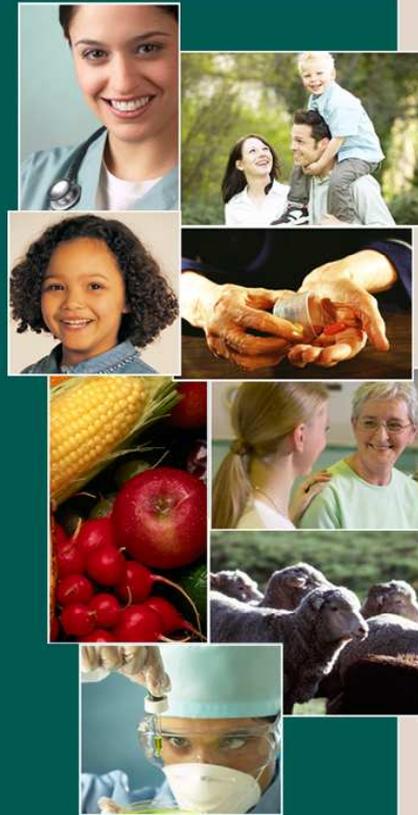


# *Health Products and Food Branch*

Your Health and Safety - Our Priority



## **Overview of Canada's Regulatory Environment**

**Brigitte Zirger  
Health Canada**



Health  
Canada

Santé  
Canada

Canada

# Outline

- Canada's System of Government
  - Division of Powers
  - Minister of Health Responsibilities
  - Making Policy, Laws and Regulations



# Federal-Provincial Division of Powers for Health

Powers set out in the *Constitution Act* of Canada,  
Part VI, s 91-95

## **Provinces** responsible for

- Delivery of health care to majority of Canadians
- Drug Formularies / Reimbursement issues
- Practice of Medicine
- Practice of Pharmacy, including the “conditions of sale” for drugs

## Division of Powers (continued)

**Federal** government has constitutional responsibility for :

- **Criminal law**, e.g., safety, efficacy and quality of therapeutic products via the *Food and Drugs Act*
- **Patents** of invention and discovery, e.g., linkages with the *Patent Act*
- **Trade and commerce**, e.g., control over importation of therapeutic products; control over the price of patented medicines via the **Patented Medicines Prices Review Board**
- **Peace, order and good government**, e.g., national standards, national emergencies
- All matters pertaining to **specific populations**, e.g., first nations, armed forces and federal prison inmates (healthcare delivery)

# Required Reading

## How Canadians Govern Themselves

by Eugene Forsey 1904-1991



<http://www.parl.gc.ca/information/library/idb/forsey/index-e.asp>

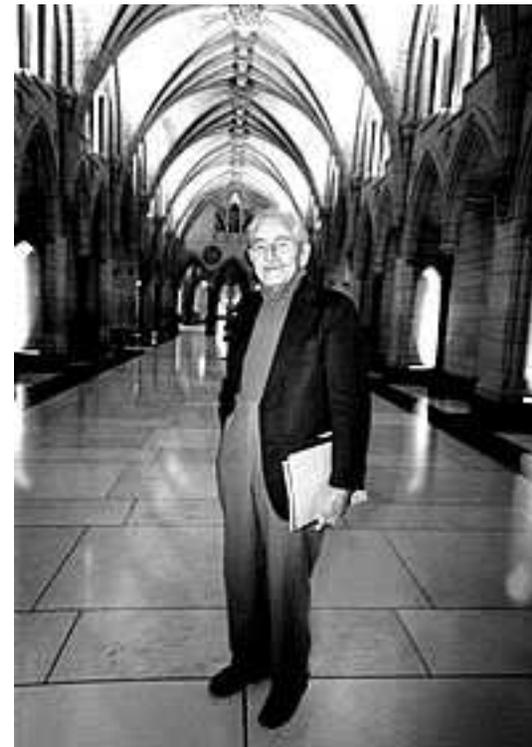


Photo: Jean-Marc Carisse

# Minister of Health Responsibilities

Stem from the *Department of Health Act*

- 4. (1) ...all matters over which Parliament has jurisdiction relating to the **promotion and preservation of the health of the people of Canada** not by law assigned to any other department, board or agency of the Government of Canada.
- 5. Minister may designate **inspectors**
  - Defined in FD&A s. 22(1) as any person designated as inspector for purpose of enforcement



## Minister of Health (continued)

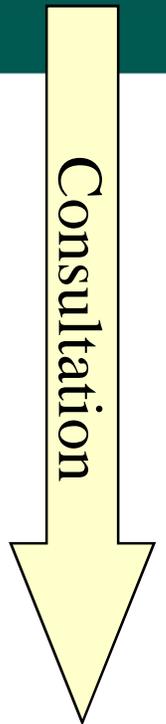
Federal Role in Health falls into five broad areas

- **Leadership** – Administration of the *Canada Health Act*
  - embodies the principals of Medicare
- **Supporting** the healthcare system
  - financial transfers
- **Protecting the health of Canadians** 
  - Falls largely to the regulatory role
- **Service Provider** - Healthcare delivery to First Nations and Inuit; drug formularies
- **Promoting** strategies to improve the health of Canadians
  - Largely through provision of information

# Making Policies

# The Policy Making Process

- Clearly identify the issue
- Analysis of the issue
  - Identification of feasible alternatives (regulatory and non-regulatory)
  - Comparison/evaluation of options based on overall net benefit, risk, cost, speed of issue resolution, etc.
  - Selection of preferred option
- Consultation - internal/external
- Approval & implementation of recommended option
  - If regulatory – amend or draft new regulations
  - If non-regulatory – development of a guidance, procedure, fact sheet, etc.

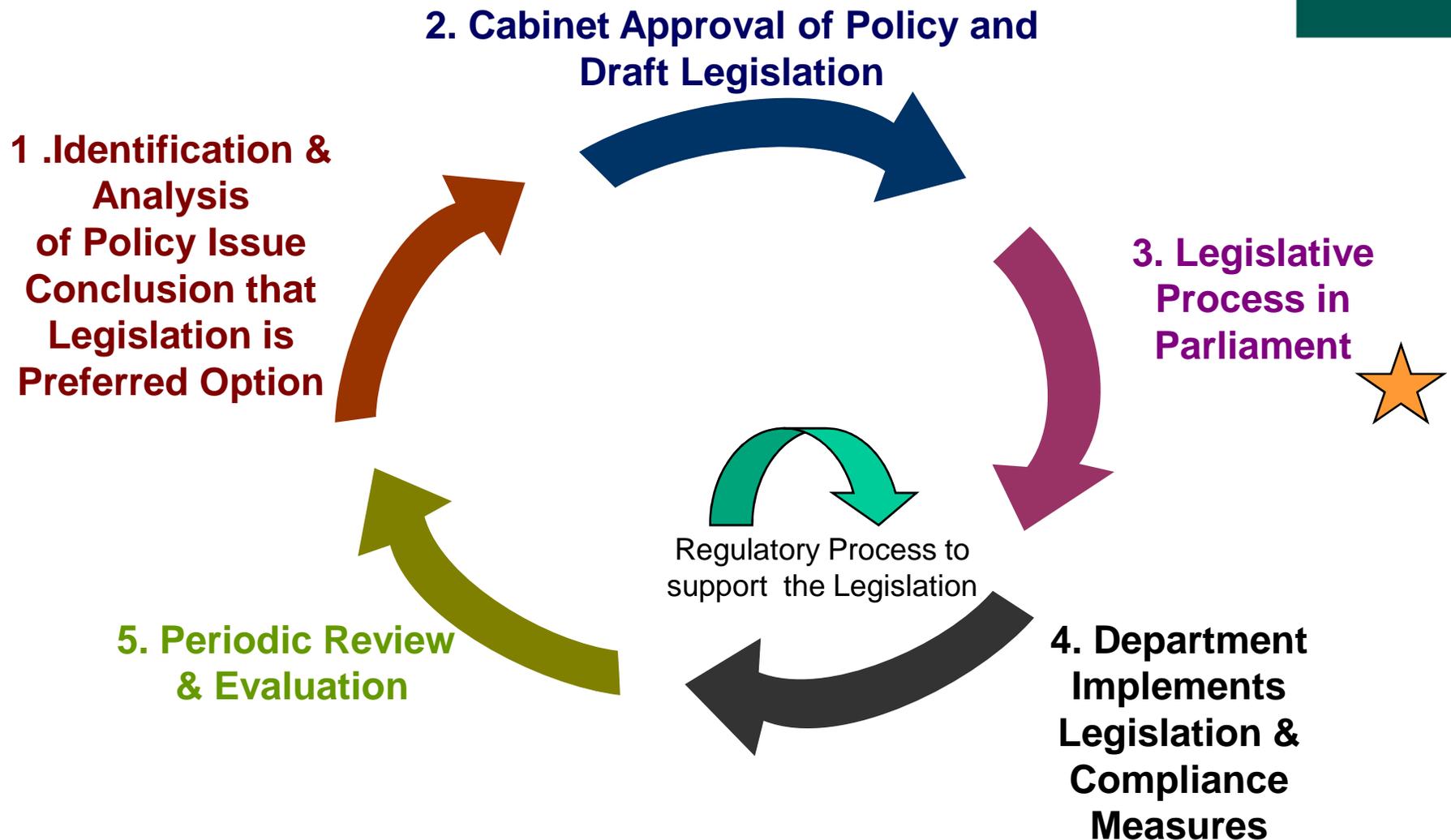


# Making Laws In Canada

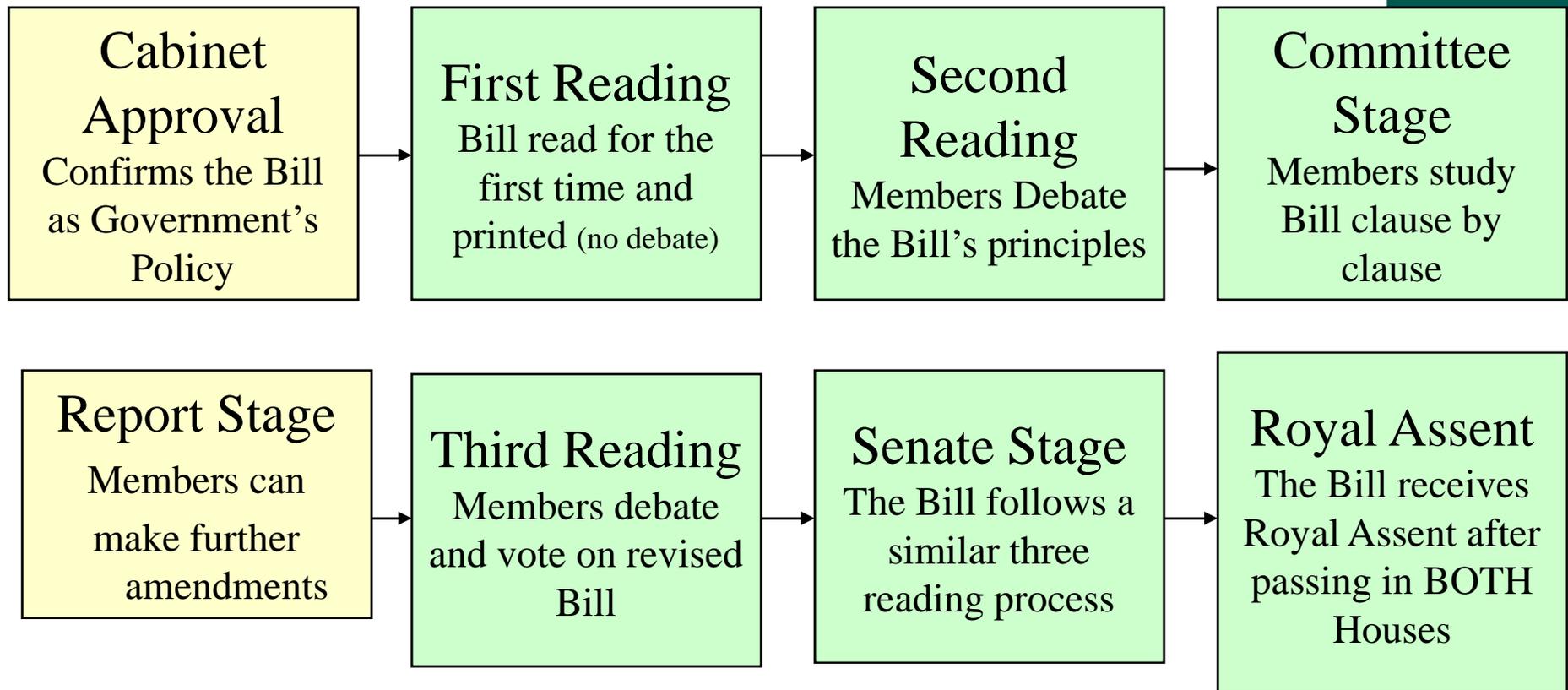
# Making Laws In Canada

- Law making is the responsibility of **Parliament, the Senate and the Crown**
  - An act authorizes the making of regulations
- Regulation making is the responsibility of the **Cabinet** (Governor in Council which is currently the Treasury Board)
- Policy making is the responsibility of **departments** and help to interpret *acts* and regulations
- *French and English versions of acts and regulations are equally authentic*

# Policy and the Legislative Process



# The Legislative Process – from Bill to Law





### Senate

[Government Bills](#)

[Other Bills](#)

[Progress of Legislation](#)

### House of Commons

[Government Bills](#)

[Private Members' Bills](#)

[Status of House Business](#)

### LEGISinfo

#### About Bills

[39th Parliament, 2nd Session](#)

[39th Parliament, 1st Session](#)

[38th Parliament, 1st Session](#)

[37th Parliament, 3rd Session](#)

[37th Parliament, 2nd Session](#)

[37th Parliament, 1st Session](#)

[36th Parliament, 2nd Session](#)

[36th Parliament, 1st Session](#)

[35th Parliament, 2nd Session](#)

[35th Parliament, 1st Session](#)

## 39th Parliament, 2nd Session (October 16, 2007 - )

### House Government Bills

The availability of a bill on the Website may be delayed by two or more working days following the completion of its stage in the legislative process, and by up to two weeks following its Royal Assent. The printed version (as opposed to this on-line version) is the official version of the bill.

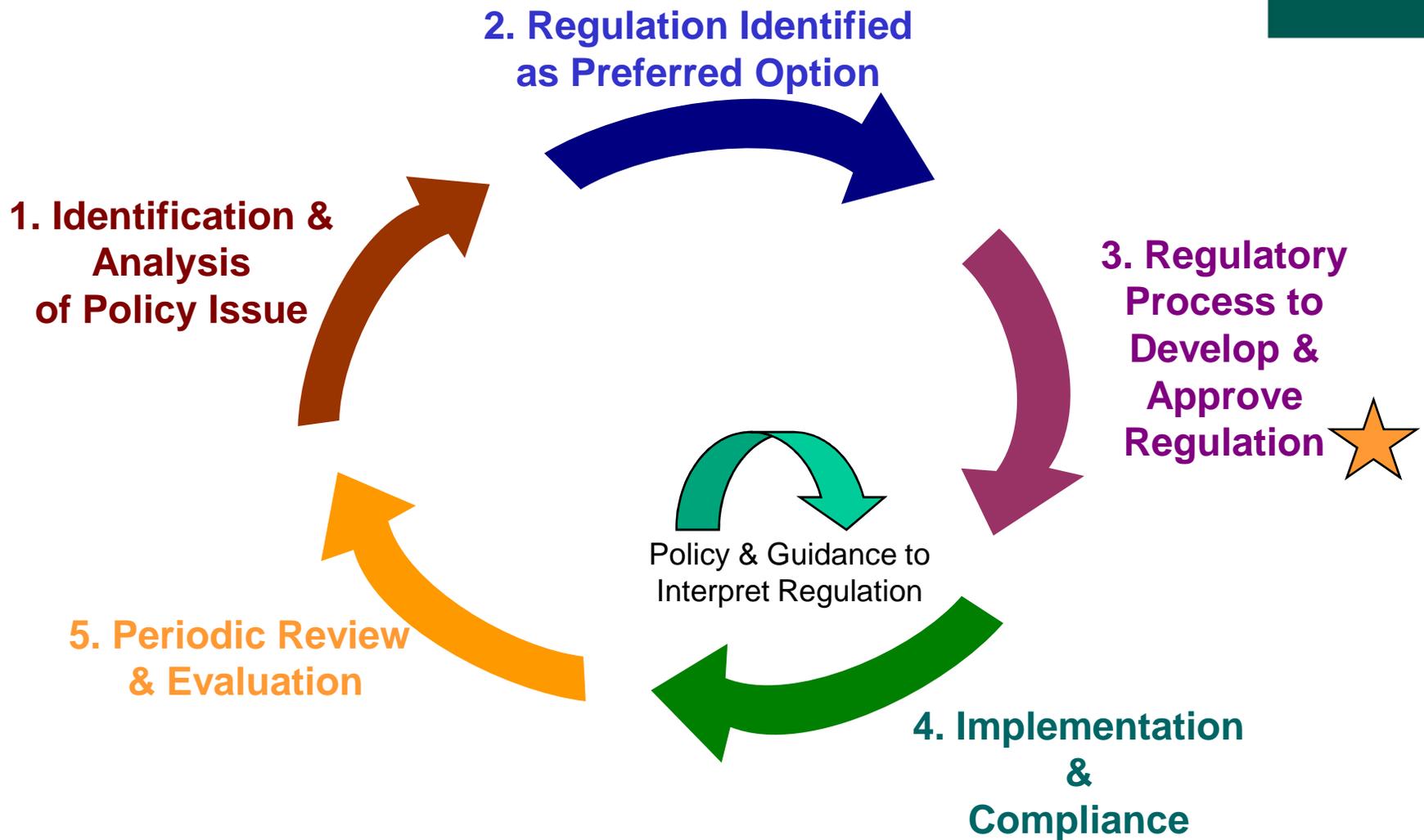
Bills may be reprinted a number of times throughout the legislative process, but not necessarily at all stages. In the tables below, you will find links to the versions of bills studied at the various stages in the House of Commons. These tables do not, however, indicate the legislative stages completed for the bills.

For information about the legislative stages completed, as well as background, analysis and other general information on most bills, please consult [LEGISinfo](#), prepared by the Library of Parliament.

# Canada Gazette

- The official newspaper of the government of Canada
- Part I – published every Saturday
  - **Public notices**, official appointments and **proposed regulations, Notices of Intent**
- Part II – published every 2nd Wednesday
  - Official notice for **enacted regulations**, orders in council, orders and proclamations, **ministerial orders**
- Part III – published ASAP after Royal Assent
  - Most recent **acts** and their enactment proclamations

# Policy and the Regulatory Process



# The Regulatory Process

- Develop a regulatory proposal and Regulatory Impact Analysis Statement (RIAS); includes **early consultation** (30 days)
- Governor in Council approval (the Treasury Board)
- **Pre-publication** in Canada Gazette, Part I to allow for public comment (30-75 days) – includes the text of the regulation and the RIAS
- Finalization of regulation with revised RIAS to reflect public comment
- Governor in Council approval (the Treasury Board)
- Registration (*usually within a day of approval*)
- “Coming into Force” (*date unique to each regulation*)
- **Publication** in Canada Gazette, Part II – includes text of the final regulation and the final RIAS

## NOTE: Schedule F MOU

- **Canada Gazette, Part I step** is replaced by one of the following:
- Schedule F additions
  - Letter to Stakeholders authorized by Assistant Deputy Minister with a comment period of 75 days
- Schedule F deletions (“switches”)
  - Notice of Intent authorized by Assistant Deputy Minister published in Canada Gazette, Part I
  - Webposting to notify stakeholders of the Notice

## *The Cabinet Directive on Streamlining Regulations (CDSR)*

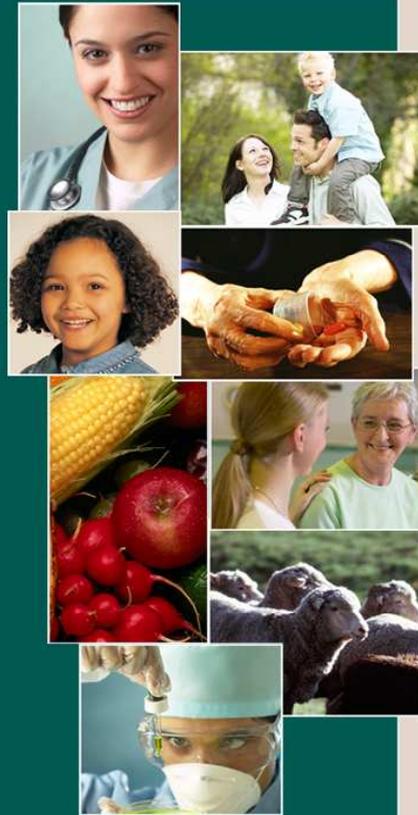
- Replaces the 1999 *Government of Canada Federal Regulatory Policy*
- Guiding Principles
  - Protecting and advancing the public interest
  - Promoting a fair and competitive market economy
  - Decision making based on evidence
  - Creating accessible, understandable and responsive regulation
  - Advancing regulatory efficiency and effectiveness
  - Requiring timeliness, policy coherence and minimal duplication

# CDSR Strengthens Regulatory Management

- Streamlines process – proportional response of regulatory process depending on impact of Triage Statement
- Requires the setting of well-defined, measurable policy objectives
- Greater emphasis on mix of instruments
- More rigorous cost-benefit analysis
- More consistent performance measurement and reporting, and evaluation and review for effectiveness and relevance
- Consultation, coordination and inter-jurisdictional cooperation throughout regulatory lifecycle

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## Questions



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