



Treasury Board of Canada  
Secrétariat

Secrétariat du Conseil du Trésor  
du Canada

Canada

This slide deck is provided in conjunction with TBS RFI 19-533 in order to provide further context with respect to possible approaches to regulatory modernization

# Budget 2018 Announcement

“

Budget 2018 proposes ... for the Government to pursue a **regulatory reform agenda** focused on **supporting innovation and business investment**.

The goal is to make the Canadian regulatory system more **agile, transparent and responsive**, so that businesses across the country can **explore and act on new opportunities**, resulting in **benefits for all Canadians**.

”



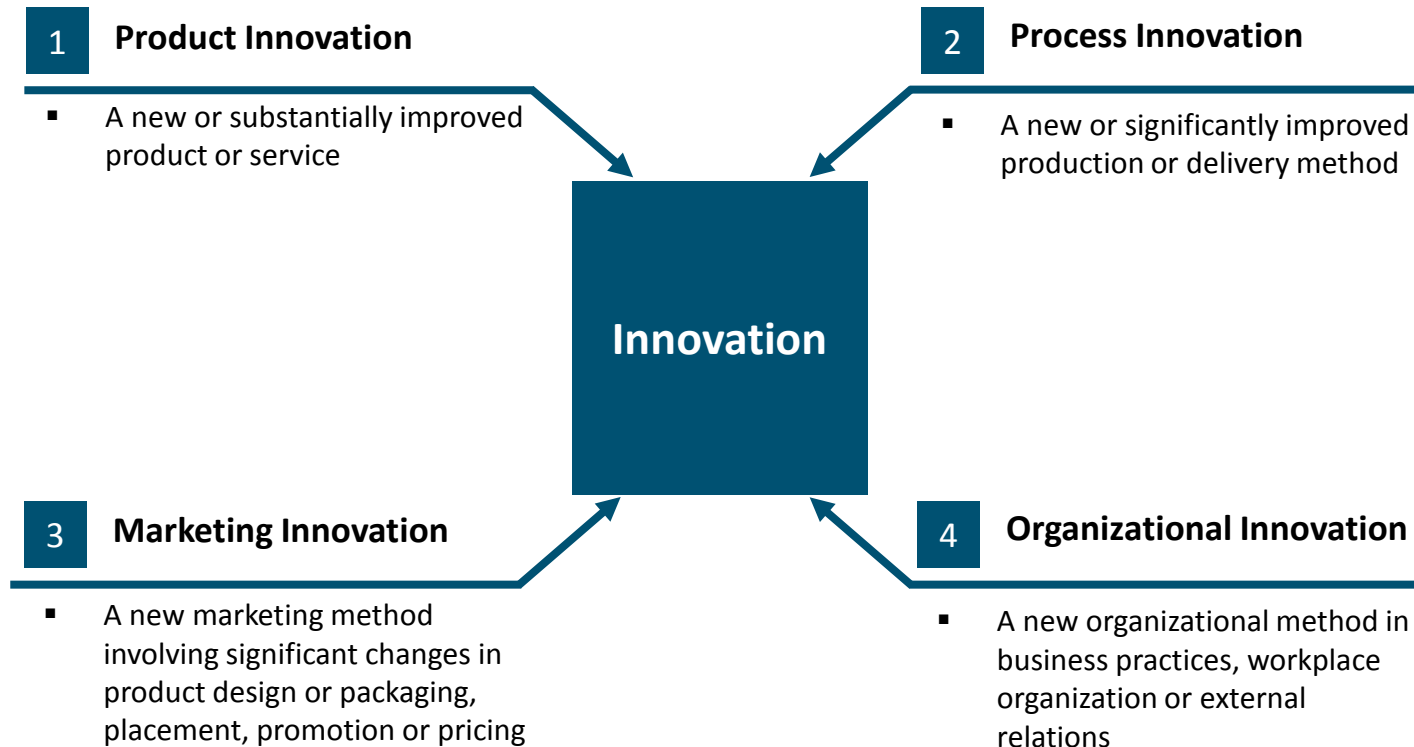
## Budget 2018 Announcement

“**Targeted reviews**, over the next three years, of regulatory **requirements and practices** that are bottlenecks to innovation and growth in Canada, with an initial focus on **agri-food and aquaculture, health/bio-sciences, and transportation and infrastructure**, including emerging technologies such as autonomous vehicles.

”

# Business Innovation and Growth

**Innovation** is central to the Government's economic agenda, its many facets lead to higher **productivity, competitiveness** and **economic growth**.



Innovation creates **benefits and risks**. Both **regulators** and **regulated parties** have a responsibility to drive benefits and manage risks.

# Regulating to Enable Innovation

Regulation may <u>IMPEDE</u> innovation when	Regulation may help <u>SUPPORT</u> innovation when
<ul style="list-style-type: none"> <li>• Practices and technical requirements <b>evolve more quickly</b> than regulations</li> <li>• New technologies or approaches are <b>not permitted</b>, even if they are more effective or less costly</li> <li>• Market <b>incumbents are protected</b> from new competitors with better business models to achieve the same (or better) outcomes</li> </ul>	<ul style="list-style-type: none"> <li>• Market rules are <b>clear and transparent</b>, with longer-term <b>certainty</b> for investors</li> <li>• New technologies and approaches are <b>permitted</b> if they are demonstrably as safe and effective as current practices</li> <li>• Regulatory requirements and activities (or processes) are generally <b>aligned</b> with other jurisdictions</li> </ul>

**BUT** there is a **systemic tension between predictability and agility** – long-term certainty is not possible with constant evolution.

# Illustrative Objectives of Regulatory Modernization

## Agility

The structure and qualities of a regulatory system allow for rapid adjustments and continuous improvement.



## Responsiveness

The regulatory system responds in a timely way to changes in technology, industry business models and society, and incorporates feedback appropriately.



## Transparency

Regulators engage regulated parties and Canadians early and often, and clearly communicate how and why decisions are made.



## Effectiveness

Regulations are evidence-based and achieve the intended policy objective.



## Accountability

Responsibilities of regulators and regulated parties are clear, and mechanisms are in place to evaluate and report on performance.



Regulations can **strengthen consumer confidence** and act as a **catalyst for innovation**. They can promote and reward business competitiveness – while protecting **health and safety**.

# #1 – Outcome-Based\* Regulations

- Outcomes clearly defined in regulations (the “what”), flexibility for regulated parties to achieve outcome (the “how”)
- Best for low-to-medium risk situations, require measurable and enforceable objectives, as well as appropriate support for small business and implementation timelines
- Tend to *decrease* compliance burden but *increase* administrative burden
- More likely to ensure that:
  - ✓ There is a clear rationale for the use of a regulatory instrument
  - ✓ New practices are permitted as long as they are as safe and effective as existing ones
  - ✓ Requirements are more enduring with technological and other change
  - ✓ There is active participation from regulated parties in the regulatory process

## EXAMPLES

- **Australia / New Zealand, and U.S. Food and Drug Administration** – Food Safety Standards Code, Food Safety Modernization Act
- **Canadian Food Inspection Agency** – Safe Food for Canadians Regulations

## #2 – Systems-Based Regulations

- Require regulated parties to have methods for assessing/managing prescribed risks, through process-oriented specifications for rules and system controls designed to meet goals.
- Tend to *decrease* compliance burden but *increase* administrative burden
- Require model systems to be preapproved for those seeking clarity (e.g. small business)
- Support innovation in various ways:
  - ✓ Prescribe requirements for a robust management system, with flexibility on activities within those systems
  - ✓ Align with risk-management best practices in many sectors
  - ✓ Allow for audit-based compliance in combination with inspection

### EXAMPLES

- **Transport Canada** – Safety Management Systems
- **Canadian Food Inspection Agency**– Hazard Analysis and Critical Control Point systems



## #3 – Standards and Guidelines

- Use of standards and guidelines from third parties can complement legal instruments
- Requires trustworthy, accessible and competent experts/standards bodies
- Standards and guidelines:
  - ✓ Can be incorporated by reference in regulations
  - ✓ Reduce prescriptivity of regulations and supports system agility
  - ✓ Can reduce costs and facilitates market access for Canadian firms (i.e. international adoption of common standards)
  - ✓ Eliminate redundant reporting requirements
  - ✓ Support alignment with other jurisdictions
  - ✓ May increase responsiveness, but can decrease certainty (i.e. ambulatory incorporation by reference)

### EXAMPLES

**Natural Resources Canada** – Proposed Energy Efficiency Regulations

**Transport Canada** – Motor Vehicle Safety Regulations

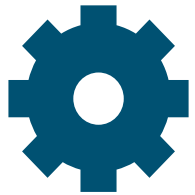
## #4 – Iterative Co-Development

- Opportunity to understand and focus on user needs (i.e. citizens and industry)
- Requires stakeholders to be willing, trusted and competent – also takes time
- Convening stakeholders early and often for meaningful dialogue can help:
  - ✓ Discover and address gaps and barriers in existing system
  - ✓ Proactively design innovation-supportive regulations
  - ✓ Increase industry compliance and accountability
  - ✓ Identify and support pathways for innovative or novel products or approaches

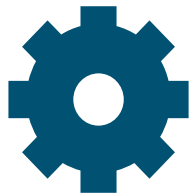
### EXAMPLES

- **International Centre of Regulatory Excellence** – Partnership between Alberta Energy Regulator, Southern Alberta Institute of Technology and University of Alberta
- **U.S. State of California** – Iterative approach for Autonomous Vehicles
- **United Kingdom** – Regulatory Sandboxes for FinTech (“Project Innovate”)

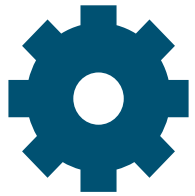
# Cross-Cutting Issues



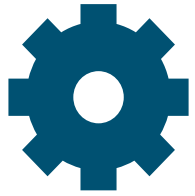
**Instrument choice  
(to regulate or not)**



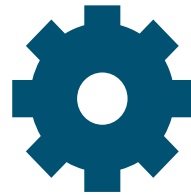
**De-regulation /  
Self-regulation**



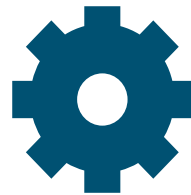
**Simplification /  
Consolidation**



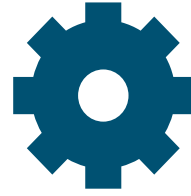
**Cumulative Burden**



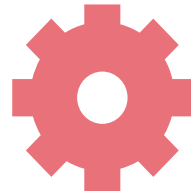
**Regulator role in ensuring  
quality vs. safety**



**International and F/P/T  
Regulatory Cooperation**



**Foresight**



**Others?**

# How can Regulatory Practices support Innovation?



How regulations are administered can also support or impede innovation

# #1 – Risk Assessment

- Applies scientific, evidence-based approaches to identify and manage risks to Canadians and industry, as well as risks to the regulatory system (e.g. compliance)
- Data systems and analytics are a strong determinant of success
- An integrated approach to risk assessment:
  - ✓ Ensures that priorities are understood
  - ✓ Ensures that oversight efforts are applied where most needed (i.e. higher vs. low-risk and higher vs. low impact)
  - ✓ Supports scanning/foresight around emerging risks
  - ✓ Includes various sources, pathways and routes of exposure

## EXAMPLES

- **Canada Border Services Agency** – Intelligence Program, Targeting Program, Advance Passenger Information and Advance Commercial Information
- **Environment and Climate Change Canada and Health Canada** – Evaluating Existing Substances

## #2 – Compliance Promotion

- Regulators have a role in facilitating compliance with requirements by regulated parties
- Risk of officially-induced error and regulator acting as both “coach and referee”
- Approaches that support innovation include:
  - ✓ Ensuring that requirements and desired outcomes are known and clearly defined
  - ✓ Providing clear guidance, including examples of model systems
  - ✓ Allowing regulated parties to propose new model systems or alternative approaches to compliance
  - ✓ Using online/digital tools (e.g. eliminating requirement for paper/faxes), and behavioural economics (i.e. nudges)
  - ✓ Recognizing differential impacts of requirements and needs of SMEs

### EXAMPLES

- **Environment and Climate Change Canada** – Use of Compliance Promotion Officers and Compliance Promotion Strategies for regulatory programs
- **Canadian Food Inspection Agency** – Compliance promotion for Safe Food for Canadians Regulations
- **Canada Revenue Agency** – Liaison Officer service for small business

## #3 – Compliance Verification

- Comprises oversight activities such as inspection and audit
- Increased use of outcomes-based / systems-based regulations requires changes to the regulator's approach to verifying compliance (i.e. culture, systems, guidance, training)
- Approaches that support innovation by managing risk and burden include:
  - ✓ Cross-designation for inspectors across federal regulators, as well as F/P/T and internationally
  - ✓ Recognizing third-party certification systems (e.g. industry, international, or NGO) where appropriate
  - ✓ Adopting international conformity assessment procedures for standards
  - ✓ Monitoring real-time data from regulated parties

### EXAMPLES

- **Canada Border Services Agency** – Joint Force Operations
- **Canadian Food Inspection Agency** – Private Certification Policy to inform risk-based inspection

## #4 – Enforcement

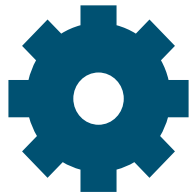
- Refers to the response by regulators to non-compliance (willful or not)
- Graduated approaches that support innovation include:
  - ✓ Using full spectrum available tools (e.g. letters, meetings, “name and shame”, AMPs, recognition/reward)
  - ✓ Responding in a proportionate and consistent manner, commensurate with severity of the infraction
  - ✓ Offering a path for the regulated party to return to compliance

### EXAMPLES

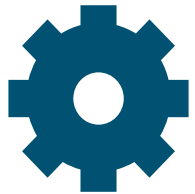
- **In General** – Delayed coming into force to give time for newly regulated parties to prepare
- **Competition Bureau of Canada** – Competition and Compliance Framework
- **U.S. Food and Drug Administration** – Information Sharing Analysis Organization certification (cybersecurity for medical devices)



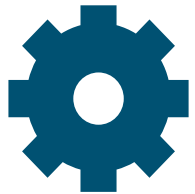
# Cross-Cutting Issues



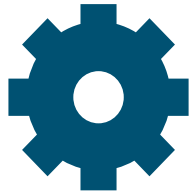
Regulator culture



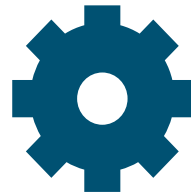
Human Resources /  
Competencies and Skills



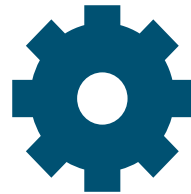
Firm Capacity



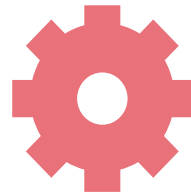
Cumulative Burden



New Technologies and  
Digital Systems (e.g. AI,  
Data Analytics)



Emergence of platform  
companies spanning  
multiple industries



Others?