Regulatory challenges of nanotechnologies

Professor Graeme Hodge

(Graeme.Hodge@law.monash.edu.au)

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Context

'unlike other cases where the discussion of the associated risks has followed the development of new technologies, the discussion on the proper regulatory framework for the governance of nanotechnology risks is accompanying the development of the technology and the associated products themselves'

Levi-Faur and Comaneshter (2007: 150)

Argument: We need to better understand regulatory phenomena in the nano-context, and to move ahead, meet 8 challenges…

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This Session

- Nanotechnology regulation as three languages

- Regulatory Frontiers

- Eight Challenges for nano-regulation

- Conclusions

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Three Languages of Regulating Nanotechnologies

NT as Science Frontier:
- 'new developments in chemistry, physics, materials sciences, medicine & biotechnologies at the atomic scale' (sciences of ENMs)

NT as Phenomenon:
- A handy label, but also part of a public policy 'word game' to frame meaning

Regulation
- The age of regulatory capitalism has seen a rethinking of the regulation concept. It is far more extensive than just law…
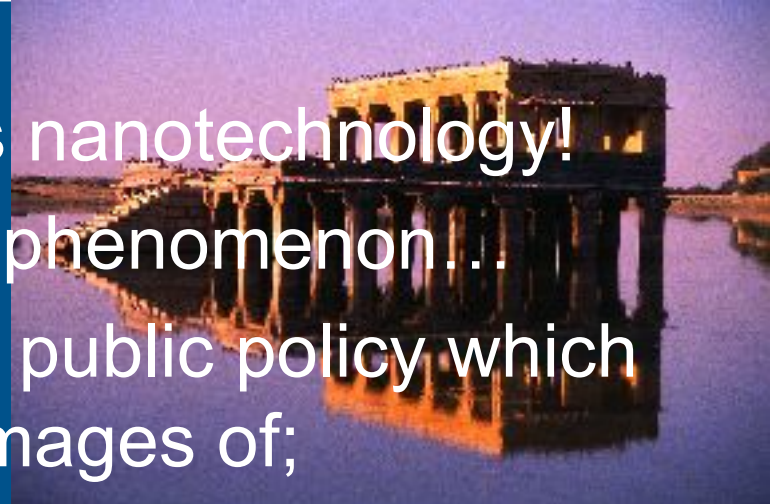
Regulatory Frameworks for NT

Regulatory activity is political activity and combines science, public expectations and opportunity…

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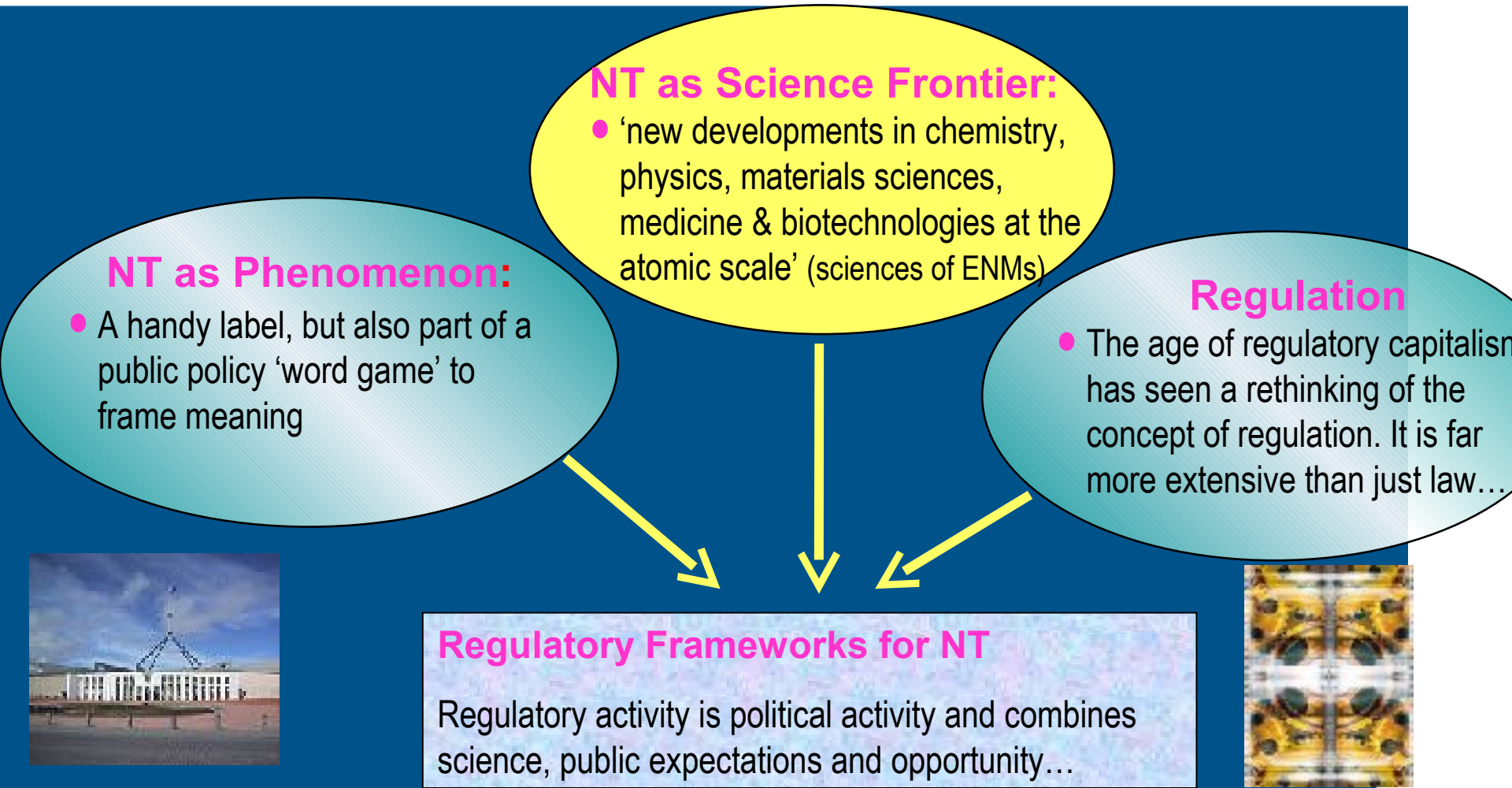
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Nanotechnology as 'Phenomenon'

- There is no such thing as nanotechnology!
- NT is a handy label for a phenomenon…
- but also a 'word game' in public policy which frames meaning… with images of;
  - all things good in development, or
  - all things bad!
- We need to move beyond this language game in order to develop good polices / regulation (it is difficult to regulate a phenomenon)

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Nanotechnology as 'Science Frontier'

- *'new developments in chemistry, physics, materials sciences, information technologies, agriculture and biotechnologies at the atomic scale'* (ie the sciences of engineered nanomaterials)

2. 18 definitions in our 2007 Frontiers of Regulation book

Major characteristics include:
- Size: 100nm to $< \frac{1}{10}$nm
- Range of technologies
- Multi-disciplinarity
- Size dependant novel properties
- Control and manipulation at atomic scale
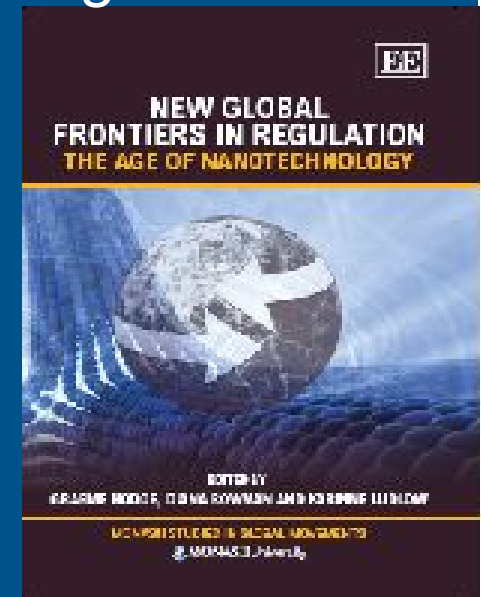
NEW GLOBAL FRONTIERS IN REGULATION
THE AGE OF NANOTECHNOLOGY

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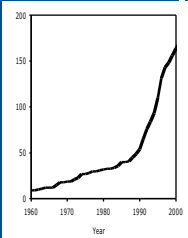
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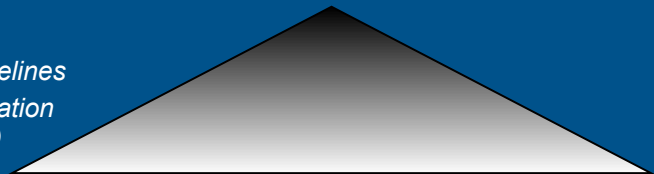# The 'Regulation' language

- The notion of 'regulation' has been rethought
- Regulation:
    - > covers multiple disciplines & is decentred across all sectors
    - > includes huge range of regulatory mechanisms/tools
    - > sees the rise of the independent regulator
    - > has expanded in economic & social arenas
    - > is about reordering priorities & power, and is a mode of policy making
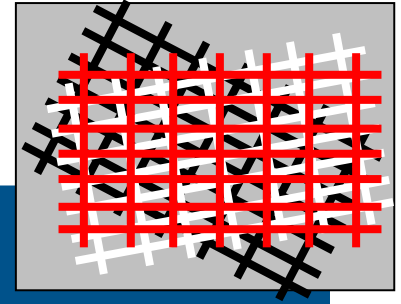   - > has international linkages…

- Regulatory activity is political activity
- Starting point - the existing regulatory space…
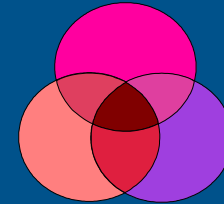
Law/regltns
Codes / G-Ls
Contracts / grants
Econ $ €
Information / transparency
Markets / licenses/ accredtn

- Gov't
- Independent Instns
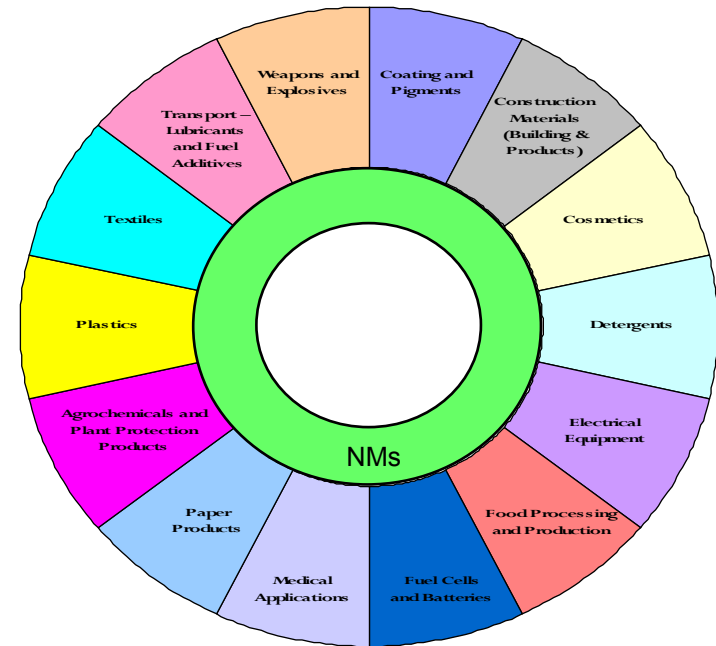- Hybrid
- Global
- Self-reg
- Co-reg
- Meta-regltn

- *'Hard' Law*
- *Codes/guidelines*
- *'Soft' Regulation* (self-regulation)

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The 'Regulation' language

- Nanotechnology products are already regulated …
- Adequacy *(of Acts, regltns, directives, codes…),* though, is in question
- Australian Review completed by Ludlow, Bowman & Hodge in 2007, covering:
  - 15 families of NMs & N-applications
  - 11 agencies (fed & state)
  - 59 legislative instruments (Acts, regulations, guidelines, codes & standards)
- A useful and necessary terrain mapping exercise

NMs — Coating and Pigments, Construction Materials (Building & Products), Cosmetics, Detergents, Electrical Equipment, Food Processing and Production, Fuel Cells and Batteries, Medical Applications, Paper Products, Agrochemicals and Plant Protection Products, Plastics, Textiles, Transport – Lubricants and Fuel Additives, Weapons and Explosives

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Regulatory Frameworks for NT

Regulatory activity is political activity and combines science, public expectations and opportunity…

So what? … Regulating NT uses all 3 languages

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Regulatory Frontiers

Several regulatory frontiers now exist:

- Regulation is political activity and combines science, public expectations & opportunity

- All frontiers see power, institutions, $, personalities & politics, as well as science

- Torts

Int^{ntl} convention frameworks / treaties

Self regulation

Co-regulation

Transparency / information

Insurance

Traditional national law/regltns

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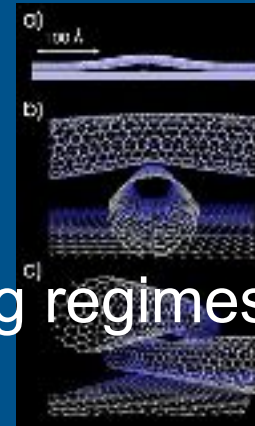# Eight Regulatory Challenges

1. Moving beyond the 'Language Game'

2. Scientific Gaps in Knowledge
   a) toxicology, exposure, risks, life cycle…
   b) developing metrology & standards

3. Regulatory Gaps and Triggers in existing regimes:
   - Are new N-forms '*new*'?
   - *Threshold weight/volume* triggers
   - *Knowledge* of NMs or their risks
   - Risk assessment *protocols*
   - *Exemptions*
   - *International* document suitability?

   - Achieving a regulatory balance to encourage innovation with appropriate precaution - comparing risks … with perfection or other (?)… → 'what is a proportional response'?

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Eight Regulatory Challenges (cont.)

1. Evaluating 'what works' amongst alternative regulatory options / tools
   - Strengths and weaknesses
2. Transparency & Trust
   - Credibility and Legitimacy is crucial
   - Specially food (& 'up-close & personal' items, cosmetics...)
- Education (amidst increasing distance between citizens & elites)
- Engagement in regulatory policy making through dialogue
   - Who? When? How? Why?

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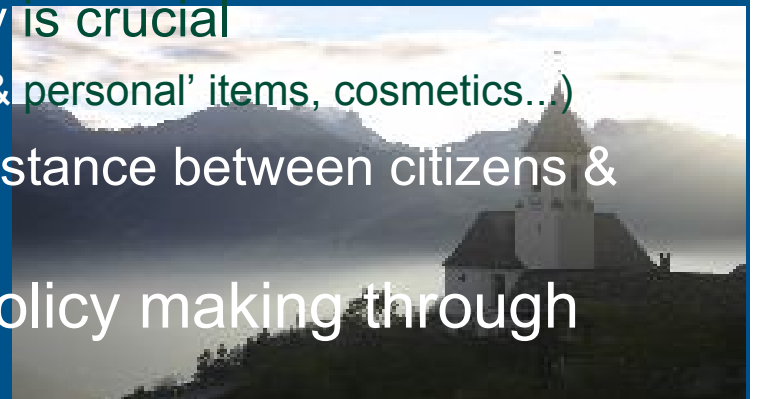
Conclusions

- Regulatory activity is political activity involving multiple languages
  - > NT as a phenomenon
  - > NT as sciences
  - > regulation as priorities and policy making
- Many possible regulatory frontiers exist
- Eight challenges will be important (overcoming language games, scientific gaps, regulatory gaps/triggers, balancing regulation, evaluating what works, transparency for trust, education & engagement)

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Questions

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