Nanomaterials and Regulation

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Background

- Royal Society and Royal Academy of Engineering Report
  - Government Response
    - DEFRA, HSE, FSA
    - DTI/OSI
  - RCEP – Novel Materials
  - UK Strategy

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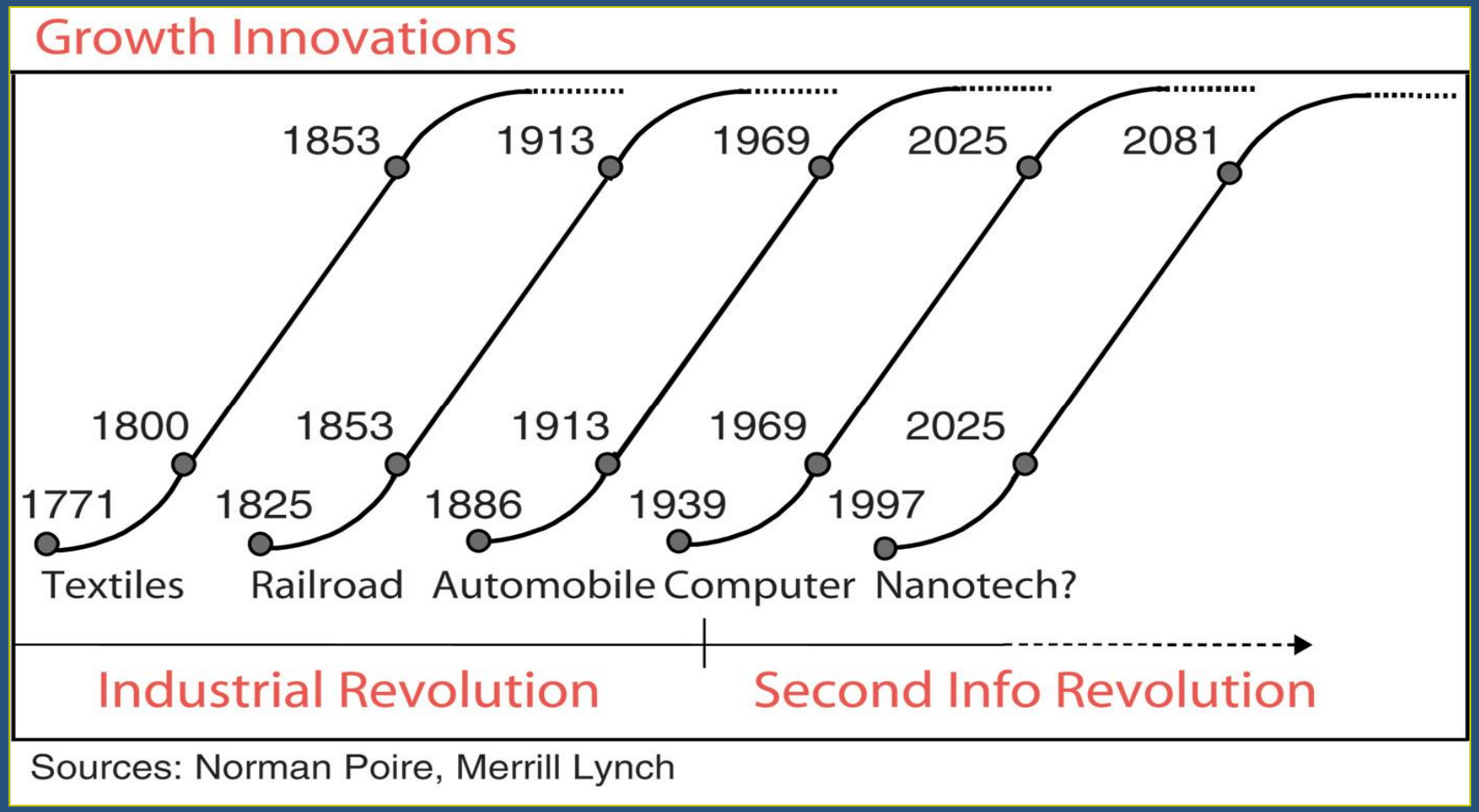
The Nanotechnology Revolution



Sources: Norman Poire, Merrill Lynch

Regulatory study

- No specific UK or EU nanosubstance regulation

- ESRC BRASS Centre 'Gap Analysis' of legislation for UK Office of Science & Innovation
  - Conclusions:
    - Gaps exist
    - …but these are not insurmountable
    - Regulatory response needs to be measured
    - International Collaboration is crucial

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5.0 NANOTECHNOLOGIES AND MATERIALS – CURRENT REGULATORY PROVISIONS

Table 2: Current Regulations[5]

Legislation	Consumer Protection	Health & Safety	Environmental Protection
Notification of New Substances Regulations 1993		X	
Registration, Evaluation and Authorisation of Chemicals (proposed)		X	
Biocidal Products Regulations 2001 (as amended)	X		
Chemicals (Hazard Information and Packaging for Supply) Regulations 2002 (as amended)	X	X	
Control of Major Accident Hazard Regulations 1999 (as amended)		X	X
Control of Substances Hazardous to Health Regulations 2002 (as amended)		X	
Dangerous Substances & Explosions Atmosphere Regulations 2002		X	
Health & Safety at Work Act 1974		X	
Management of Health & Safety at Work Regulations		X	
Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003			X
Batteries and Accumulators (Containing Dangerous Substances) Regulations 1994 (as amended)	X		X
Medical Devices Regulations 2002 (as amended)	X		X
Medicines Act 1968	X		X
Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 (as amended)	X		
Motor Fuel (Composition and Content) Regulations 1999 (as amended)	X		
End-of-Life Vehicles Regulations 2003			X
Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2005			X
Directive 2002/96/EC on Waste Electrical and Electronic Equipment			X
Packaging (Essential Requirements) Regulations 2003			X
Producer Responsibility Obligations (Packaging Waste) Regulations 2005			X
Veterinary Medicines Regulations 2005	X		
Building Regulations 2000 (as amended)	X		
Textile Products (Indications of Fibre Content) Regulations 1986 (as amended)	X		
Electrical Equipment (Safety) Regulations 1994	X		
Control of Pesticides Regulations 1986 (as amended)	X	X	
Fertilisers Regulations 1991 (as amended	X		
Plant Protection Products Regulations 2005 (as amended)	X		
Detergents Regulations 2005	X		

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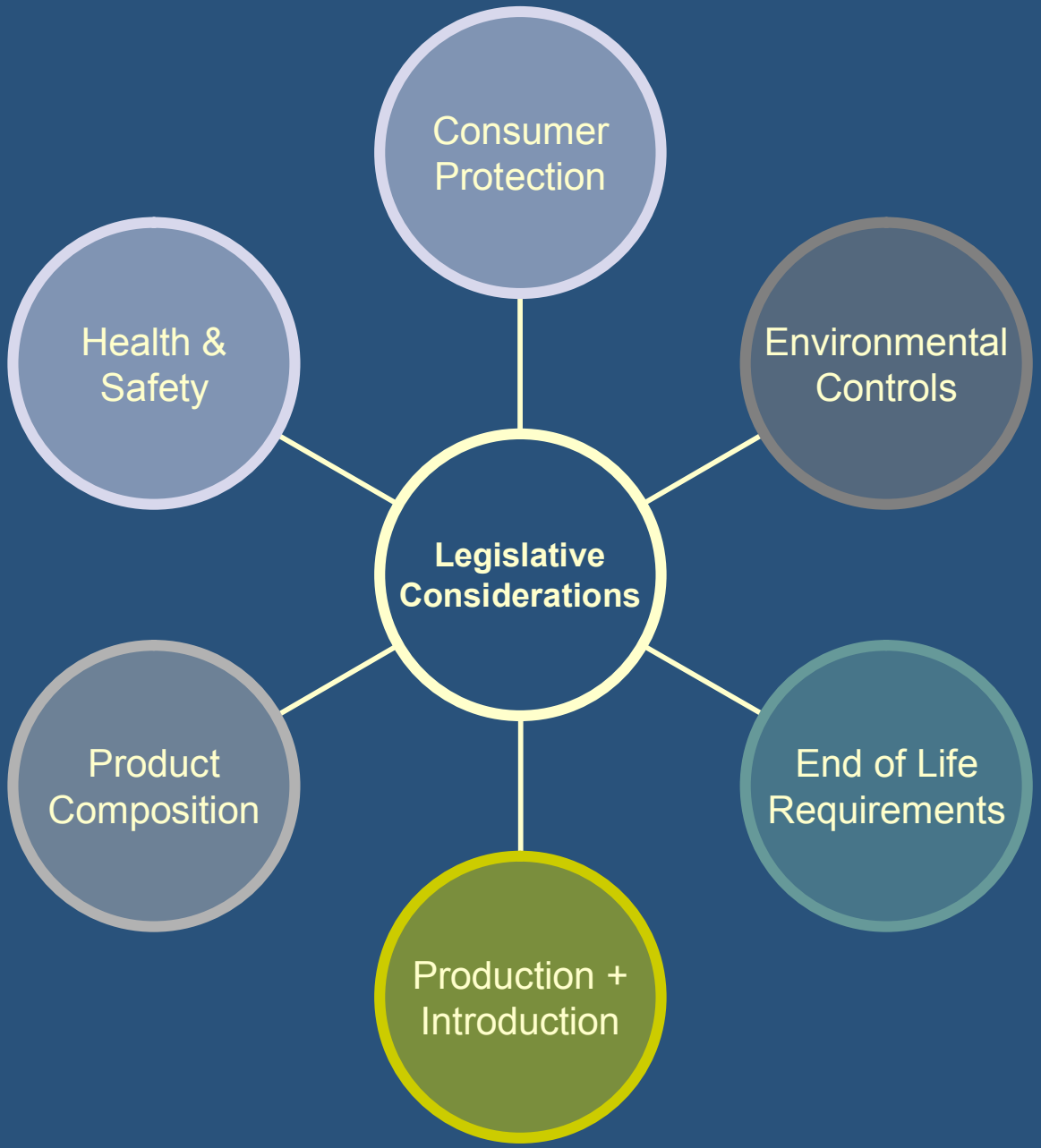

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Risk governance

- Life cycle analysis
- Scope and definition
- Risk characterisation
- Risk assessment procedures
- Risk management and communication
- Risk monitoring and reporting

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Why shortfalls arise

The Potential for Gaps

In Existing Legislation

- Thresholds
- Equivalent Products
- Listed Substances
- Non Regulated Materials
- Life Cycle Issues
- Data & Experience Gaps
- Regulated Processes
- Piecemeal Regulation
- Jurisdictional Issues

EU Commission: “Regulatory Aspects of Nanomaterials”


COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17.6.2008
COM(2008) 366 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

REGULATORY ASPECTS OF NANOMATERIALS

{SEC(2008) 2036}

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- Relevant legislative fields
  - Chemicals
  - Worker Protection
  - Products
  - Environmental Protection

- “The regulatory challenge is…to ensure that society can benefit from novel applications of nanotechnology, whilst a high level of protection of health, safety and the environment is maintained.”

- “Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework.”

Regulation

- Little specific regulation at present
  - Uncertain fit with existing regulation (REACH, novel foods etc.)
  - Slow process of adaptation (cosmetics, food additives)
- May be hard to show breach of more general liability regimes
  - GPS Directive
  - General Food Law
- Time needed
  - Definitional Issues and Standard Setting
- Regulation needed
  - Environment/health protocol
  - Stable research/investigation
  - “Departments and Agencies within Government are working to ensure that regulations and policies in all sectors are applied appropriately to nanomaterials and that the issues identified by BRASS are addressed.”

Thank You

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