



# **REGULATORY FRAMEWORKS: AS ENABLERS FOR INNOVATION**

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# **REGULATORY FRAMEWORKS:**

**Concepts and Trends.....**

**“A regulatory framework can be defined as the macro-level steps that a regulator must complete in order to bring forward regulations. (Ref: 1)”**

Regulatory framework can also be looked at as the high-level questions that a conscientious regulator would ask of themselves throughout the process of regulations development.

Questions such as:

- “why do I need to regulate this behaviour”?
- “Who is harmed by the behaviour?”
- “Is this harm serious enough to warrant government intervention?”, etc.

**Framework:** a framework is defined as the basic, underlying structure to a set of regulations. A framework is composed of a several complementary elements or concepts in support of something larger.

**Regulatory framework as an accountability mechanism:** a method by which the regulator accounts for the responsibilities conferred upon it.

The globalization of the world's economies is applying growing pressure on governments to **liberalize trade practices**. Businesses and individuals express displeasure at restrictive trade practices, often embodied in regulations that prohibit or at the very least inhibit commerce.

Furthermore, governments are recognizing that regulations impose a **fiscal burden** upon companies and citizens. Enforcement and compliance activities require significant investments in personnel and equipment. In an era of fiscal restraint, regulations are often viewed as an expensive solution to social and market imbalances.

These mounting pressures have forced governments from all over the world to re-look at their existing and proposed regulations:

## Two new trends:

- **Deregulation, and**
- **Harmonization of regulations with other nations**

## Framework of Elements for the review of regulations:

- **Policy goals:**
  - Economic,
  - Social,
  - Cultural
- **Policy instruments (means to achieve goals):**
  - ⑩ Regulations
  - ⑩ Self Regulation
  - ⑩ Others
- **Policy Implementation**
  - Enforcement capability and capacity
  - Compliance mechanisms
- **Evaluation (have we achieved goals?):**
  - Impact Assessment (Both Ante/ Post Regulation)

# **INNOVATION & IT's INTERPLAY with REGULATORY FRAMEWORKS.....**

## Dictionary Definition of *innovation*

- **1:** the introduction of something new
- **2:** a new idea, method, or device

## Innovation Characteristics at conflict with Standardisation:

- New & Future oriented
- Expanding/ redrawing the existing boundaries
- Entering new areas
- Intellectual Property Rights

1. Objectives
2. Timelines
3. Impact analysis based approach
4. Balance between science and other factors
5. Prohibitions, inhibitions and incentives
6. Decision making in the face of insufficient data
7. Cost benefit analysis
8. Non-discriminatory (un-biased) approach

## Factors influencing Impact of regulation on innovation:

- type of regulation,
- the sectors,
- the companies and the
- time horizon of the impacts.

## Differences between short and long term impacts:

- Short term impacts of regulations are often negative
- Long term implications by forcing or encouraging their adoption; and accelerating the uptake of innovations and their spillover benefits.

## Time Invariance:

- Earlier studies find slightly more negative impacts,
- More recent investigations tend to reveal more positive implications especially in relation to environmental regulations.

## Innovation Culture (within regulatory bodies)

- Generally promotes the positive innovation impact of regulations. However, this aspect has not been analysed yet.

## Research Gaps:

- Development of appropriate indicators of the regulatory framework.
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- Relationships between processes within companies to react to regulations (in view of heterogeneous impacts on innovations).
- Impact of Interaction levels between companies and Regulators:
  - Regulations are per se not only exogenous to companies, but often there is close interaction between regulators and the regulated companies, (which should further explain some of the existing ambivalence)

## **Extended timelines:**

- **Sufficient time for transition**
- **Cost benefit analysis**
- **Removal of barriers to adoption**
- **Voluntary versus Mandatory approach**

- **Goal: Need for sugar reduction:**
- **Removal of barriers to adoption**
  - **Permission to use sugar alternatives**
  - **Labelling**
  - **Modification of product standards**
- **Engagement with stakeholders**
- **Voluntary versus Mandatory approach**

## Context:

- Regulations intention is to protect consumers' safety.
- A progressive regulation should enable innovation that solves consumers problems and give them more choices. Where choices should be made affordable and accessible.

## Novel Food:

- while we need benchmarking to we also need to study
  - what has worked and what has not
  - What has really impeded innovation
- Extremely complex and expensive processes (as in EU) to approve novel food to commercialize in the market act as strong deterrents for investment in innovation.

- (I) **Be bold!** If a novel food manufacturer plans to use a novel ingredient/food already marketed by someone else, the review of this novel ingredient/food shall be considerably simplified in the approval system where the composition, intended use, metabolism, level of concerned substances contained have been assessed and approved.
- (II) To be bold to innovate and progress regulations in country, a positive list of internationally approved novel ingredients can be used as a basis of a fast track assessment, delivering time saving and trusting to a certain extent, of self-governance to manufacturers with good track records.
- (III) To ensure some level of control, authorities may include additional requirements in this fast track, such as authorised conditions of use, labelling and post market requirements for traceability to be fulfilled.

- To enable innovation including timely commercialisation, there must be a formal process of having regulators at the front end of an innovation process (during conceptualization, not towards the end of finished product).
- Every innovation cycle has phases of development, with time and resource contributing to the cost of creating the product.
- Regulatory roadblocks that frequently raise the technical barrier to trade at the point of commercialisation impedes the very nature of innovation, and it can be argued that the impact is greater for Small and Medium Enterprises (SMEs) than for larger manufacturers.

Therefore, regulators having the willpower to innovate a approval system to be involved in innovation steps to Ensure concerns are addressed early on than to approve or reject at the end of a finished product, would enable a thriving innovation climate that brings targeted solutions to consumers.

Based on the general insights from the conceptual approach, the empirical analyses, and also the gaps identified, the following proposals for more innovation-friendly and innovation targeting regulatory policies can be developed:

1. Strengthen the focus on innovation in regulatory policy.
2. Increase the quality of the regulatory framework regarding innovation.
3. Include innovation in ex ante and ex post regulatory impact assessments.
4. Optimise the frequency and timing of reviewing existing regulations.
5. Coordinate the policies of all relevant regulatory bodies to foster innovation.
6. Move innovation into the centre of public policies in general and in the set of objectives and the general culture of regulatory bodies in particular.
7. Integrate regulation in the research on innovation systems.
8. Assess, evaluate and develop mechanism to engage regulator at the front end of innovation cycles.

1. A guide to the Making of Federal Acts and Regulations. Government of Canada. Department of Justice. November 1995.
2. Regulatory Frameworks: A report submitted to the Royal Commission on Worker's Compensation in British Columbia
3. <https://www.innovationpolicyplatform.org/document/impact-regulation-innovation>
4. Interactions with subject matter experts.



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We are innovative solvers, drawing on deep consumer insights and a broad product portfolio to help our customers turn challenges into high-value business opportunities

