Closing the Gap: Developing Emerging Technology Policy

Dr. Pierre Charest, Director General
Science Policy Directorate, Health Canada

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Canada

Outline

- Science Policy at Health Canada
- Managing Health Risks and Public Policy Development
- Current issues
- Key Policy Questions
- Common Approach and Challenges
- Concluding Remarks

About Health Canada

Helping the people of Canada maintain and improve their health through:

- Regulating products and substances to protect health and safety
- Providing health services to First Nations and Inuit
- Working with our partners to support the health care system and administer the *Canada Health Act*
- Encouraging Canadians to take an active role in their health
- Generating and sharing knowledge and information, on which personal decision-making, regulations and standards, policy development, and innovation in health rely
- Contributing to global health

Health Canada Vision for Scientific Evidence

- Health Canada is trusted to make effective decisions through innovative approaches to access, conduct, assess and share quality scientific evidence required to help promote and protect health of Canadians

Science Policy at Health Canada

Two facets:

1. Accessing and generating the scientific evidence necessary to support health policy commitments and

2. Anticipating and addressing impacts of emerging science and technologies on health policy, health care delivery and regulation

*This presentation will focus on the **second facet***

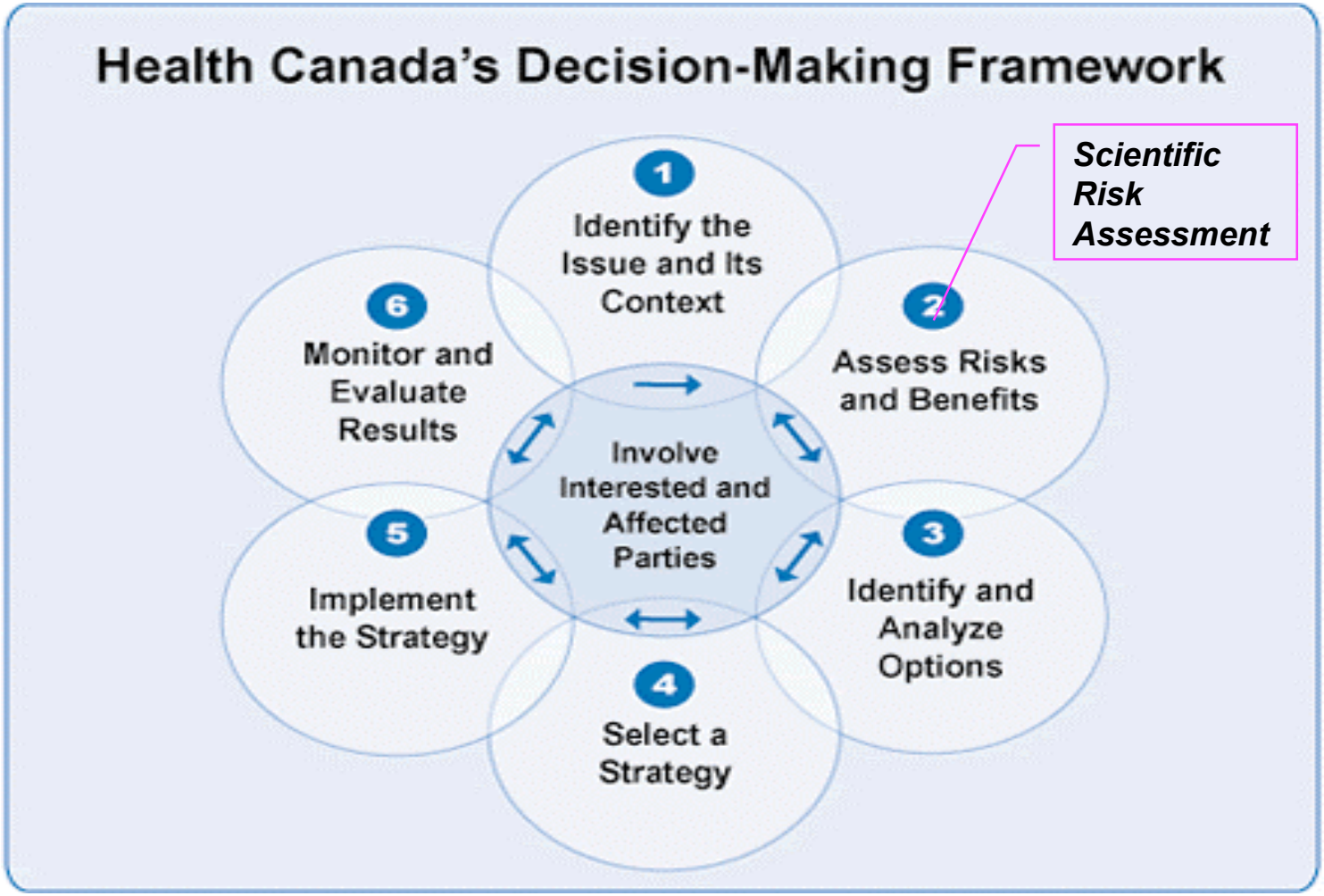
Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks

- The framework is intended to provide a common basis for risk management decision-making throughout the Department and is intended to be applicable to the range of health risks that fall within Health Canada's mandate

- These health risks include: **diseases** (both communicable and noncommunicable); **substances** (chemicals, radiation, microbes); and **products** (food, medical devices, drugs, tobacco, and consumer products)

Taken from: Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks, August 1, 2000

Health Canada Decision Making Framework, cont'd






Taken from: Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks, August 1, 2000

Scientific Risk Assessment Process

Trigger

Endpoint

Broader decision making context –
Lines often blurred between assessing and managing risk and benefit

Consider Physical, Biological & Chemical Properties

Risk Elements
-Exposure
-Fate
-Susceptibility
-Hazard

Assess Risks
(Benefits if applicable)

Manage Risks

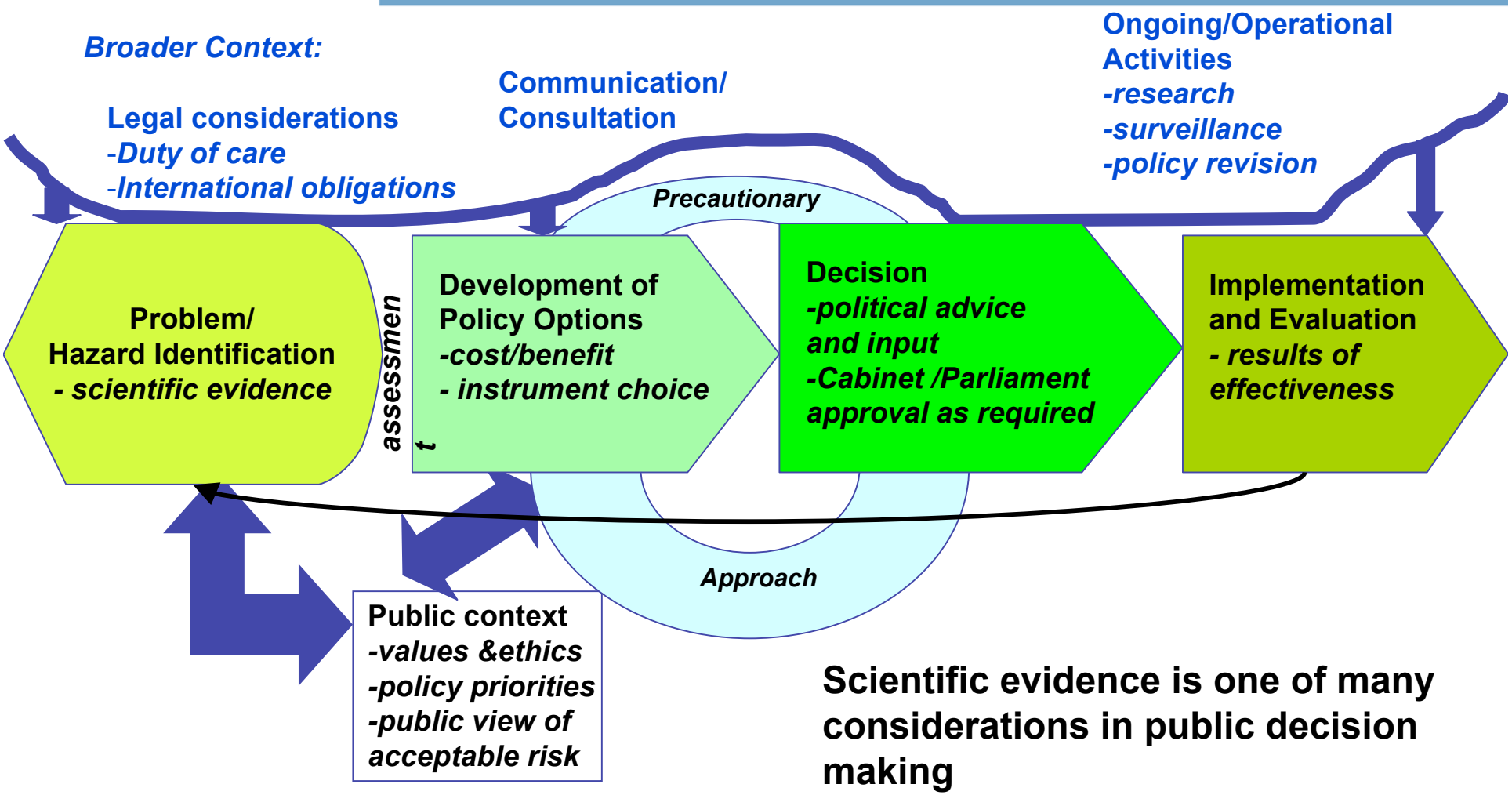
Decide, Document & Act

Review & Adapt

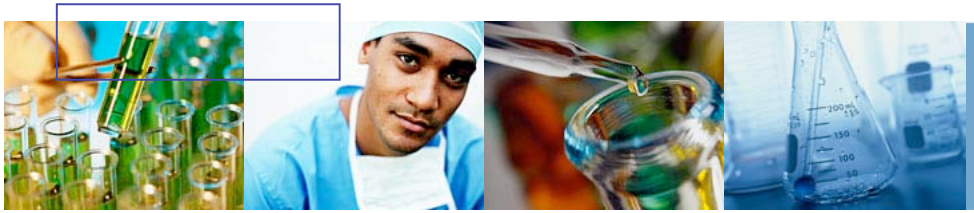
Evidence Base: Access, Conduct, Assess and Share




Risk Management in Public Policy



Scientific evidence is one of many considerations in public decision making

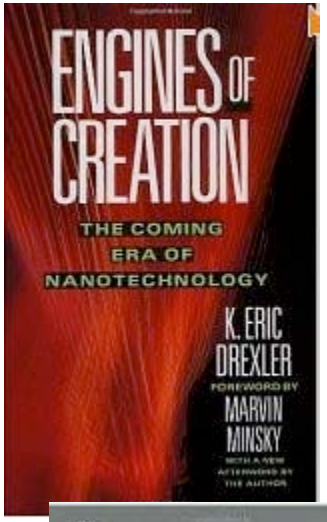


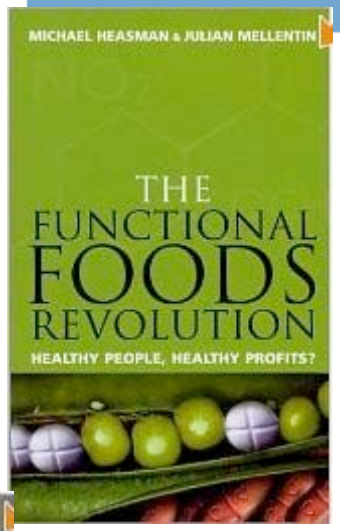
Adapted from Risk Management and Canadians Report of the ADM Working Group on Risk Management, (PCO), Annex A

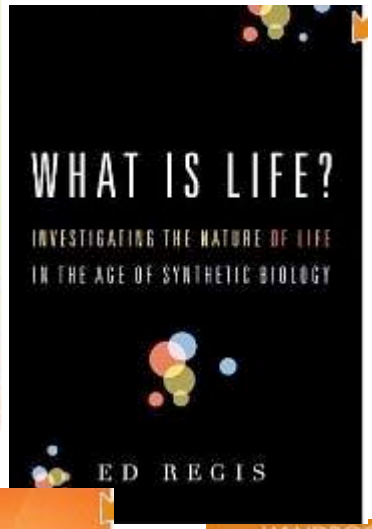
Public Policy Development Simplified

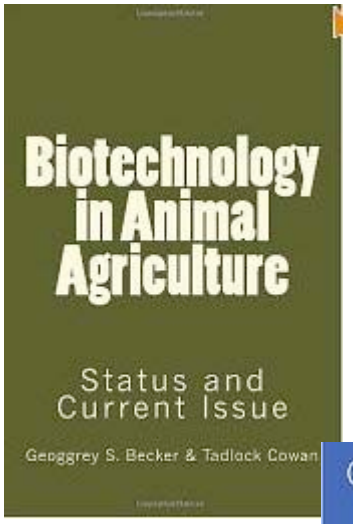
- Frame the problem (s) through analysis (e.g. scientific risk assessment) and determine its urgency
- Engage responsibility centres and stakeholders
- Clarify roles and responsibilities
- Determine policy goals and commitments related to the issue
- Articulate options, their advantages and disadvantages
- Make evidence-based recommendations
- Instrument choice and target outcomes largely dictate next steps

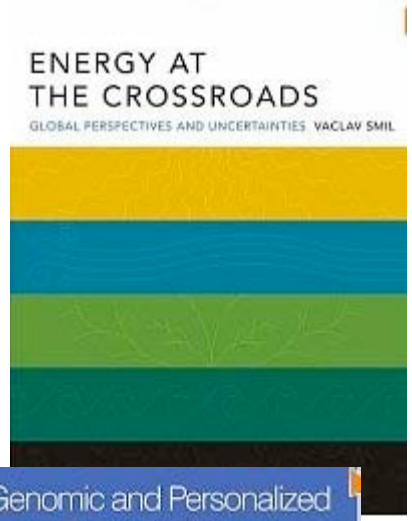
Current Issues

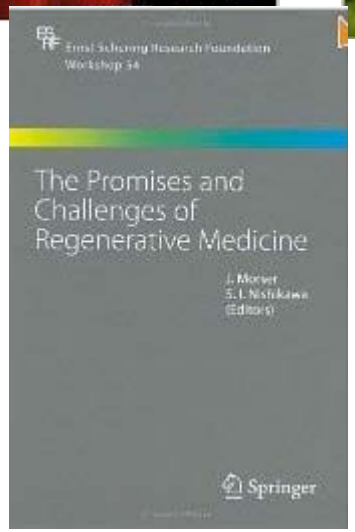


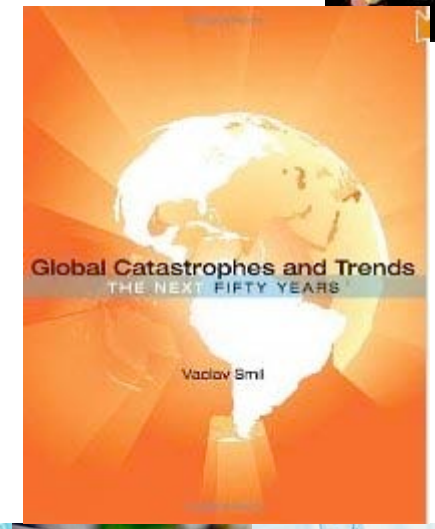


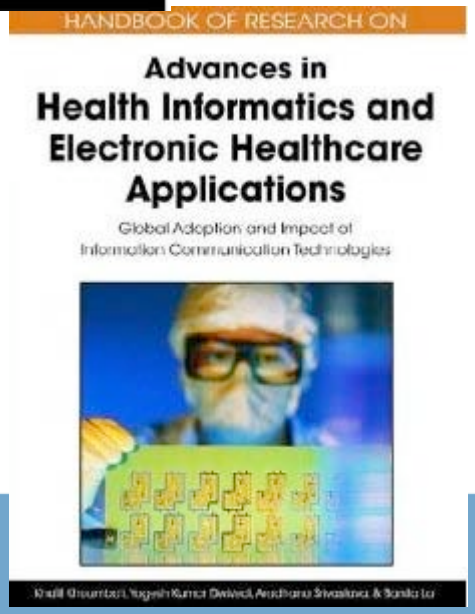


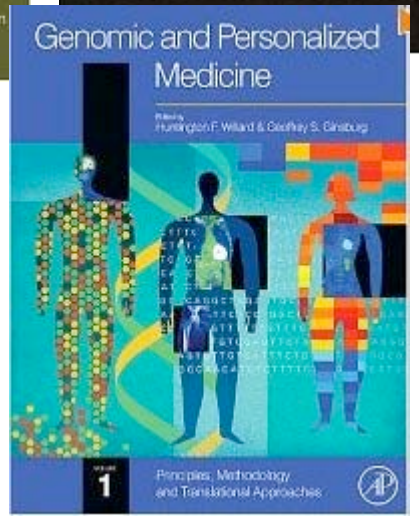












Policy Complexity

Applications resulting from emerging science and technologies will require government decision making to some degree

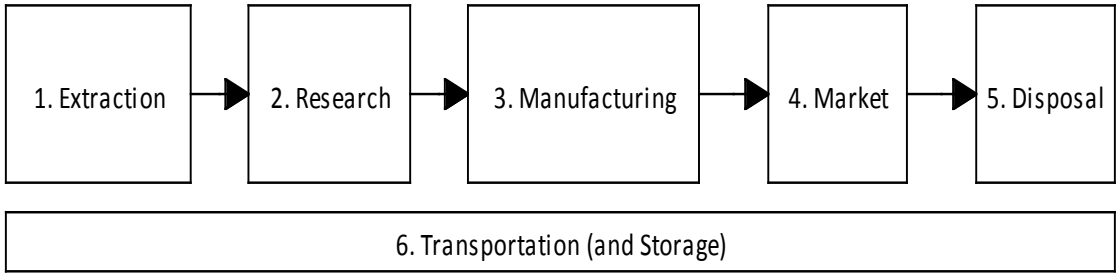
Consider:

- Policy implications across lifecycle

- Multiple potential sources of exposure

- Multiple pieces of legislation and regulatory triggers

-Known unknowns



Product lifecycle from "cradle to grave":

Emerging Technology Key Policy Questions

- Is it sufficiently different (or complex, or of such a magnitude) to warrant revising the approach to coordination, governance and/or regulation?
- Will it promote health such that there is a role to facilitate its uptake into a sustainable health care system? Contribute to global health goals?
- Should health science and research priorities be set for both internal and external research activities in order to address present and future knowledge needs?

Common Policy Approach

Emerging science and technology health policy development should address:

- Scientific evidence base and skills/capacity
- Legislation/regulation/policy impacts, including ethical, legal and social perspectives
- Health system innovation and knowledge transfer
- Awareness (Internal and External)

***Incremental*, build evidence - Collaboration is essential**

Key Policy Challenges

How to best engage with scientists?

- Access information across the evidence chain: research, data sharing, knowledge synthesis/translation, options, decisions
- Culture of safe, open dialogue on divergent conclusions, judgements and assumptions, data gaps, lack of validated methods, pressures
- Communicating openly in hierarchies

How to reduce/address uncertainty?

- Reporting schemes (mandatory/voluntary)
- Risk assessment methodologies
- Complex product classifications
- Precaution on specific products
- Right balance of pre &post market regulation
- Addressing ethical, legal and social issues

How to achieve regulatory cooperation?

- Overcoming trade/IP barriers – e.g. confidential business information
- Efficiency in reviews
- Common language/nomenclature
- International and domestic standards

How to support consumer choice?

- Labelling?
- Accessible, balanced information
- Targeted public engagement

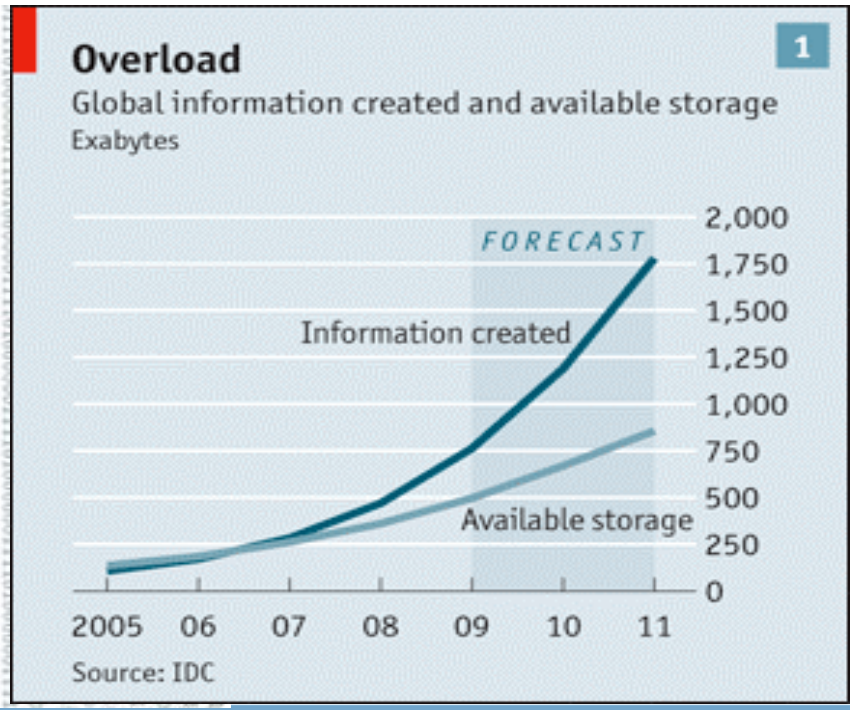
A Stand-Alone Challenge

The data deluge

Businesses, governments and society are only starting to tap its vast potential

Feb 25th 2010 | The Economist

1200 exabytes of digital data will be generated this year – 1 exabyte equals 10 billion copies of The Economist



Closing Remarks

- Science is global and crosses national borders
- Regulators around the world face similar policy challenges raised by emerging technologies
- Partnerships and collaborative models (domestic and international) are *essential* for scientific risk assessment and risk management
- Adaptability and flexibility necessary
- Informed decisions require quality, impartial advice based on best available evidence and rational analysis