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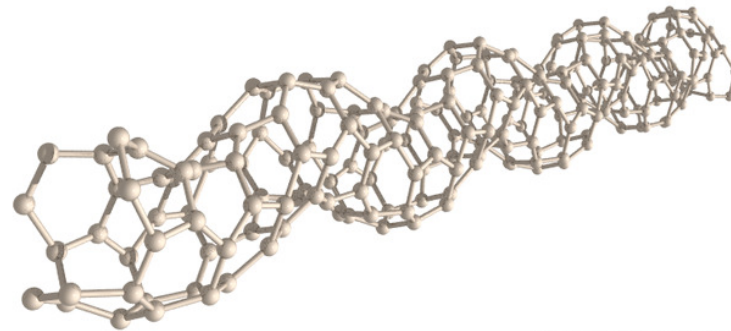
Regulation of nanomaterials: The international dimension

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Overview

1. **Why international cooperation?** The pros and cons of international nanomaterials regulation
2. **Convergence or divergence?** Key characteristics of national regulatory approaches
3. **What next?** The future agenda for international nanomaterials regulation



Rodriguez, Bhaskar & Fangohr (2007)

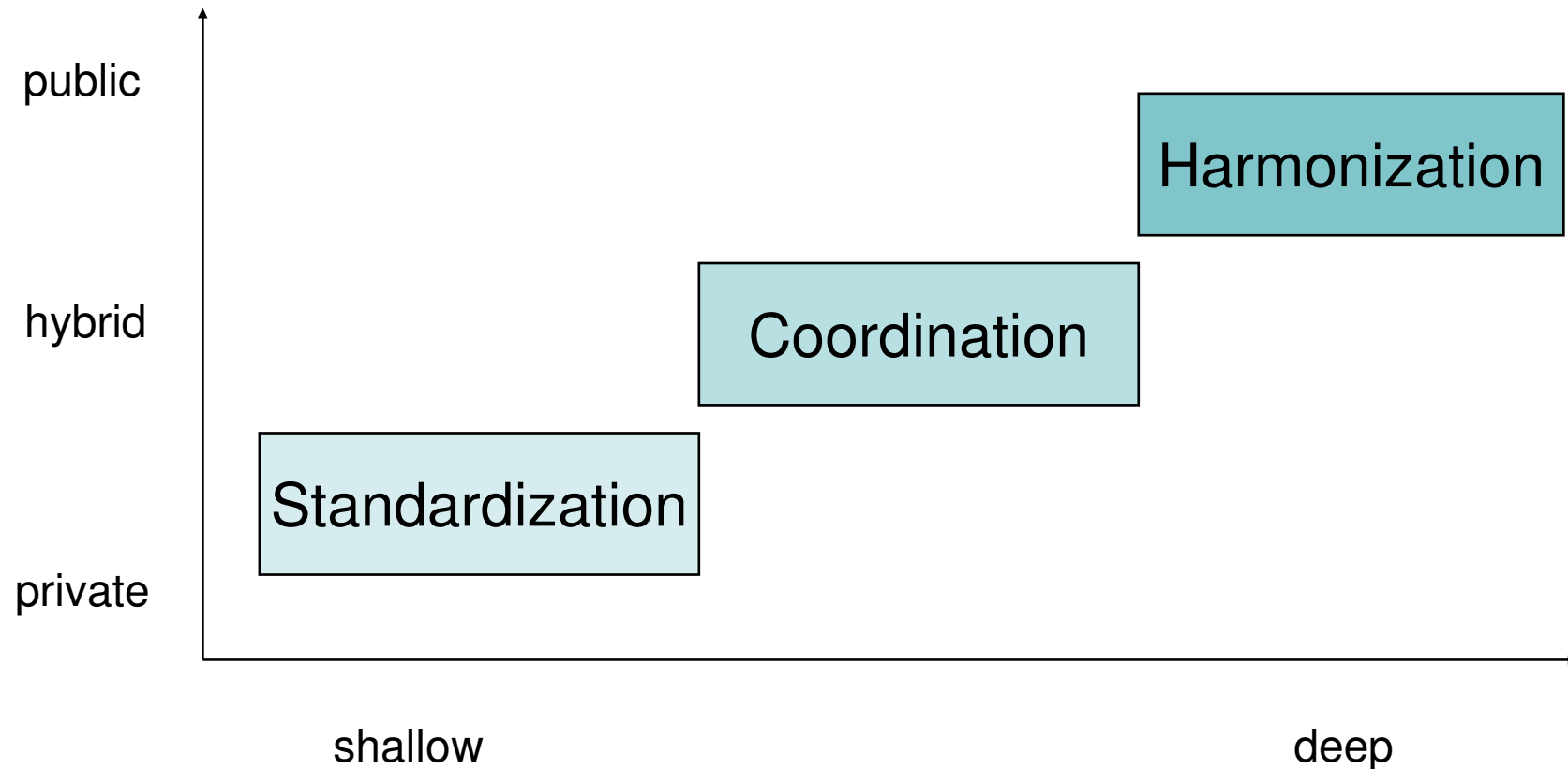
Background on LSE research

2008-09: 'Regulating Nanotechnologies in EU and US' (with Environmental Law Institute, Chatham House & Project on Emerging Nanotechnologies)

- Comparison of EU & US regulatory approaches: chemicals, food, cosmetics
- Policy recommendations for regulatory cooperation & convergence



1. Varieties of international cooperation



Why international cooperation?

Standardization (e.g. ISO)	<ul style="list-style-type: none">• to create scientific building blocks (definitions, characterisation, metrology, etc.)• to promote international commercialisation• to inform regulatory processes
Coordination (e.g. OECD)	<ul style="list-style-type: none">• to facilitate information exchange and coordinate research strategies• to promote learning processes between regulators
Harmonization (treaty-based)	<ul style="list-style-type: none">• to create internationally agreed principles, standards and rules for regulation• to avoid potential trade conflicts

Barriers to international cooperation

Standardization	<ul style="list-style-type: none">• well-established process + broad support among scientists, regulators and industry• but: uneven participation by emerging economies
Coordination	<ul style="list-style-type: none">• driven by leading nanotechnology countries and companies in OECD• but: limited participation by emerging economies• only limited scope for policy convergence
Harmonization	<ul style="list-style-type: none">• currently no international forum for deep harmonization• low demand, but high political costs

2. Dominant regulatory approach

- Rejection of technology-based regulation (unlike European GM food regulation)
- Reliance on existing sectoral regulations (chemicals, food, cosmetics, medicines)
- Divided regulatory authority (e.g. EPA vs. FDA)
- Commitment to ongoing regulatory review + piecemeal revision
- Focus on developing guidelines for implementation

Key regulatory challenges

- High degree of scientific uncertainty regarding environmental, health and safety risks
- Incomplete scientific building blocks (e.g. definitions, metrology, testing methodologies)
- Knowledge gaps re commercialisation paths and presence of nanomaterials in products/markets
- Regulatory resource constraints
- Growing globalization of nanotech industries undermines purely national/regional approaches

Convergence or divergence of regulatory approaches?

- Convergence effects to be expected from:
 - Standardization (e.g. ISO)
 - International coordination efforts (e.g. OECD working parties)
 - Bilateral information exchange and collaboration (e.g. European Commission + EPA/FDA)
- But potential for divergence:
 - Existing differences in underlying regulatory frameworks (e.g. TSCA versus REACH)
 - EU is strengthening consumer labelling requirements (e.g. novel foods and cosmetics law)
 - Underdeveloped and uneven regulatory frameworks in emerging economies (e.g. China, India)

3. Future international agenda

- **Strengthen and speed up** existing international processes (e.g. ISO and OECD)
- **Broaden participation in existing processes** (esp. emerging nanomaterials producers in South)
- **Widen global governance agenda**: new forums (e.g. IFCS + SAICM) and regulatory issues (e.g. capacity building; trade implications of regulatory divergence)

Thank you!

Further information at:

www.lse.ac.uk/nanoregulation