The Hare and the Tortoise:
Nanotechnologies and the Race for Regulatory Certainty

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Starting Propositions

1. The regulatory benchmarks which we measure against ***are not*** *– and cannot be* **-** perfection
2. Transatlantic / global divergence is already a hallmark of our regulatory systems
3. Regulation is an inherently political activity

Starting Propositions

4. New technologies will always be characterised by periods of ‘under-’ and ‘over-regulation’ (the so-called ‘pacing problem’)
5. Regulators are bound by their statutory mandates and the powers vested in them

The Current Scientific Context for Regulation

Risk and the **nanoscale...**

Nanoscale-associated behavior

- Assumption that **size** leads to "novel" behavior
- Attempts to define and **regulate** by size
- Pressure to **fit** science to ideas

The Current Policy Context Driving Regulation

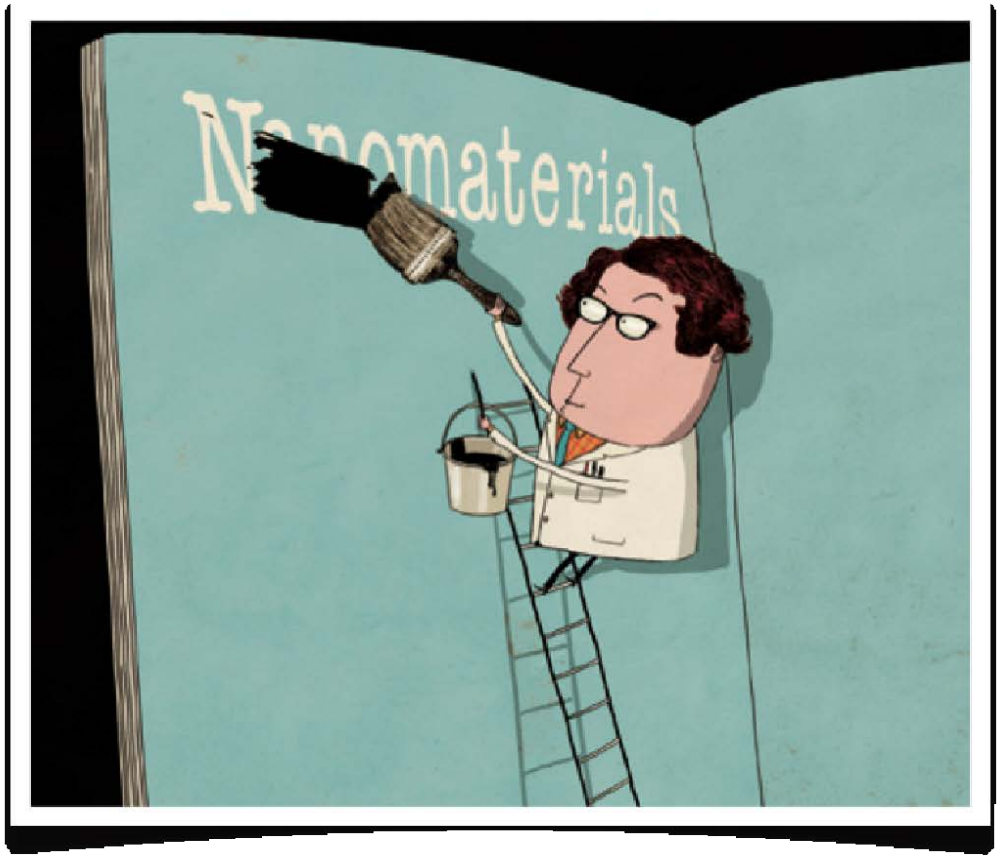
We have a '**Wicked Problem…**'

> **A Wicked Problem:** a problem "which [has] a multitude of stakeholders showing interest, but an inability for stakeholders to agree on either the nature of the 'problem' (to the degree that it exists at all), or on the most desirable solution to be applied"

Klijn, E-H. (2008), It's the Management, Stupid', On the Importance of Management in Complex Policy Issues, Uitgeverij LEMMA: The Hague

The Current Policy Context (cont.)

Regulators: Don't define nanomaterials



Maynard AD. 2011. Nature 475: 31

The Current Policy Context (cont.)

Regulating the **Nanoscale**

> **Nanomaterial** n. (regulation) a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm – 100 nm.

European Commission, October 2011

Regulatory Developments: The European Union

- Introduction of the **Cosmetic Regulation** (‘09)
- Collapse of the negotiations around the **Novel Food Regulation** (March ‘11)
- **Food Information to Consumers Regulation** (Oct. ’11)

> *Article 18: “All ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets”*

- Review of the **REACH Regulation** (2012-)

Regulatory Developments: Beyond the European Union

- (Overall) preference to retain regulatory ***status quo***
- Reliance on existing regulatory tools (e.g. US EPA and ‘Significant New Use Rules’ for CNTS)
- Small tweaks to existing frameworks (e.g. Australia & removal of exemptions for ‘new’ nanoparticles)
- Data gathering: voluntary calls for information, which have proved to be ‘underwhelming’
- Focus on safety rather than social regulation (privacy, misleading and deception conduct)

Implications

- Two races being run: EU v other jurisdictions; technology v regulation
- Lack of regulatory certainty adversely impacting R&D (esp. REACH)
- Existing ‘softer’ tools are not being used to their full potential (more flexible & nimble)
- Guidance documents needed
- Strict size-based definitions appear problematic

Moving Forward: Addressing the Regulatory Divergence

Criteria: **Emergent Risk**

> The likelihood of a new material causing harm in a manner that is **not apparent, assessable or manageable** based on the current state of knowledge

Moving Forward (cont.)

Criteria: **Plausibility**

> The **science-based likelihood** (qualitative) of a new material, product or process presenting a risk to humans or the environment

Moving Forward (cont.)

Criteria: **Impact**

> The **likelihood** of a new material, product or process having a **substantial impact** on human health or the environment

Together, **they suggest that:**

> Special consideration should be given to the research into the potential impact and oversight of materials, products and processes that have **plausible potential** to cause **substantial** harm in a manner that is **not apparent, assessable or manageable** based on the current state of knowledge.

Conclusions

- Start line is now far behind & the hare is currently in front
- International regulatory harmonization for nanotech would seem to be a ‘fairytale’
- Focus @ the global level should be on standard setting, data gathering, priority setting and provision of guidance documents

Conclusions

- Enough knowledge now to begin to ‘triage’ regulatory pathways
- Real regulatory challenges lie in the next generation of products
- Technology-neutral frameworks that focus on novelty/characteristics may give more flexibility & certainty (focus on emerging technologies more generally, such as synthetic biology, rather than just nanotech)