Overview of Risk Analysis in Food Safety Regulations

Seminar on Food Safety Risk Analysis in ASEAN

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Outline

- Food Safety Management and Role of Regulators:
  - Importance of Food Safety Standards / Decisions

- Anchoring Food Safety Decision-making in Risk Analysis

- Considerations to Achieve a Well-Functioning Food Regulatory / Standard Setting System

Food Safety Management is a Collaborative Endeavour

Food safety management requires a collaborative approach:

- Industry
  - Farmers, food manufacturers, food distributors, food service establishments and retailers

- Consumers

- Government(s)/Regulators

Role of the Regulator

- Oversight on Managing the Interaction between Food Producers and Consumers

- Delegated Authority from Consumers as to Protect them (from Health Concerns and Fraud)

- Empowered to Make Decisions on behalf of the Public (Consumers)

- Is the Centre of Attention in Case of Deficiencies in Food Safety
  - e.g., Food Safety Incidents
What Does a Regulator Do?

- Competent Authority Making Decisions to Ensure Consumer Protection and Fairness in Food Production and Trade
- Primary Risk Manager
- Decisions Made are not always in the Form of Regulatory Measures

Robustness of the Decision-Making Process

- Trust in its Integrity
- Predictability

Risk Analysis Provides Structure to Food Regulatory Decisions

- Risk Analysis is the logical framework that underlies decision-making concerning all kinds of risks (not only for food safety and nutrition)
- Applicability to Food Safety and Nutrition Decision-Making Developed through the FAO/WHO Food Standards Program and particularly the Codex Alimentarius Commission (Codex)

Definition of Food Risk Analysis

- An Iterative and highly interactive process that should be followed by food decision-makers to address food safety and nutrition issues, using robust evidence, including scientific information and regular exchange with all parties and stakeholders involved

Comprises 3 components:
- Risk Assessment
- Risk Management
- Risk Communication
Risk Analysis ... Providing the Structure For

**Robust Food Decisions**

- **Risk Assessment**
  - Scientific Advice & Information Analysis
- **Risk Management**
  - Regulation & Control
- **Risk Communication**
  - Dialogue with All Stakeholders

A Functioning Food Control System

- **Robust Governance & Collaboration**
- **Functioning Institutions**
- **Scientific Capacity**

Risk Analysis Pillars

- **Responsive Food Safety Actors**
  - Visible aspects of Food Control Systems
  - Risk Management includes regulatory and non-regulatory decisions
  - Risk Communication can be part of the Risk Management Approach: e.g., Advice to Consumers

Iterative, Non Linear Approach

- Monitoring and review
- Risk assessment
- Hazards identification
- Option assessment
- Option implementation
- Preliminary activities
- Risk evaluation
- Risk characterization
- Risk communication
- Consumers, industry, and other interest parties
Example of Application to New Regulatory Measures

**Food Allergens as Food Safety Hazards: Issue Identification**

- Data on Public Health Impacts is lacking:
  - 1/3 to 3/5 of Anaphylaxis cases treated in hospital emergency room visits are attributed to Food.
  - 32 out of 63 confirmed anaphylaxis deaths in Ontario between 1986 and 2000 were food related.
  - 1/3 Consumers attributed food allergy incidents to issues with food labeling (2008 study)
  - Food Allergy Incidents are preventable through an accurate and clear declaration of ingredients
  - Existence of a 1999 Codex Standard on Food Allergen Labeling

- Food allergies, Celiac Disease and Sensitivity to Sulfites affect an estimated 1.75M Canadians.

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Is there an International (FAO/WHO) Scientific Assessment that could be Used?

- JECFA Assessment Established a List of Priority Allergens (to support the Codex Standard)
- Adaptation to National requirements (Priority allergens relevant to the country)
- Use Criteria Set by JECFA to establish Canadian List of Priority Allergens
Consideration of Mandatory Allergenic Ingredient Labeling (based on 1999 Codex Standard)
Consider Canadian situation: In conjunction with food ingredient labeling requirements (support to them, no duplication, enhancement options)
Consider Aspects related to:
- Enforceability
- Impact on Small Business: Phased implementation?
- Impact on International Trade
- Comparability with Major Trading Partners
- Possible benefit versus costs:
  - Estimated Food Allergy Incident Costs to Canadian households with a sensitive/allergic individual amount to $5.7 B CAD annually.
  - Source: Health Canada’s Regulatory Impact Statement associated with the development of Regulations 1220: enhanced food allergen labeling proposal

Option Implementation

Engagement and Communication
Requirement of Evaluation at A Periodic Stage

Check Effectiveness in Addressing the Risk / Issue

- Regulatory Measures need to be Evaluated on a Periodic Basis

- Evaluate not only ability to reach the objective, but also any possible unforeseen effects.

- Re-initiate the approach
  - Complete involvement of stakeholders and partners

Benefits from Following Structured Approach

- Clarity
  - Roles and responsibilities, accountability, procedures
  - Clear identification of areas anchored in science and how other evidence is used

- Transparency

- Possible Stronger Buy-in from Partners and Stakeholders because of Participative and Interactive Approach

- Dynamic: Evolutionary Nature

Compliance with SPS Agreement

**Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection**

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.

2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
Compliance with SPS Agreement (2)

Article 5: Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.

5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, (...)

Risk Analysis is Part of a Larger Set of Requirements for Food Control Systems

A Well Functioning Food Control System Requires:

- Functioning Food Safety Institutions
  - Minimum Scientific Foundation: Availability of Scientific Data and Other Evidence
  - Robust Governance Structure between Competent Authorities / Within a Competent Authority

- Participation of Key Stakeholders and Partners

- Application of the Risk Analysis Framework in Decision Making (with all associated values: Transparency, Predictability, Inclusiveness, etc.)