

Risk management of nanotechnology products at Health Canada

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Health Canada's mandate:

- Consumer Product Safety
- Diseases & Conditions
- Drugs, Food & Health Products
- Emergencies & Disasters
- Environmental & Workplace Health
- Air Quality
- Climate Change & Health
- Contaminated Sites
- Environmental Contaminants
- Environmental Health Assessment
- Noise
- Occupational Health & Safety
- Radiation
- Water Quality

Federal Tools for Managing Health and Safety Risks

Legislation (not an exhaustive list)

- Food and Drugs Act
- Canadian Environmental Protection Act, 1999
- Pest Control Products Act
- Hazardous Products Act
- Fisheries Act
- Consumer Packaging and Labelling Act
- Canada Agricultural Products Act
- Feeds Act
- Seeds Act
- Fertilizers Act
- Assisted Human Reproduction Act
- Hazardous Materials Information Review Act
- Health of Animals Act
- Plant Protection Act
- Canada Labour Code (Part II, OHS)

Governance Issues

Are current regulatory approaches adequate?

- If nano-particles *are* sufficiently different, are existing federal frameworks sufficient to protect public health and safety?
 - Even if current approaches are sufficient for passive nanostructures (e.g., coatings), they are less likely to be adequate for the types of active nanostructures (e.g., biodevices) expected to emerge fairly soon.
- And what about provincial governments?
 - More likely to balance regulation against economic development
 - Provincial governments vary widely in capacity
 - Problem of a patchwork regulatory system

Health Canada Activities

- Canada leads ISO (nomenclature)
- Participation in OECD
- Issue identification paper and Health Portfolio strategy
- Health Canada-Environment Canada working group
- Research collaborations on assessing and characterizing toxicological effects of nanoparticles
- Health policy research (ethics)
- Federal lead in NT proposal to Council of Canadian Academies (National academy of science)

Initiatives

- Review of legal frames
- Canadian Council of Academy Report
- International activities
- Training and staffing
- International science collaborations
- Tracking systems and long term safety

International Activities

NT is an international field which is attracting much attention by governments, industry, academics and NGOs. NT has emerged as a national strategic priority in virtually all OECD countries, Some initiatives include:

- OECD Working Party on Manufactured Nanomaterials
- OECD Committee on Science and Technology Policy
- ISO TC229
- International Risk Governance Council (IRGC)
- International Council on Nanotechnology (ICON)
- Global Dialogue on NTs and the Poor (Meridian Institute)
- Global Nanotech Network (GNN)

Regulatory tools

Premarkert evaluation based on existing regulations

Science and research

New guidelines and not regulations

Information based practices

Strong partnership development

Social and stake holder engagement

Precautionary principal

No premarket evaluation

Risk management frameworks (Difficult to apply)

Voluntary Regulatory and best practices (Dupont, Defra)

Economic based

Liability based

Social and stake holder engagement

Partnership

Precautionary principal

Science and research

Patchwork of Canadian laws and statutes applicable to the assessment and regulation of health, environmental & safety risks of new technologies, including:

Health Canada	Law (Regulations)
Food & Drug Administration	Food, Drug & Act (FDA)
Canadian Environmental Protection Act	CEPA Act
Consumer Product Safety	

New Substances Program

- Ensures no new substance is introduced into Canada before an assessment is made to determine whether it is, or could be, toxic to the environment or human health.
- Where potential health or environmental risks are identified, the program will ensure these risks are mitigated.
- Under CEPA 1999, Environment Canada and Health Canada are responsible for conducting risk assessment and risk management of chemicals substances including nanomaterials.
- There are many challenges in ensuring that human health and the environment are protected from impacts of nanomaterials.

Challenges of the modern regulator

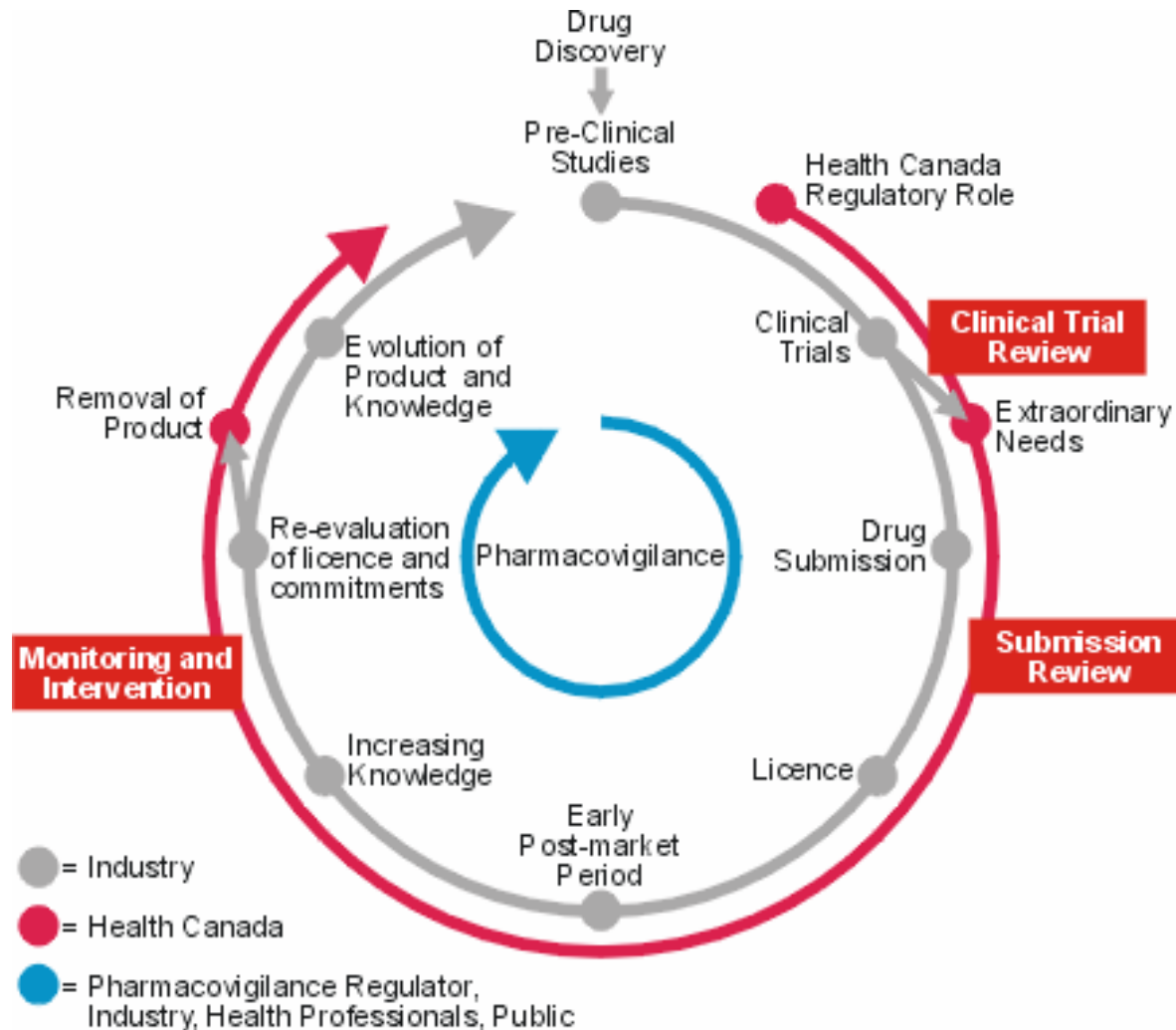
- **A severely limited, inflexible and outdated legislative and regulatory toolkit** – Food and Drugs Act was last modernized in the 1960s following the thalidomide tragedy
- **High profile safety incidents in recent years** (e.g., global withdrawal of Vioxx) and related public concerns have led to an international shift
- **Increasing public expectations** regarding nanotechnology
- **Rapid advances in science and medical technology** leading to increased complexity of products being submitted to Health Canada

Blueprint Summary

Objectives:

1. Life cycle approach
2. Interventions proportional to risk
3. Strengthened compliance and enforcement tools
4. Modern approach to food safety and nutrition
5. Make best use of all types of evidence
6. Pro-active and enabling regulatory system
7. Special emphasis on specific populations
8. Transparency, openness and accountability
9. More and better information to consumers
10. Partner in an integrated system

Progressive Licensing Framework



Progressive Licensing Framework: Four Guiding Principles

- Life-cycle management
- Evidence-based approach
- Good planning
- Accountability

Life-cycle

The central concept of Progressive Licensing is that over time there is a progression in knowledge about a drug-device.

- The emphasis of the new framework is to identify opportunities within this progression over the full life-cycle of a drug-device, rather than placing the regulatory focus primarily upon pre-market assessment.
- This represents a fundamental shift from the idea that the pre-market testing of a drug-device assures its safety and efficacy.
- The new proposed model is that a drug-device should be evaluated throughout its life-cycle for its benefit-risk profile.

Steps in life cycle assessment

- Prediction of long term risks and establishing measurement tools.
- Building Scientific expertise and access to databases
- Advising & encouraging companies to provide long term safety assessment of their products at the time of submission similar to risk management approach for pharmaceuticals.
- Encouraging industry to perform safety research at least 10-25% of their product development budget
- Involving CIHR (Canadian Institute of Health Research)
- Encouraging academic device development to perform toxicological research. Examples: University of Toronto medical device development by use of quantum dots, the surface chemistry as well as eco toxicological aspects.

Environmental Considerations

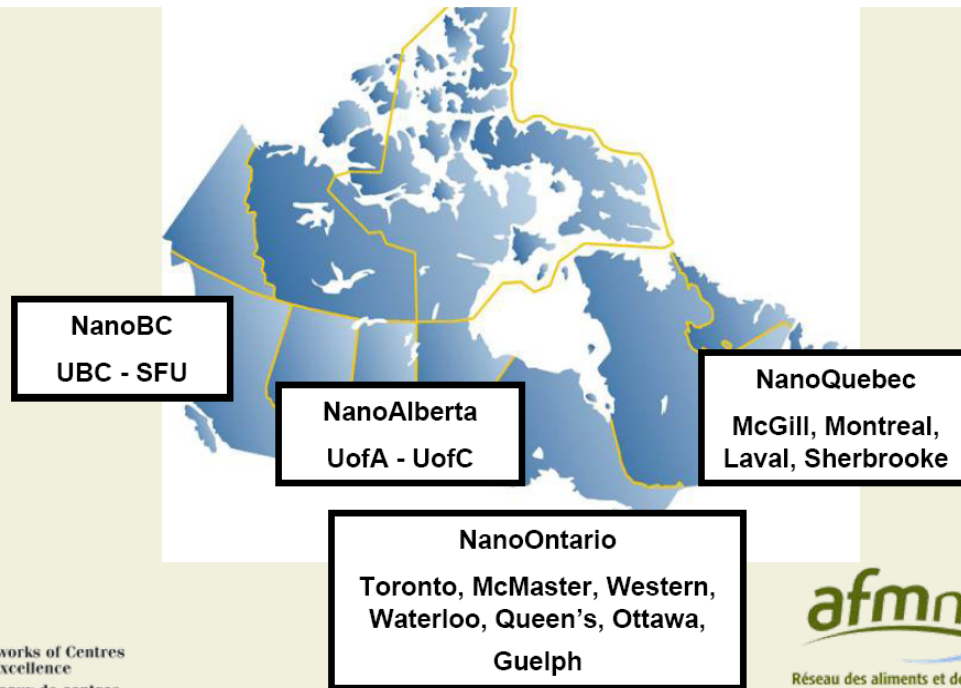
Depend on reported physical characteristics and biological effects of specific nanomaterials.

- 1. Facility design considerations
 - Limiting cross contamination between different products manufactured in the same facility.
 - Limiting contamination by components of machinery used in the manufacturing process
- 2. Impact of nanotechnology products on the environment
 - Disposal of unused/expired products.
 - Potential environmental impact of material entering the environment after administration.

Tracking systems

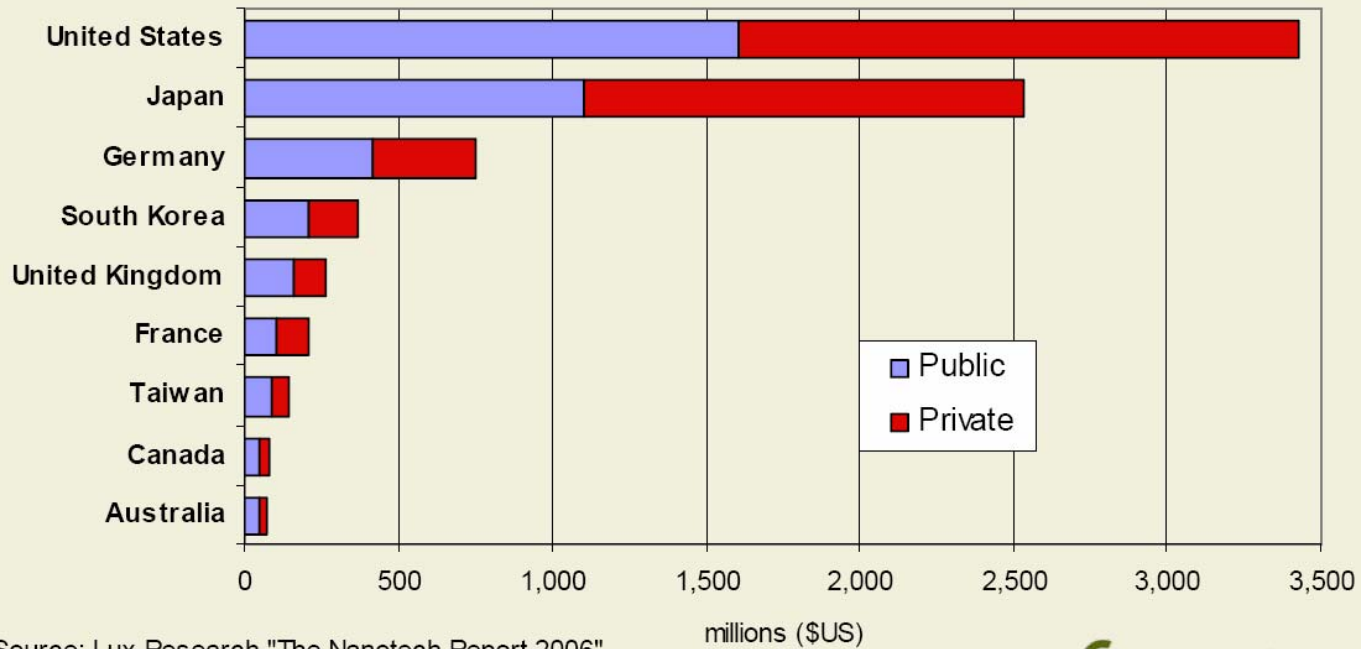
- Shared data bases for Dietary supplements, Food ingredients, Device, Drug and Biologics.
- Long term safety track, endpoints
- Class based characterization of nanotechnology products.

Major University Activities in Nanotechnology in Canada



Research Funding

Total Nanotechnology Funding (2005)



Source: Lux Research "The Nanotech Report 2006"



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Réseau des aliments et des matériaux d'avant-garde
ADVANCED FOODS & MATERIALS NETWORK

Public, Stake Holder consultations

- The general public has understandably modest knowledge about use of nanotechnology in medicine and its potential implications
- Public attitudes, while still unshaped, are generally nuanced--positive, but cautious, largely as a result of generally careful media coverage
- Subsequent public attitudes will be framed by media coverage of any controversies that arise
- Issue definition will matter in shaping such public perceptions (example of GMOs)
- Public perceptions will have policy impacts

Specific example: Food; Research Paper with the WHO

Two fundamental issues:

- To what extent does the existing regulatory framework allow regulators protect
- Consumers from potential hazards posed by nanotechnology applications in food?

- Are existing risk assessment procedures appropriate from nano-particles in foods?

Gaps

- Lack of science capacity (in standards as well as measurements) in and outside the government for research to support regulation needs
- Impact of different classes of nanotechnology products on human health and the environment is not well established
- Lack of information on exposure (e.g., baseline, sources, routes, bioaccumulation, compartmentalization, persistence)
- Appropriateness of existing tools/lack of tools
- Rapidly evolving nature of the technology