



Australia

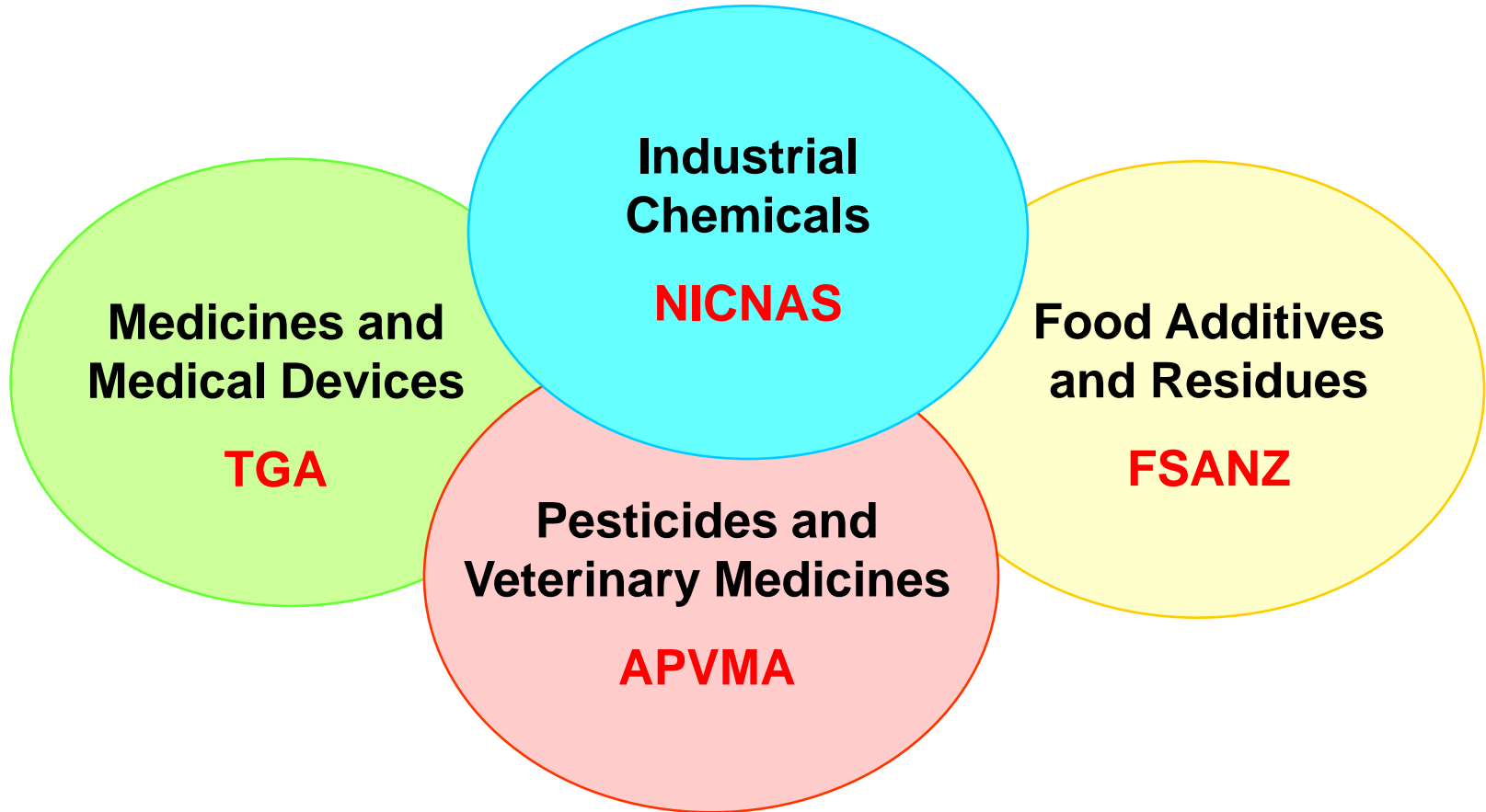
The Changing Regulatory

Environment

Marion Healy
National Industrial Chemicals
Notification and Assessment Scheme
(NICNAS)

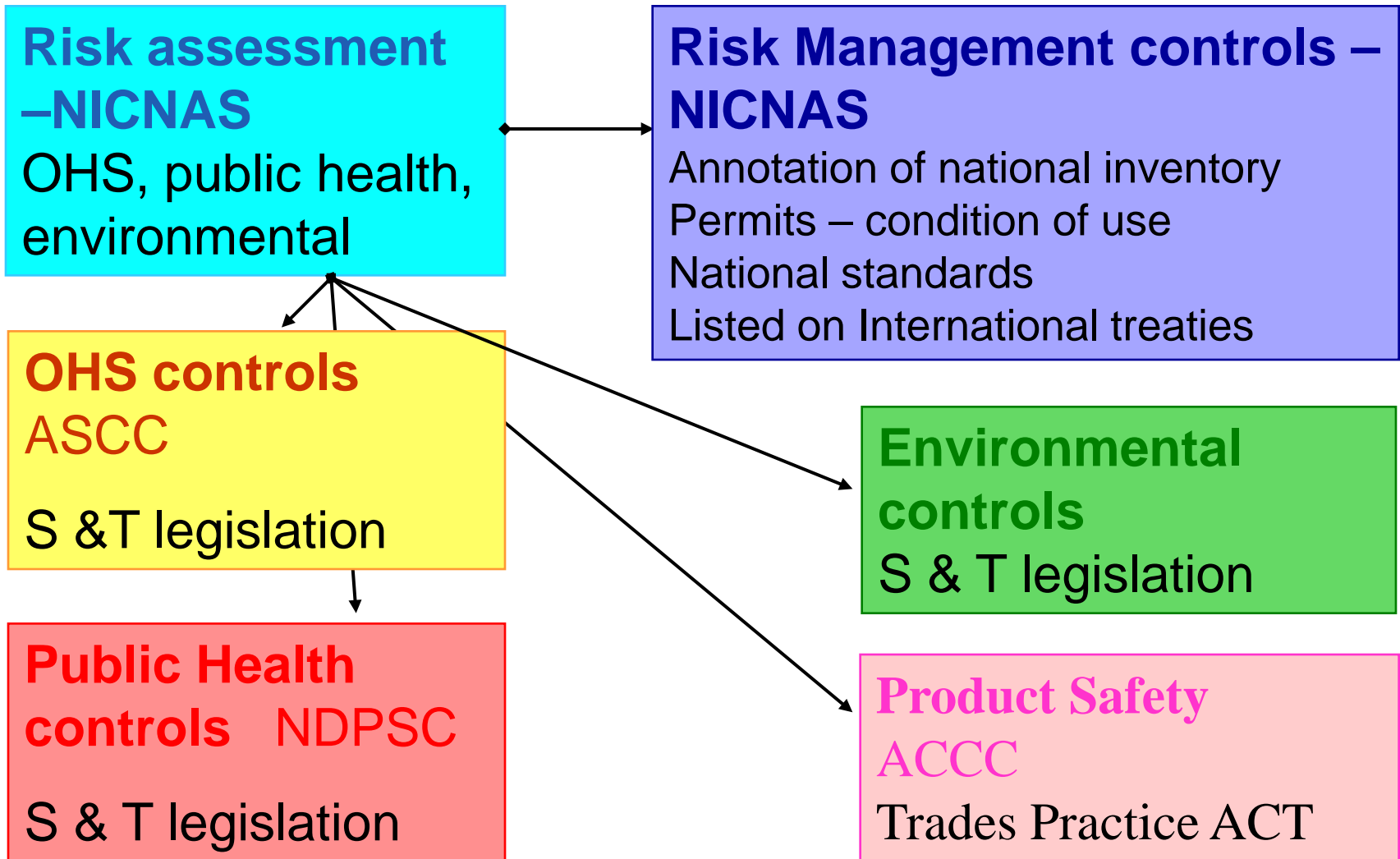


Regulation of chemicals





Regulation of industrial chemicals





NICNAS Functions

- Assesses risk to workers, the public and the environment associated with industrial chemicals
 - Covers new and existing chemicals
- Regulates introduction of industrial chemicals
- Chemical entity scheme (not product registration)
 - Pre market assessment and notification
- Maintains national inventory
- Maintains register of 'introducer' of industrial chemicals
- Chemicals in cosmetics to cement, and includes paints, solvents, plastics etc



1. Existing Chemicals: Screening the National Inventory

Recommendations

- Develop an overall framework for screening of chemicals of concern
- Screen inventory listed chemicals for hazard and/or risk indicator elements
- Develop a framework to identify the circumstances under which down-stream use information is sought as being necessary for prioritisation
- Develop scientifically based criteria for prioritisation of chemicals for assessment
- Publish the prioritisation process and decisions



1. Existing Chemicals: Comparing Inventories

Total AICS: 38 435

Regional overlap with inventories	
Japan (ENCS)	12 368
Korea (ECL)	15 223
New Zealand (NZIoC)	16 590
Philippines (PICCS)	15 165
Cumulative overlap (all)	25 954
Only AICS	12 481

North America and Europe	
TSCA	22 191
DSL	16 410
Europe	24 714
Cumulative overlap (all)	31 225
Only AICS	7 210

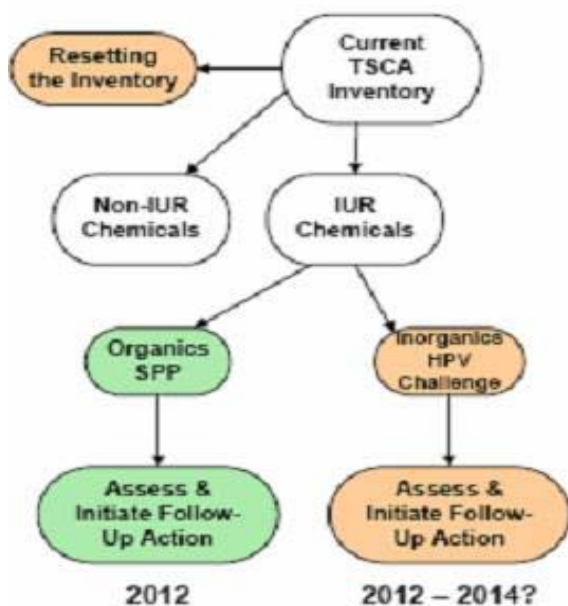
OECD* and AICS	33 291
AICS only	5 144

* OECD inventories considered include Japan, S.Korea, USA, EU, Canada and NZ

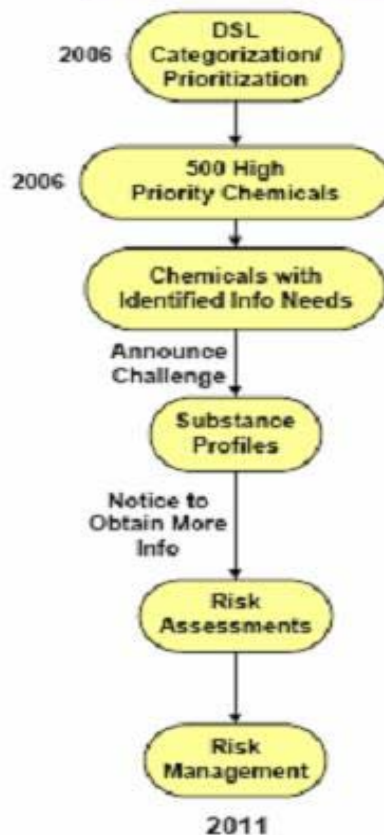


1. Existing Chemicals US, Canada and EU approaches

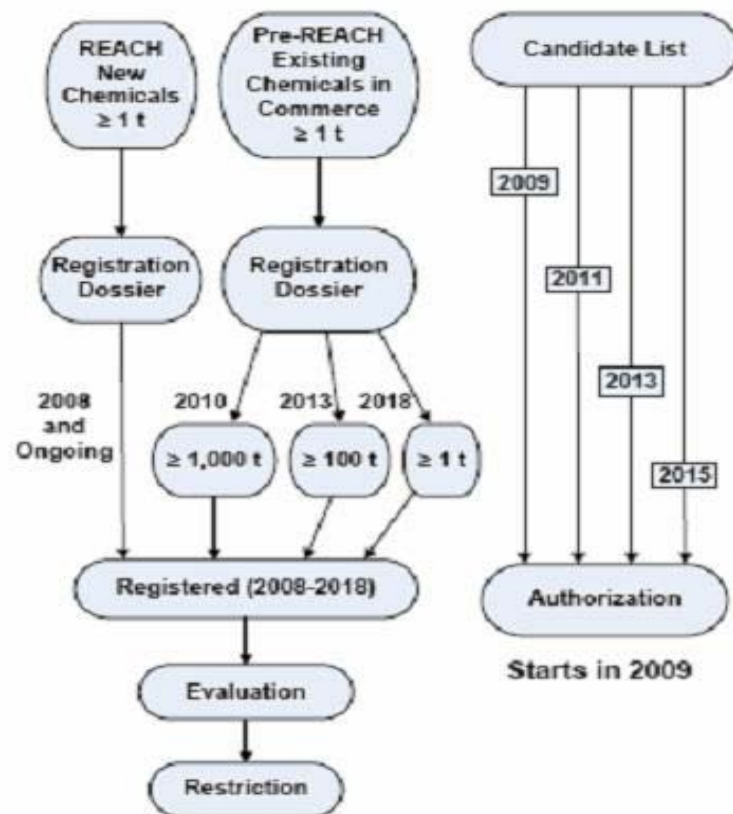
U.S. ChAMP



Canada Chemical Management Plan²



EU REACH Registration & Authorization Candidate List



¹ DSL = Canadian Environmental Protection Act Domestic Substances List

² Other aspects of the CMP are not shown on this figure.

1,000 t = 2.2 M lbs.; 100 t = 220k lbs.; 1 t = 2.2k lbs.

* Extracted from EPA briefing on ChAMP May 2008



2. International harmonisation

Bilateral: Canada



New Chemicals

- Cooperative work program - since late 1990s
 - Formal Cooperative Arrangement
- Recognition of Canada as an Approved Foreign Scheme under NICNAS – 2007
 - implemented for limited/standard notifications
- Next phase –implemented in December 2008
 - Polymers of low concern



Benefits for all stakeholders



2. International harmonisation

Bilateral: USA



Cooperative arrangement signed December 2008

- US EPA; new and existing chemicals
- AIM: achieve efficiencies in assessing/ managing; enhance ability to protect human health and the environment
- SCOPE:
 - Exchange health & safety data & information; chemical assessments
 - Share risk reduction and risk management tools
 - Sharing of information on topics of specific interest, eg. (Quantitative) Structure Activity Relationship analysis, Green Chemistry and Stewardship activities (eg. PFA and nanomaterials)
 - Exchange of expertise



Benefits for all stakeholders



2. International harmonisation

Multilateral

OECD Clearing House on New Chemicals

- Established November 2008 – Joint meeting
- Focus – notification and assessment of new chemicals
 - Mutual acceptance of notifications, criteria for polymers of low concern, definitions, notification software, etc
- Chair = Australia
- First meeting: 21-24 April 2009, Sydney



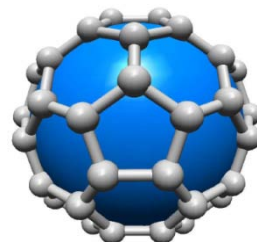
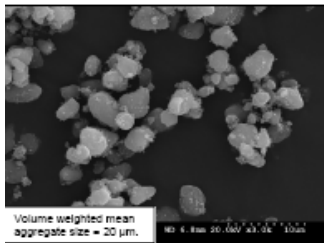
3. Emerging issues: Nanotechnology

- Manipulation of matter at the smallest scale
 - (from 1 to 100 nm)
- Review - Possible Impacts of Nanotechnology on Australia's Regulatory framework
 - Released July 2008
 - Australia's framework generally well suited to regulating nanotechnologies

■ BUT



Scanning Electron Microscopy Image



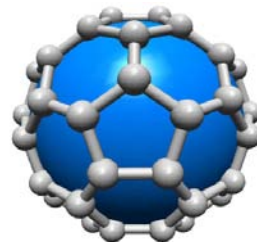
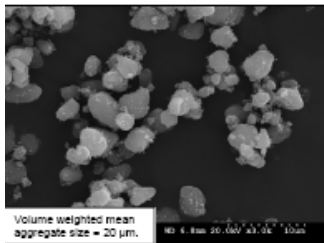


3. Emerging issues: Nanotechnology

- Identifies 6 regulatory triggers that warrant further attention:
 - New or existing chemicals
 - Thresholds by weight or volume (exemptions)
 - Knowledge of presence of nanomaterials
 - Risk assessment protocols
 - R & D exemptions
 - Use of international documents /guidelines (eg. OECD)



Scanning Electron Microscopy Image





3. NICNAS Nanotechnology Strategy

	NICNAS	National	International OECD, ISO
Definition			Working definition
Risk assessment	New vs Existing Literature reviews (HSE) Call for relevant information	Cross government approach: Expert advice Build technical capacity	Test protocols Testing representative nanomaterials – groups
Adequacy of management protocols	Regulatory requirements: new and existing chems		Adequacy of voluntary programs
Stakeholder engagement	Advisory group, Communication material	National Nanotechnology Strategy	Communication material



4. Globally Harmonised System for classification and labeling

Implementation being examined across workplace, ag/vet and consumer chemicals

■ **Workplace**

- Australia has national criteria for human health classification and labelling
- New chem classifications with national and GHS criteria give similar outcomes
- GHS principles underpinning integration of hazardous substances/dangerous goods requirements
- Take account of Australia's approved criteria for classification

■ **Ag/vet chemicals & consumer products**

- Implications for current labelling arrangements being explored



4. Globally Harmonised System for classification and labeling

APEC Chemicals Dialogue

- Coordination – to promote and support rapid implementation, simplifying regulations and labeling requirements while improving safety and environmental protection
- Established a virtual working group to progress work
- Established mechanisms for structured information sharing
- Established a consumer products sub-group to develop guidance for the consumer products sector



Evolution of the Regulatory Environment



Improved efficiency and effectiveness

- framework for screening inventory
- bilateral notifications

12 months



Regulatory framework for
nanomaterials

12-24 months



Screening inventory: identification
of chemicals of concern

Co-notifications - OECD

Implementation of GHS?

12 – 36 months



Australian Government
Department of Health and Ageing
NICNAS

Regulating chemicals for your protection

explore

www.nicnas.gov.au

freecall

1800 638 528