologies.
- Our goal was to come up with an easy to use step wise process as a first step to bridge gaps in current performance.
- The guidance has its limitations, it will be a living document to be updated / improved in the years to come.
- The guidance has proven to be of help for semi-technicians to understand the RA process in general
- The ICCA RA process is not applied in REACH countries, because here REACH is in the lead



Improve performance – Risk Assessment Guidance



Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY



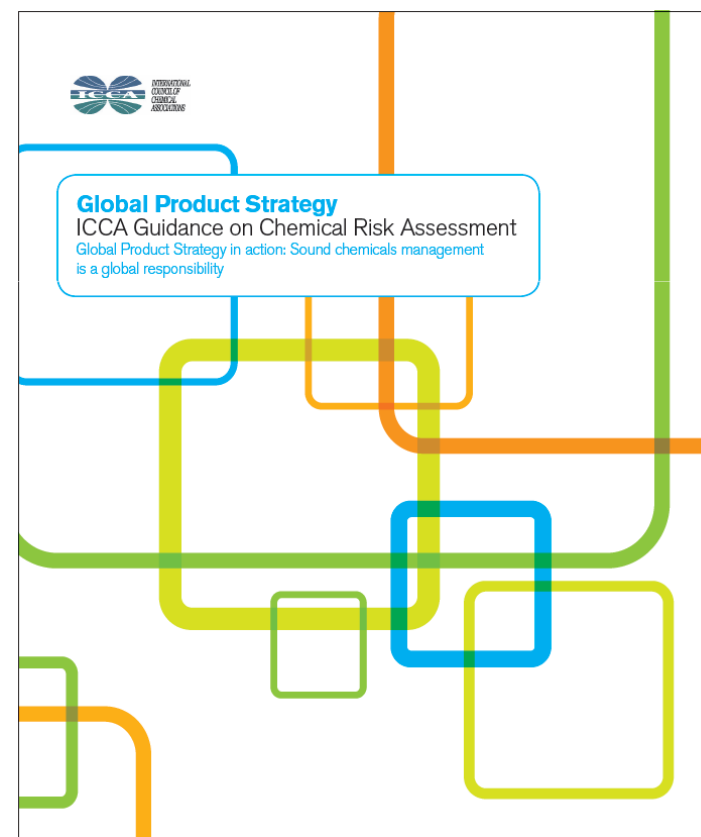
GPS Guidance on Risk Assessment

Section One: Preparation

- **Step 1:** Select chemicals for assessment
- **Step 2:** Gather information
- **Step 3:** Prioritize chemicals into Tiers
- **Step 4:** Develop Tier-relevant information (“Base Set of Information”)

Section 2: Implementation

- **Step 5:** Characterize Hazard
- **Step 6:** Assess Exposure
- **Step 7:** Conduct Risk Characterization
- **Step 8:** Document outcome (GPS Safety Summary)





STEP 1: Select Substances for Risk Assessment

STEP 2: Gather information

STEP 3: Allocate Substances into Tiers

STEP 4: Complete Tier-relevant Information

STEP 5: Characterise Hazard

STEP 6: Assess Exposure

STEP 7: Conduct Risk Characterization

STEP 8: Document outcome and Communicate to the public



Step 1: Select substances for assessment

GPS risk assessments should be performed for industrial chemicals:

- » Sold (“in commerce”) or transported world-wide in quantities of more than 1 metric ton per year by company and those that
- » Pose a major threat to human health and/or the environment (e.g. known carcinogens, etc.) even if they are sold or transported in smaller amounts than 1 metric ton per year

The inventory should be kept strictly company internal due to antitrust / competition law compliance





Step 2: Gather information

- **How to obtain the information:** sources to access information on GHS information, Phys/Chem, Hazard and Exposure Information
- **Evaluate the quality of the Information:** Reliability, Relevance and Adequacy of data for assessment
- **Close data gaps:** As long as the information is considered reliable, alternative sources are accepted e.g.
 - » Route-to-route extrapolation / Read-across from related substances
 - » In vitro methods / (Quantitative) Structure Activity Relationships
 - » Animal tests should always be the "last resort"



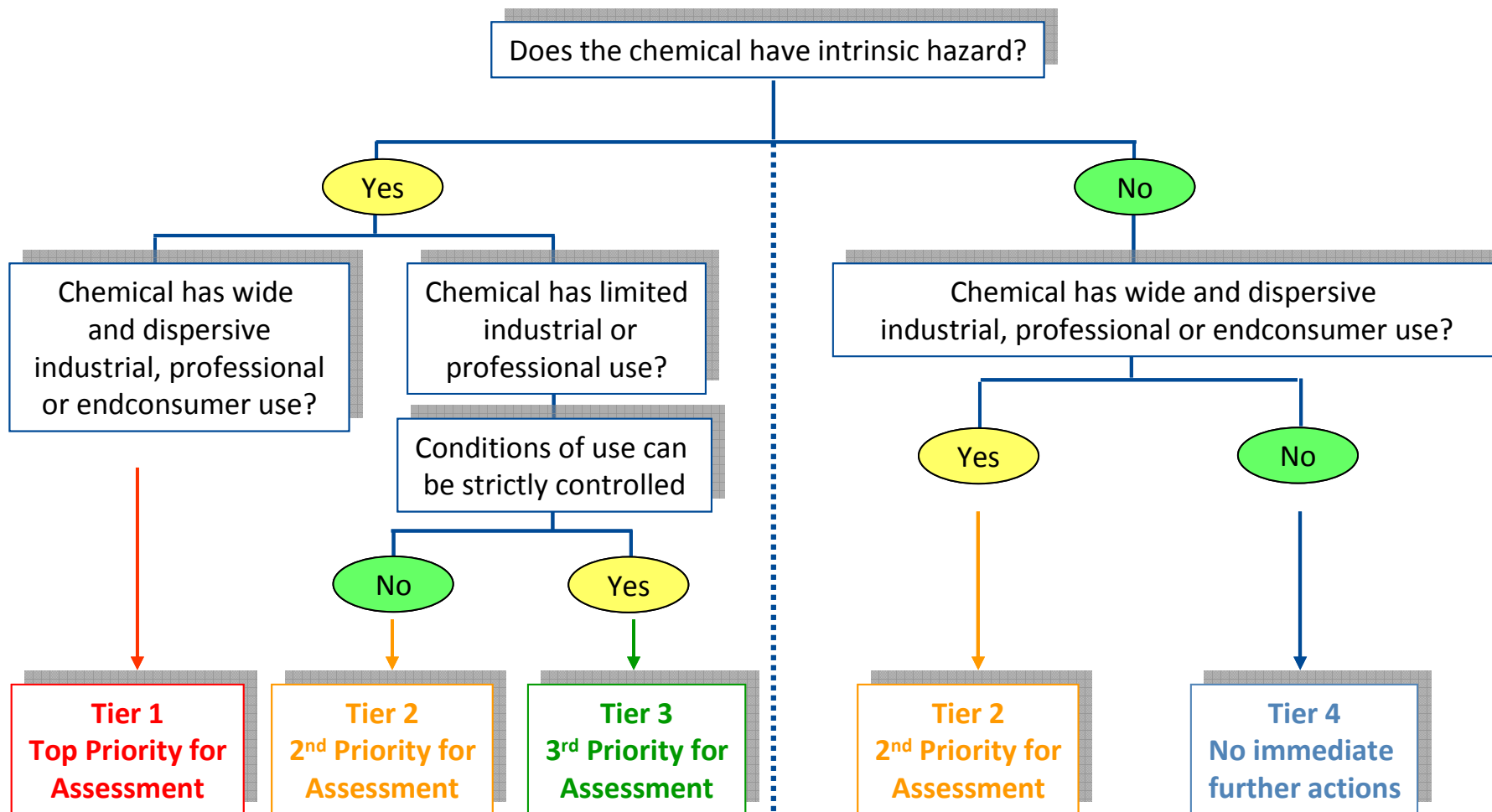
Step 3: Prioritize substances into Tiers

- Under GPS the prioritization of chemicals into “Tiers” is based on an initial evaluation of their hazard and / or exposure potential.
 1. Identify if your chemical has intrinsic hazard.
 2. Identify use, dissemination and exposure control of chemical
 3. Allocate chemicals into Tiers
- Each Tier is associated with a specific set of information. Chemicals with higher hazard and / or exposure potential require more information and are assessed first.

Just because a chemical is identified as high priority for RA does not mean that the RA outcome will show the chemical is of highest risk. Even a hazardous substance can be safely used in accepted applications.



Step 3: Prioritize substances into Tiers





Step 4: Base Set – Standard Parameters (for all)

Substance Identity

- CAS Number(s)
- Name(s)
- Structural Formula
- Composition being assessed
- Use Pattern (categories types)
- Sources of Exposure

Phys / Chem

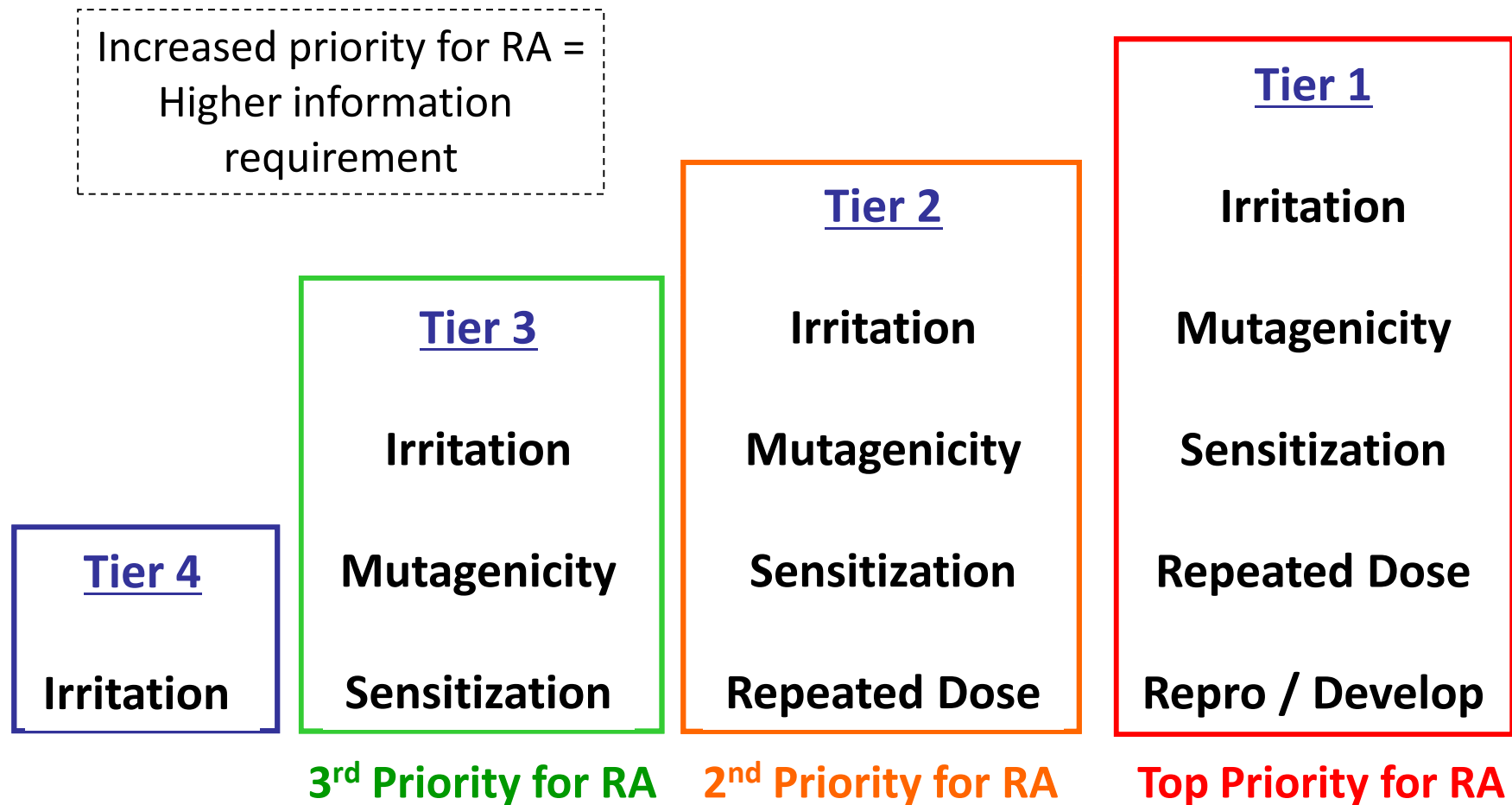
- Physical state
- Melting Point
- Boiling Point
- Relative Density
- Vapour Pressure
- Partition Co-efficient
- Water Solubility
- Ignition temperature
- Explosiveness

Tox / Ecotox

- Acute toxicity data (relevant route of exposure e.g. oral, dermal, inhalation)
- Acute Toxicity (most sensitive species: fish, daphnia or algae)
- Biodegradability

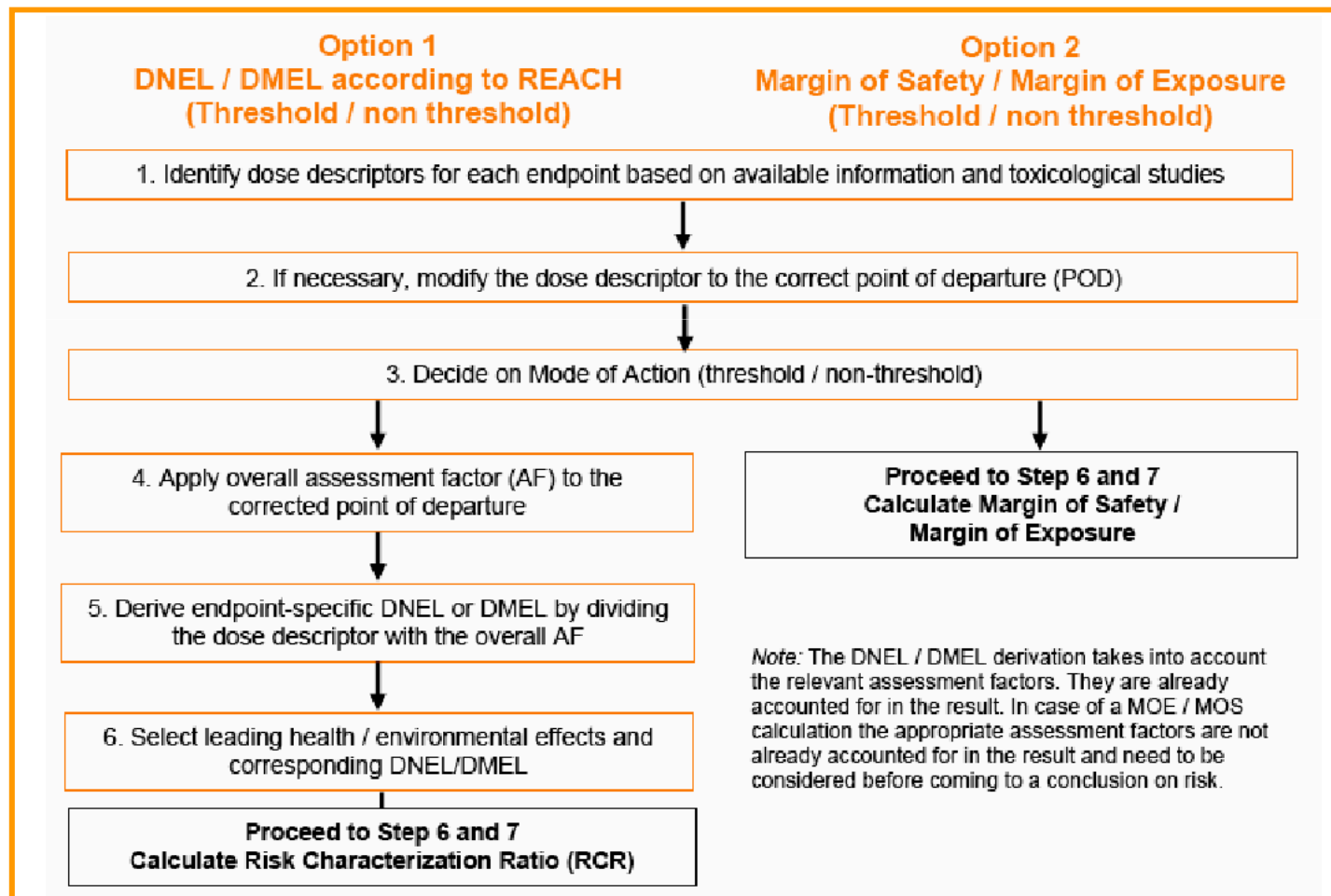


Step 4: Base Set – Tiered Information





Step 5: Characterize Hazard





Step 6: Assess Exposure

Step-wise process

- » Collect information on chemical properties
- » Collect information on the uses and the typical operating conditions and risk management (exposure control) measures applied
- » Set up an Exposure Scenario for each use
- » Estimate exposure for each scenario, using estimating tools (e.g. ECETOC TRA) or measured data

Perform the respective assessment for:

- » Human Exposure - Workplace and Consumer scenarios
- » Environmental Exposure Assessment



Step 7: Conduct Risk Characterization

Risk Characterization Ratio (RCR)

- Threshold or non-threshold effect
 - » $RCR = EXPOSURE / DNEL$
 - » $RCR = EXPOSURE / DMEL$
- Environmental
 - » $RCR = PEC / PNEC$



$RCR \geq 1$ Risk is high

Detailed assessment and RMMs required

$RCR < 1$ Risk is controlled

No further action required

Margin of Exposure (MoE)

- $MOE = \frac{NOAEL \text{ or } NOAEC}{Exposure}$
 - » If $MOS > Overall \text{ Assessment Factor}$
→ No concern
 - » If $MOS < Overall \text{ Assessment Factor}$
→ Concern



$MOE > 100$ No concerns

$MOE < 100$ Concern

Refine analysis or control exposures

$MOE < 1$ Cause for high concern

Direct measures needed



Step 8: Document outcome (Safety Summary)

- After the RA it is important to check the efficiency of the safety measures adopted, document the outcomes of the assessment and reviewing the assessment regularly to keep it updated.
- As this documentation will contain data of proprietary nature it will stay company internal and does not have to be shared with co-producers or the public (no mandatory exchange of dossiers).
- ICCA has develop a GPS specific format that can be used to communicate the essential information in a transparent way with interested stakeholders (GPS Safety Summary).
 - » To provide the general public with a short easy to understand overview of relevant information for the chemical
 - » Does not replace technical materials such as the (M)SDS



Step 8: GPS Safety Summary - Template

- Summary
- Chemical identity
- Uses and Benefits
- Physical/chemical properties
- Health Effects
- Environmental Effects
- Exposure
- Risk Management Recommendations
- Handling and storage
- Disposal consideration
- State Agency Review
- Classification and Labeling
- Conclusion
- Contact Information within company
- Date of finalization of the Safety Summary
- Disclaimer



Thank you!

lhe@cefic.be

