



Australian Government

Department of Health

National Industrial Chemicals

Notification and Assessment Scheme

The NICNAS IMAP Program

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NICNAS

- National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
 - Commenced 1990
 - Covers both human health and environment
 - Manages Australian Inventory of Chemical Substances
 - Premarket assessment of new chemicals
 - Existing Chemicals assessed on priority basis (PEC)
- Includes ingredients in formulated cosmetics



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Existing Chemicals Program Review

- Conducted 2003-2006
- Primary recommendation was to accelerate prioritisation and assessment of 38000 grandparented chemicals
- Implementation planning and program design phase
- Inventory Multitiered Assessment and Prioritisation (IMAP) program commenced June 2012
- 3000 chemicals identified for assessment



- Minimum read across/QSAR hazard data objective for all chemicals
 - Not “no data, no hazard”
- Integration of exposure and hazard throughout
- Preparation of a report on available information for most chemicals
- Where possible, use this information to support risk management recommendations



Exposure data (or otherwise!)

- Canada had use/volume data from DSL compilation
 - No similar data for AICS
- After consultation, program designed around lack of “real” data
 - Uses inferred from international information
 - Mostly default volume
- Based on combination of use and volume
 - See Nazaroff et al 2012 (EHP Vol 120 p1678)



Three level problem formulation

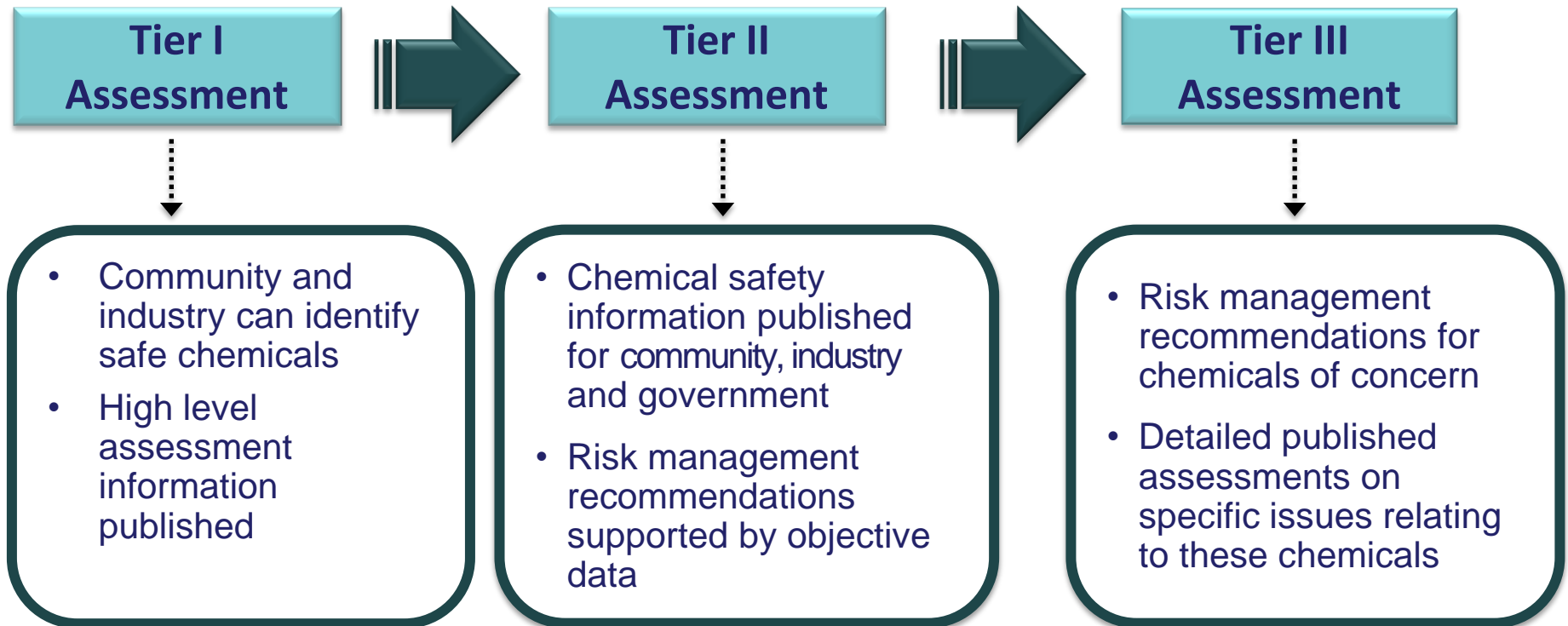
1. Is there a problem? **Tier I**
 - Can concerns be dismissed based on readily available information?
2. Identify magnitude of problem. **Tier II**
 - Assemble known data
 - Look for straightforward resolutions based on objective knowledge
3. If needed, fully analyse problem and potential solutions. **Tier III**



- Tier I – identify chemicals not needing resourcing (de-cluttering!)
 - Lack of hazard
 - Lack of use
 - Hazards controlled given known uses
 - End result is statement of Tier I criteria met
- Tier II – Provide more information
 - Identification of chemicals for which risk management can control known risk
 - Propose further assessment for remainder



Outcomes





Tier I Matrix

Increasing Exposure →

		Exposure Band				
		0 (no exposure)	1	2	3	4
Increasing Hazard ↓	0 (no indication hazard)	Not Prioritised	Not Prioritised	Not Prioritised	Not Prioritised	Not Prioritised
	1	Not Prioritised	Not Prioritised	Not Prioritised	Not Prioritised	Prioritised
	2	Not Prioritised	Not Prioritised	Not Prioritised	Prioritised	Prioritised
	3	Not Prioritised	Not Prioritised	Prioritised	Prioritised	Prioritised
	4	Not Prioritised	Prioritised	Prioritised	Prioritised	Prioritised



Exposure Bands

- Use broadly categorised as:
 - Cosmetic (100% of chemical available for exposure)
 - Domestic
 - Commercial
 - Site Limited (0.1% available for exposure)
- Multiplied by introduction volume (known for some chemicals including HVIC) to obtain score
- Under default volumes, cosmetics = band 4 to site limited = band 1



Hazard Bands

Hazard band	Hazard indicators (aligned with GHS)
Hazard band 4	Carcinogenic Mutagenic Reproductive/developmental toxicity Endocrine disruption Neurotoxicity
Hazard band 3	Fatal (acute) Significant Toxicity (repeat) Respiratory sensitisation Full thickness destruction of skin tissue (limited exposure)
Hazard band 2	Toxic (acute) Harmful (repeat) Skin sensitisation Full thickness destruction of skin tissue (prolonged exposure) Eye damage
Hazard band 1	Harmful (acute) Irritant



Product Life Cycle

- In IMAP Tier I, product life cycle may be relevant
 - Chemical manufacture and formulation
 - Use by consumers only in dilute formulations
- May consider the relevant hazard information for the chemical as used during each life cycle stage

Increasing Exposure →

		Exposure Band				
		0 (no exposure)	1	2	3	4
Hazard Band	0 (no indication known)	Not Prioritised	Not Prioritised	Not Prioritised	Not Prioritised	Not Prioritised
	1	Not Prioritised	Not Prioritised	Not Prioritised	Not Prioritised	Prioritised
	2	Not Prioritised	Not Prioritised	Not Prioritised	Prioritised	Prioritised
	3	Not Prioritised	Not Prioritised	Prioritised	Prioritised	Prioritised
	4	Not Prioritised	Prioritised	Prioritised	Prioritised	Prioritised

↑ Increasing Hazard



Risk 21 comparison

- Clearly a different matrix to Risk 21
 - Does not meet the criterion of same scale on both axes
 - Based on even lower data availability
- However, covers a broader range of hazards, quantitative and non-quantitative
- Uses surrogates for exposure and hazard
- Can be considered a lower tier again



Tier II

- More “classical”
- Provides information for stakeholders
- Considers whether existing risk management is appropriate
- Proposes risk management where this can be done on objective grounds
 - Classification
 - “Scheduling”



- Much of the data sourced in IMAP can be considered “objective”
 - Results of well-reported guideline studies
 - Conclusions from well-regarded international sources
- These data can be referred to risk management agencies for consideration under their processes



Quantification

- IMAP – almost total lack of quantitative exposure data
- Can determine chemicals to be priorities to obtain data from industry...
- But can justify risk management in many cases without quantification
 - “Scenarios”



What do we mean by “risk assessment”?





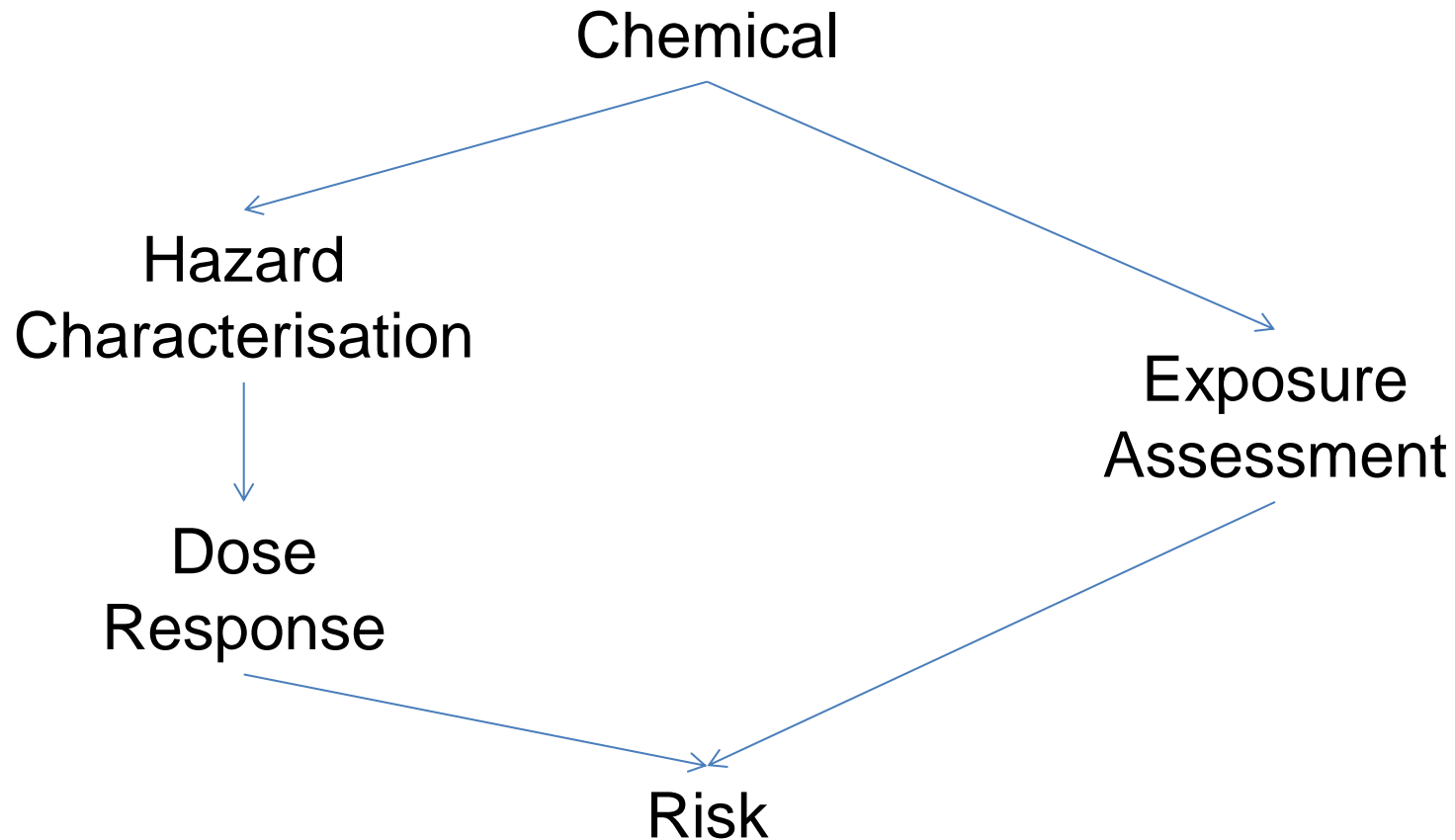
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What do we mean by “risk assessment”?



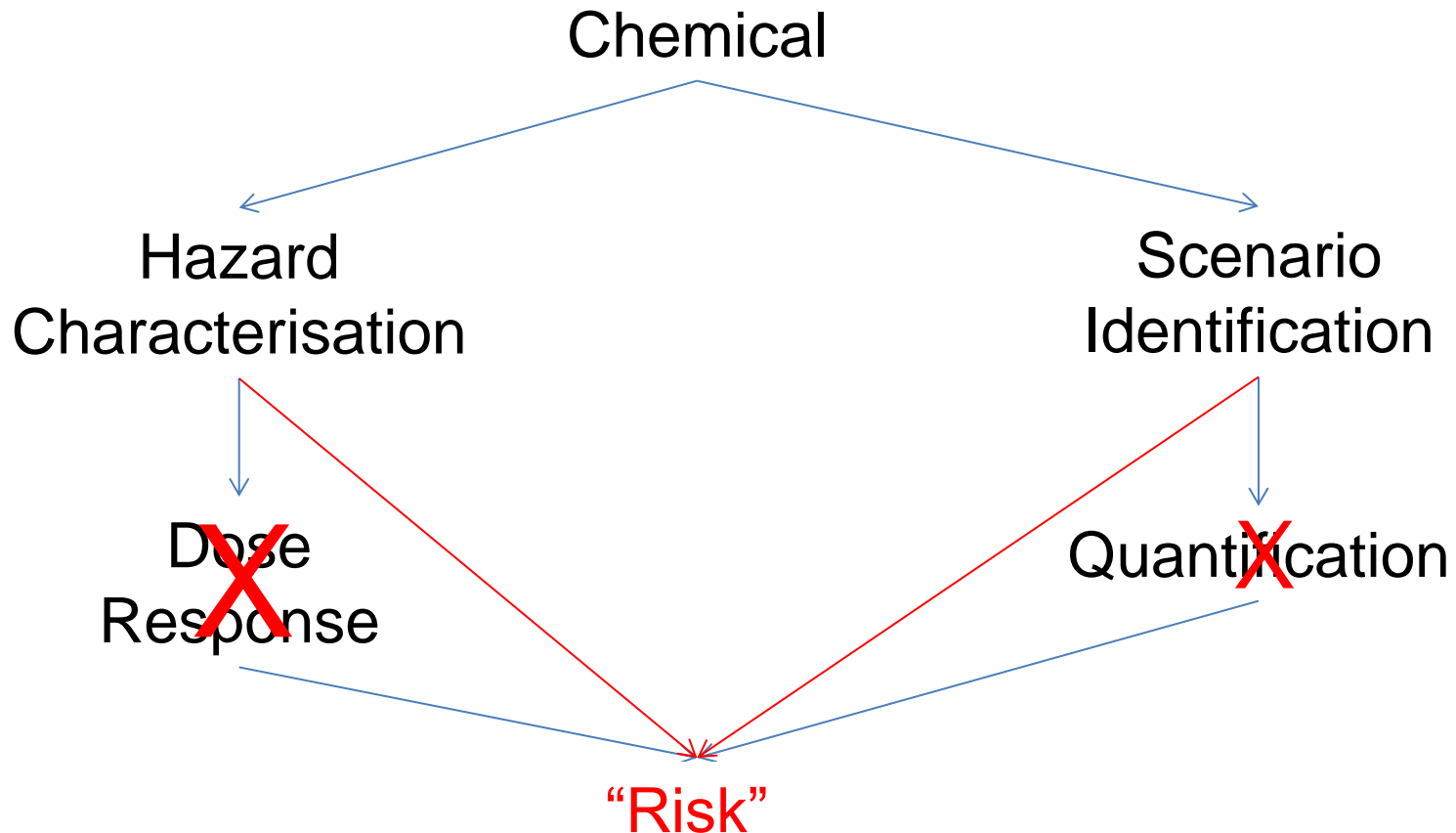


Risk Assessment





Risk Assessment





Scenarios

- Almost total lack of volume and concentration data
- Uses largely estimated from international sources
- Are there circumstances where the identified hazards lead to clear risks under identified scenarios?
 - Sensitising hair dyes
- Risk shown to be real but magnitude uncertain



Hazard characterisation

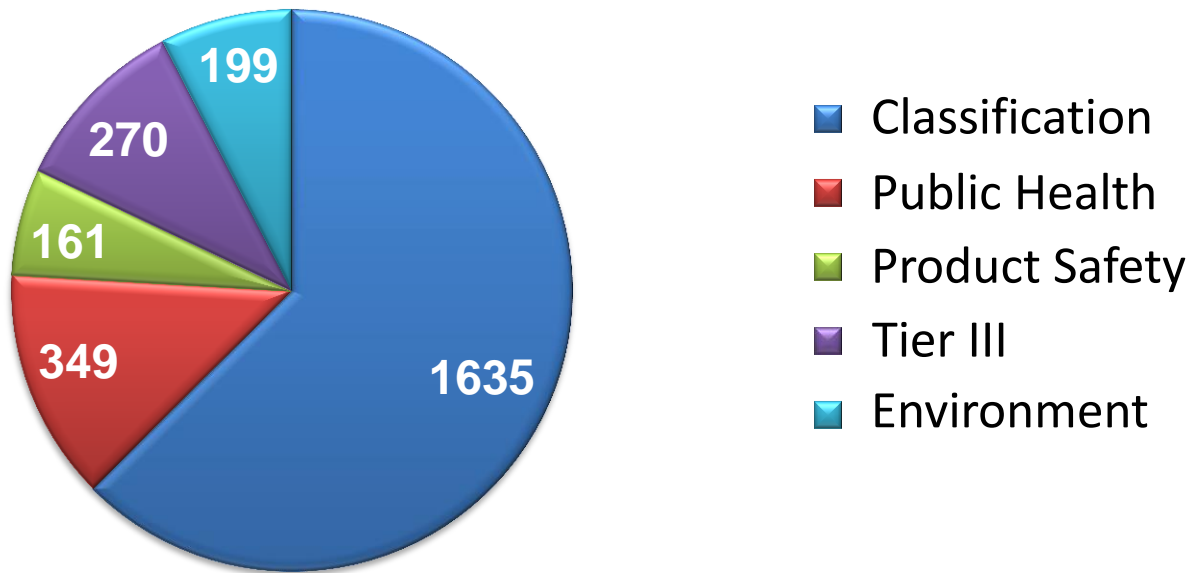
- Objective data
- Expert judgement using:
 - Read across/grouping
 - (Q)SAR (mostly mechanistic support)
 - Bioelution (metals)
 - Other hazard data/mechanistic
- Can accommodate future data types
 - Particularly hazard characterisation



IMAP Tier II Recommendations

Impact for risk management

Tier II Recommendations Tranches 1 to 16



At February 2016 2614 recommendations were made for 2045 unique chemicals assessed at Tier II.



Further risk management?

- Good outcomes where:
 - Risk management aligned with GHS criteria
 - Non-quantitative hazard eg sensitisation, genotoxic effects
 - Proposal for adoption of international standard (eg SCCS)
 - When seen to be proportionate
- May need further assessment and information gathering for quantification
- Question – revisiting control banding/TTC using more up to date hazard characterisation?



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