Regulatory Risk Analysis in the European Union, United States, and Canada

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Overview

- European Union
- United States of America
- Canada
- Commonalities
- Conclusion

Risk analysis : European Union, Canada, United States

- Structures for risk analysis
  - Risk assessment
  - Risk management
  - Risk Communication

- Principles of risk analysis

Risk Analysis in the European Union

Risk Assessment

- Agencies: EFSA- EMEA-EEA-ECDC-ECHA
- Commission Scientific Committees: SCENIHR, SCCP, SCHER, SCOEL

Risk Management

- Parliament- Council- Commission

Risk Communication

- Commission
- Agencies and Scientific Committees on opinions and scientific matters

Risk Analysis in the European Union

- **Risk assessment**

- Several scientific bodies assist EU institutions on a variety of risk related issues

- The general aim is to provide the EU with independent scientific risk assessment advice

Risk Analysis in the European Union

RA Body	Area of Competence	
EFSA	Food and feed safety, Animal health and welfare, Plant health	
EMEA	Safety/effectiveness medicines human use; Safety/effectiveness medicinal products for veterinary use, Pharmaco-vigilance	
ECHA	Registration, evaluation of chemicals (REACH)	
ECDC	Communicable disease, surveillance, preparedness and response	
EEA	Air, water, soils pollution, climate change, natural resources and bio-diversity	
SCENIHR	Emerging or newly identified health risks	
SCHER	Risks related to toxicity and eco-toxicity of chemical, bio-chemical and biological compounds	
SCCP	Health risks of non-food consumer products	
SCOEL	Occupational exposure to chemicals	

Relationships between EU Risk Assessment Bodies

- EU bodies are independent, but
- Committed by legislation to resolve or clarify diverging opinions
- Many areas and subjects of common interest
- Commission promotes collaboration, while respecting independence
- Annual meetings of Chairs and Vice-Chairs of Scientific Bodies and Agencies

EU Risk Assessment bodies

- Composed of a number of Scientific Committees and/or panels
- Members appointed either through an open selection procedure (e.g. EFSA, Commission Scientific or in some instances by Member States (e.g. ECHA) on the basis of proven scientific excellence
- Rules and guidance on
  - Conflict of interest
  - Openness, transparency and confidentiality
  - Submission of Risk Assessment dossiers
  - Stakeholder relations

EU Risk Management

- Commission proposals for legislation to the European Parliament and Council based on
  - Results of risk assessment
  - Consultation within the Commission
  - Stakeholder Consultation
  - Impact Assessment
- Legislation is enacted after EP and Council comment and agree on proposal (co-decision)

EU Risk Communication

- Commission is primarily responsible for risk communication via
  - DG Press
  - Commissioner services
  - Commission services responsible for the subject
- Agencies and Scientific Bodies sometimes also conduct Risk Communication on results of RA (e.g. opinion summaries, popularized opinions)
- Variety of communication tools used

EU Risk Analysis Principles

- EU policy is to be based on best available scientific knowledge

- The scientific advice structure is based on principles of
  - Separation between Risk Assessment and Risk Management
  - Independence, Competence and Transparency

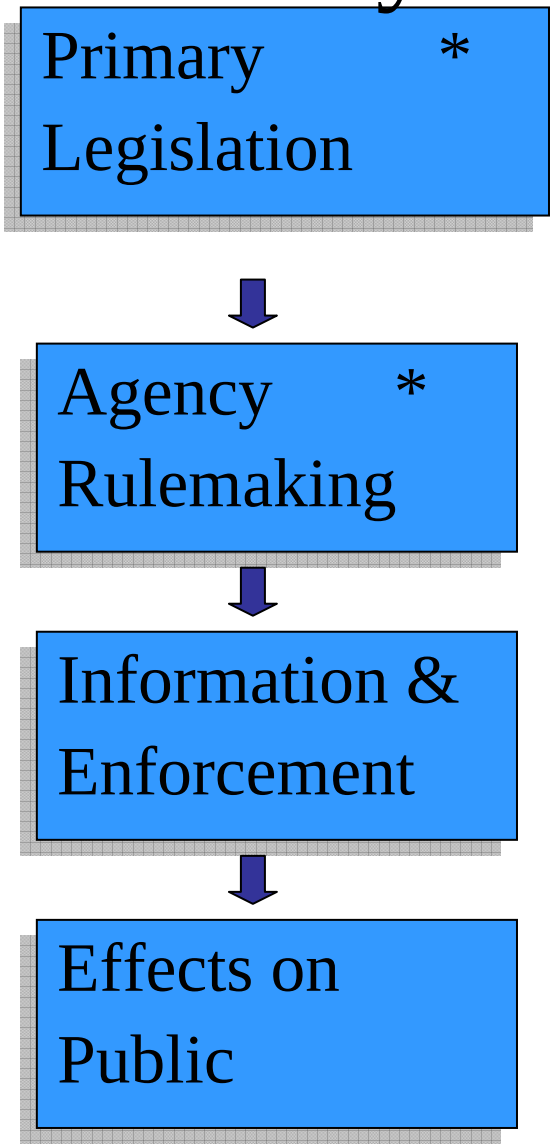
EU Risk Analysis Principles – some examples

- EU Treaty (references to scientific evidence/data as basis/justification for policy and measures)
- EU Commission: Communication on Consumer health and Food Safety (1997)
- EU Commission: Communication on Collection and Use of Expertise (2002)
- EU Food Law
- EU Commission Decision establishing Scientific Committee on Occupational Exposure Limits (1995, 2006)
- EU Regulation on REACH and establishing ECHA
- EU Commission Decision establishing Scientific Committees in the field of Consumer Safety, Public health and the Environment (2004, 2008)

EU Risk Analysis Definition (Communication on Consumer health and Food Safety (1997)

- **Definition of Risk Analysis**:
  - A systematic procedure comprising:
    - ✓ the scientific evaluation of hazards and the probability of their emergence in a given context (risk assessment)
    - ✓The assessment of all measures making it possible to achieve an appropriate level of protection. It includes assessing the impact of policy alternatives in light of RA results and the desired level of protection (risk management)
    - ✓The exchange of information with all the parties concerned (risk communication)

Risk Analysis in the United States



Legislative Branch: Clean Air Act

Executive Branch: Diesel-Engine Exhaust Rule

Executive and Judicial Branches: "Guidance" and "Certification", Procedures for Engine Suppliers

Cleaner Air (At a cost)

*Public input is part of the process

Risk Analysis in the United States

How Regulation Has Changed,1980-2008:

- Decline of economic regulation
- Rise of regulation where science is critical determinant
- Majority of rules address public health, safety, environment, and homeland security
  - Food and Drug Administration (Department of Health and Human Services)
  - Environmental Protection Agency
  - Occupational Safety and Health Administration (Department of Labor)
  - Department of Agriculture
  - National Highway and Transportation Safety Authority; Federal Aviation Authority (Department of Transportation)
  - Department of Homeland Security
  - Department of Agriculture

Risk Analysis in the United States

Scientists in the U.S. Federal Government

- 206,000 Scientists and Engineers in all Agencies (2002 data)
  - Includes: 85,358 Engineers; 32,405 Life Scientists; 25,345 Social Scientists
    - Also includes computer and mathematical scientists and physical scientists

  - Department of Defense: 89,409 Scientists; 56,909 Engineers
  - Department of Agriculture: 19,056 Scientists; 1,908 Engineers
  - Department of Health and Human Services (includes foods and drugs and NIH): 10,916 Scientists; 681 Engineers
  - Environmental Protection Agency: 8,598 Scientists; 2,044 Engineers
  - Nuclear Regulatory Commission: 1,699 Scientists; 1,248 Engineers

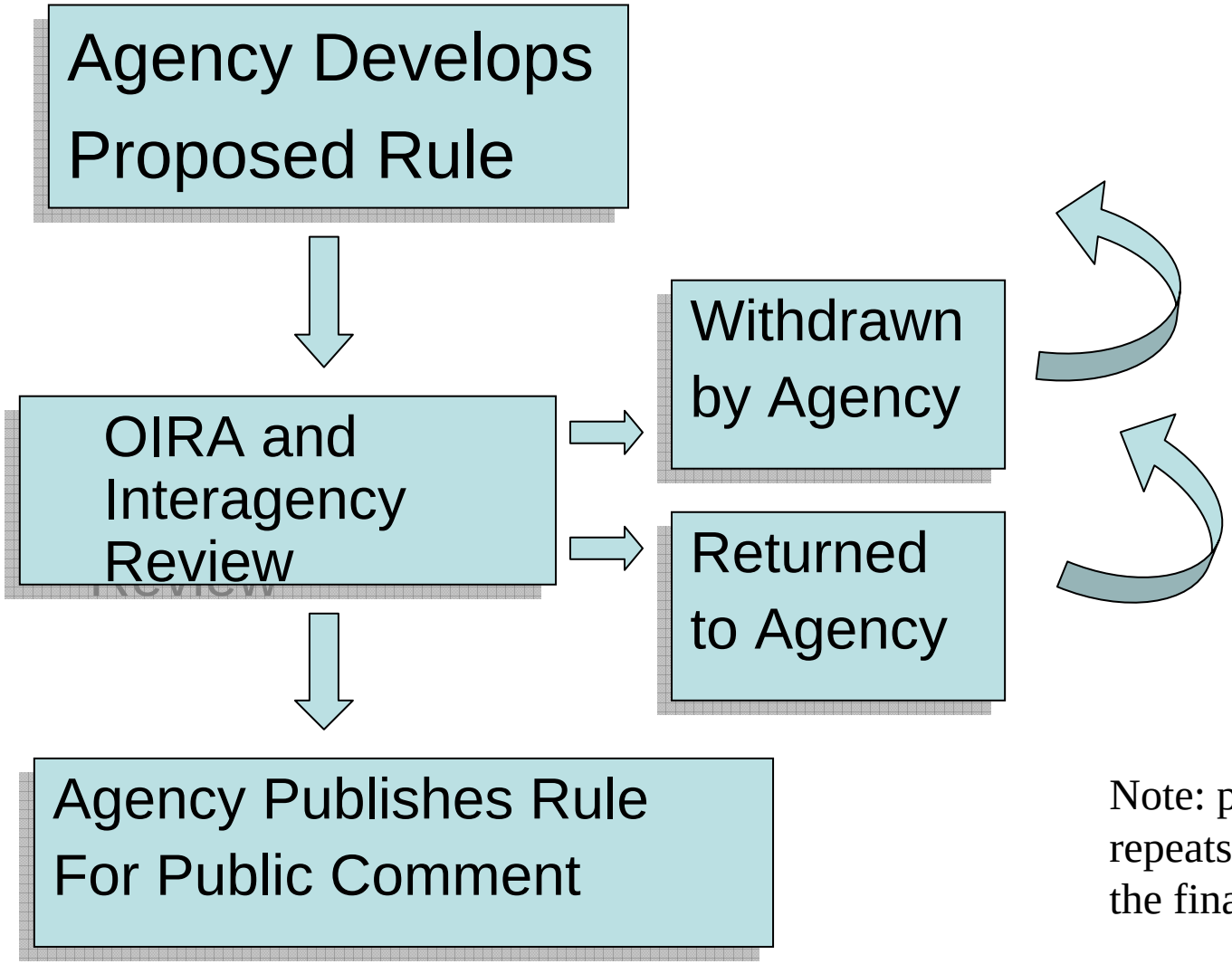
Risk Analysis in the United States

Scientific Resources used by the U.S. Government

- Peer-reviewed journal publications
- Agency laboratories
- Grants, contracts, and cooperative agreements to answer specific scientific questions
- Expert review panels for peer review:
  - National Academy of Sciences
  - Agency Advisory Committees
  - Internal agency review
  - Interagency review

Risk Analysis in the United States

How Rule Review Works:



Note: process repeats itself for the final rule

Risk Analysis in the United States

Role of Scientific Review: Ensuring Quality

- Scientific review enhances OMB's ability to evaluate the scientific underpinnings of regulatory impact analyses, risk assessments, and health and safety guidance.
  - Scientific review includes providing a clear separation between:
    - The Science
    - Science Policy
    - Policy
- This process also engages scientists throughout the government.
- Ensures that agency science is presented in an accurate, clear, concise, and unbiased manner.
  - Assists with Risk Management
  - Assists with Risk Communication

Risk Analysis in the United States

Role of Scientific Review: Ensuring Quality

- Is the rule based on best available, peer-reviewed science?
  - Where the performance standards of the Information Quality Guidelines and Peer Review Bulletin met?
- Is the risk analysis transparent and appropriately conducted?
  - Were the OMB and OSTP Principles for Risk Analysis followed?
- Are benefits and costs identified, quantified and weighed?
  - Was Circular A-4 followed?
- Are regulatory alternatives considered?

Risk Analysis in the United States

Ensuring Quality

- Responsive, consultative, science-based system
  - Opportunity for the public at large to comment
- Operates synergistically within multiple layers of checks and balances
  - Involving social norms, market forces, liability law, and voluntary standards
- Benefits from executive, legislative and judicial oversight
- System allows for an iterative process of information collection, risk assessment, and risk management when regulating emerging risks

Risk Management in the United States

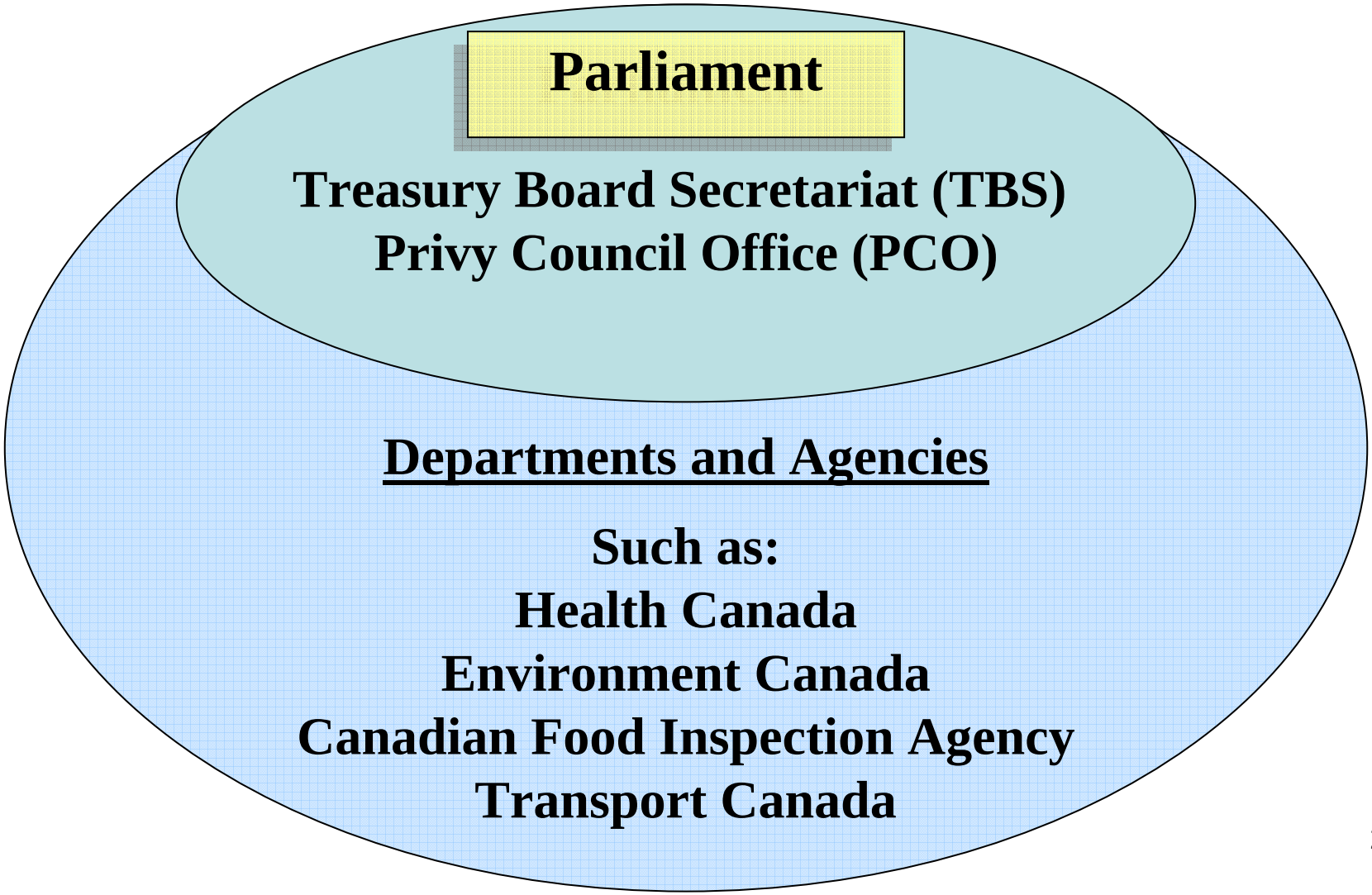
- Risk-only Approach
  - Consider only risk to keep hazards below a certain "safe" level
    - Endangered Species Act, Food Quality Protection Act

- Feasibility Approach
  - Recognizes the utility of the activity that generates the hazard and requires reductions to the extent that they are technologically or economically feasible
    - Clean Air Act Maximum Achievable Control Technology standards

Risk Management in the United States

- Benefit-Cost Balancing Approach
  - Considers overall societal welfare and attempts to balance the positive and negative consequences; identifies “unreasonable risk”
    - Toxic Substances Control Act
- Hybrid Approach
  - Combines a risk-only regulatory goal with a technology-based enforceable standard. Used when the “safe” levels are not achievable
    - Safe Drinking Water Act—maximum contaminant level goal

Risk Analysis in the Government of Canada



Overview of the Canadian Legislative/Regulatory Process

1. Primary legislation
(Parliament)

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2. Development and Drafting Regulations & RIAS
(Department & Agencies)

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3. Approval for Publication in the *Canada Gazette*
(Treasury Board)

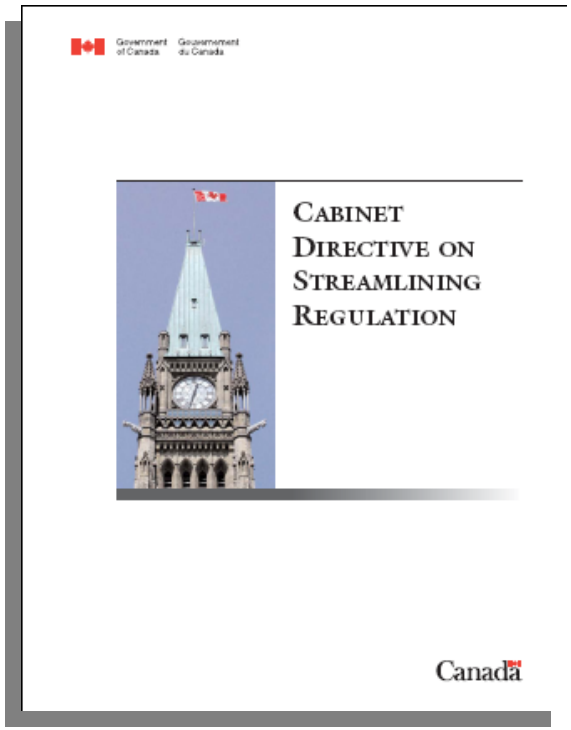
↓

4. Parliamentary Review
(Standing Joint Committee for Scrutiny of Regulations)

Overview of the Canadian Regulatory Process

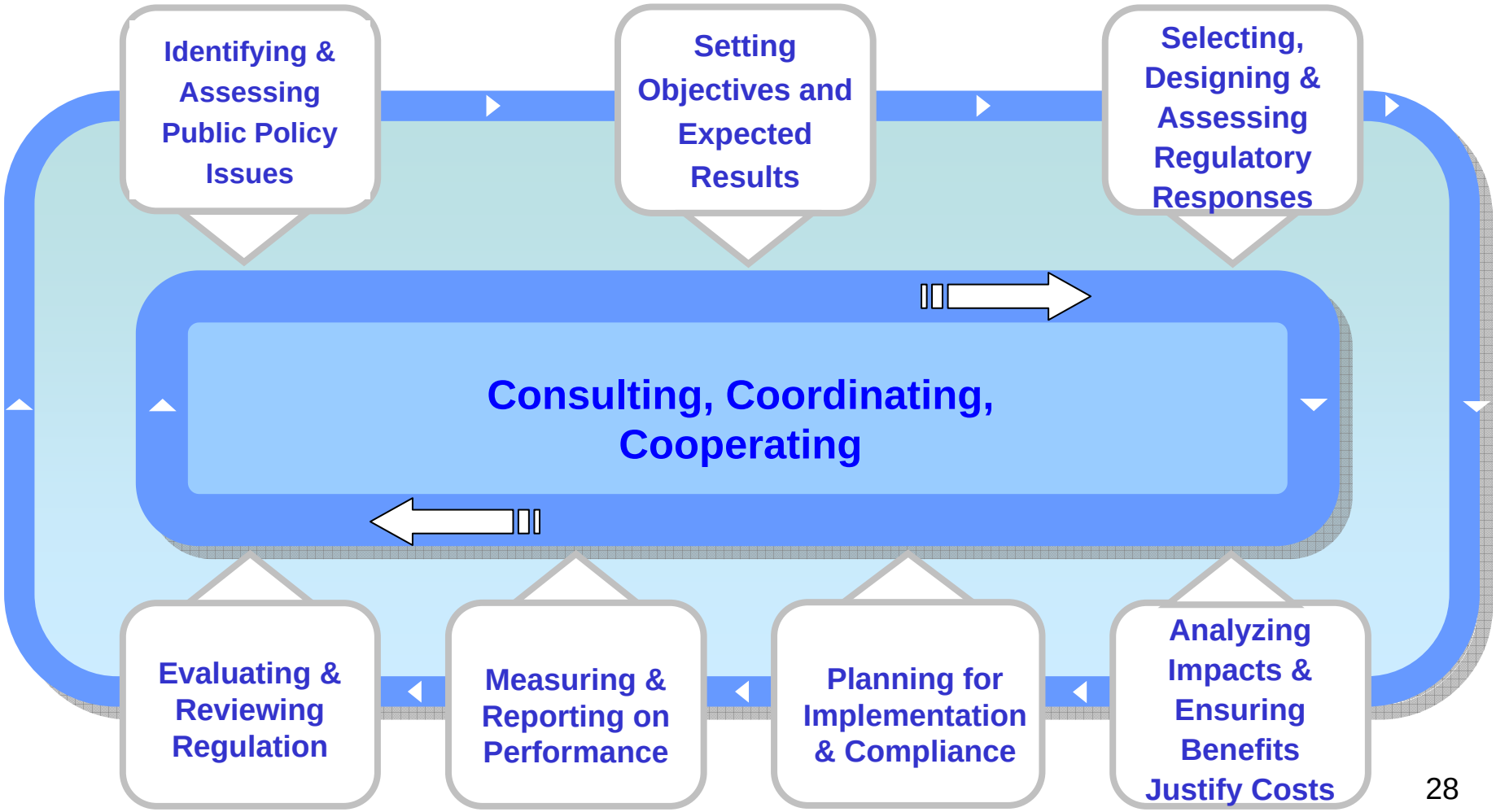
Canadian Regulatory Risk Analysis Approach

"The Government of Canada is committed to protect and advance the public interest by working with Canadians and other governments to ensure that its regulatory activities result in the ***greatest overall benefit to present and future generations of Canadians***."

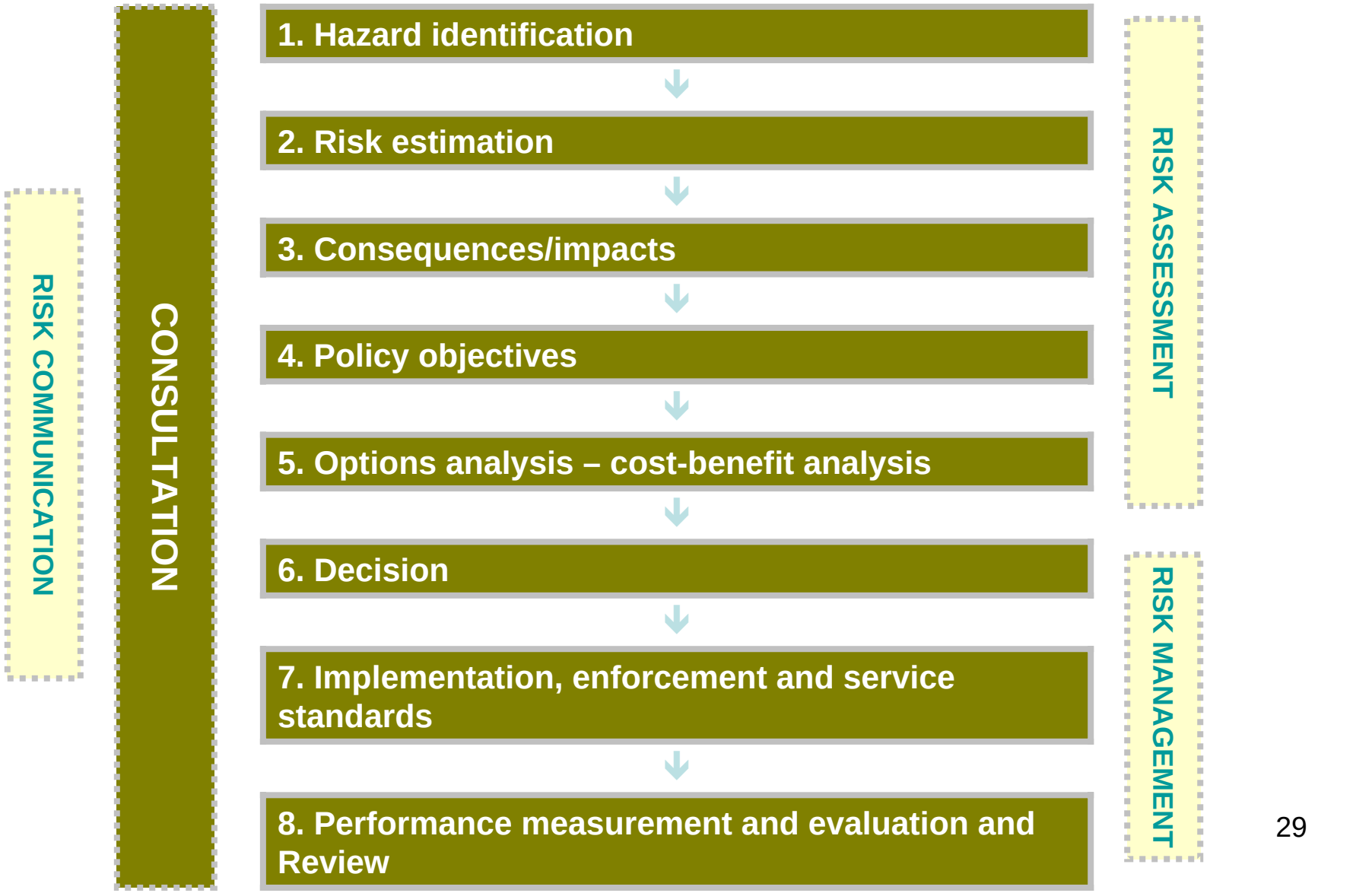


- Protect and advance the public interest
- Promote a fair and competitive market economy
- Make decisions based on evidence
- Require timeliness, policy coherence, and minimal duplication
- Create accessible, understandable and responsive regulation
- Advance efficiency and effectiveness

Cabinet Directive on Streamlining Regulation



Risk Analysis Guidance



Goals of Risk Assessment

- Foster a performance-base regulatory system
  - Enhances transparency and accountability
- Better analysis makes better regulations
  - Added rigour and discipline to the analysis will promote more better regulations
- Assists decision-markers in making evidence based decisions
  - Regulations based on best available science
  - Robust information on the full range of impacts on all Canadians (health, environment and social and economic well-being)
- Fulfil International requirements
  - Such as, WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)
    - Regulatory measures are based on an assessment, of the risks to human, animal or plant life or health, taking into account risk assessment techniques
    - In assessing the risk, need to take into account economic factors
- Public expectation that regulations are based on sound science

TBS Initiatives for Risk Analysis Excellence

Champion and leader

- CDSR
- Triage Statement
- Regulatory Impact Analysis Statement
- Guides

Strategic Advisor

- Center of Regulatory Expertise
- Support the regulatory practitioner on each regulatory submission

Challenge and oversight

- Verifies CDSR compliance
- Briefs Ministers
- Highlights risk assessment in regulatory submissions

Backdrop of Varying Governmental Structures

- EU: separation of risk assessment and risk management
  - Agencies and scientific bodies provide advice to the European Commission
  - Scientific bodies are independent

- US: federal agencies conduct risk assessments and make risk management decisions
  - Scientific experts and risk managers exist within the same agencies
  - Checks and balances are provided by legislative and judicial branches

- Canada: federal departments/agencies conduct risk assessments and make risk management decisions
  - Scientific experts and risk managers exist within the same departments/agencies
  - System is transparent and open with oversight mechanisms

Backdrop of Varying Governmental Structures- however there are many similarities

- Each has agencies that generally focus on distinct areas:
  - Food
  - Chemicals
  - Occupational Health
  - Medicines
  - Communicable Disease
  - Environment
- Each use a risk assessment framework to inform regulatory decisions

More Similarities than Differences

- EU: risk management based on the best available scientific knowledge
  - Emphasis on: Independence, Competence, and transparency
- US: agencies employ the best reasonably obtainable scientific information to inform risk
  - Emphasis on: quality, transparency, and accountability
- Canada: make decisions based on evidence and the best available science while recognizing that the application of precaution may be necessary when there is an absence of full scientific certainty and a risk of serious or irreversible harm
  - Emphasis on: inclusiveness, transparency, accountability, and public scrutiny

More Similarities than Differences

- All have rules and/or guidance relating to:
  - Conflict of interest
  - Transparency
  - Stakeholder involvement
  - Regulatory Impact Assessment
  - Peer review
  - Collaboration and coordination within the governmental structure

Conclusions

- Core principles are common among EU, US and Canada
  - Work towards developing a common set of principles should help to emphasize and validate an approach using the best available science
- Solid basis for sustained dialogue and collaboration

References

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