



REVIEW OF KEY FOOD REGULATORY FUNCTIONS

NFSA Senior Staff Meeting

17-18 June 2023

*Babylon Hall, InterContinental Semiramis Hotel
Cairo, Egypt*

Introduction and Objectives

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Map Food Regulatory Programs

Using Codex Guidance :

*Principles and Guidelines for National Food
Control Systems: CXG 82-2013*

And

*Best Practices in Food Regulatory
Operations*



A Food Competent Authority

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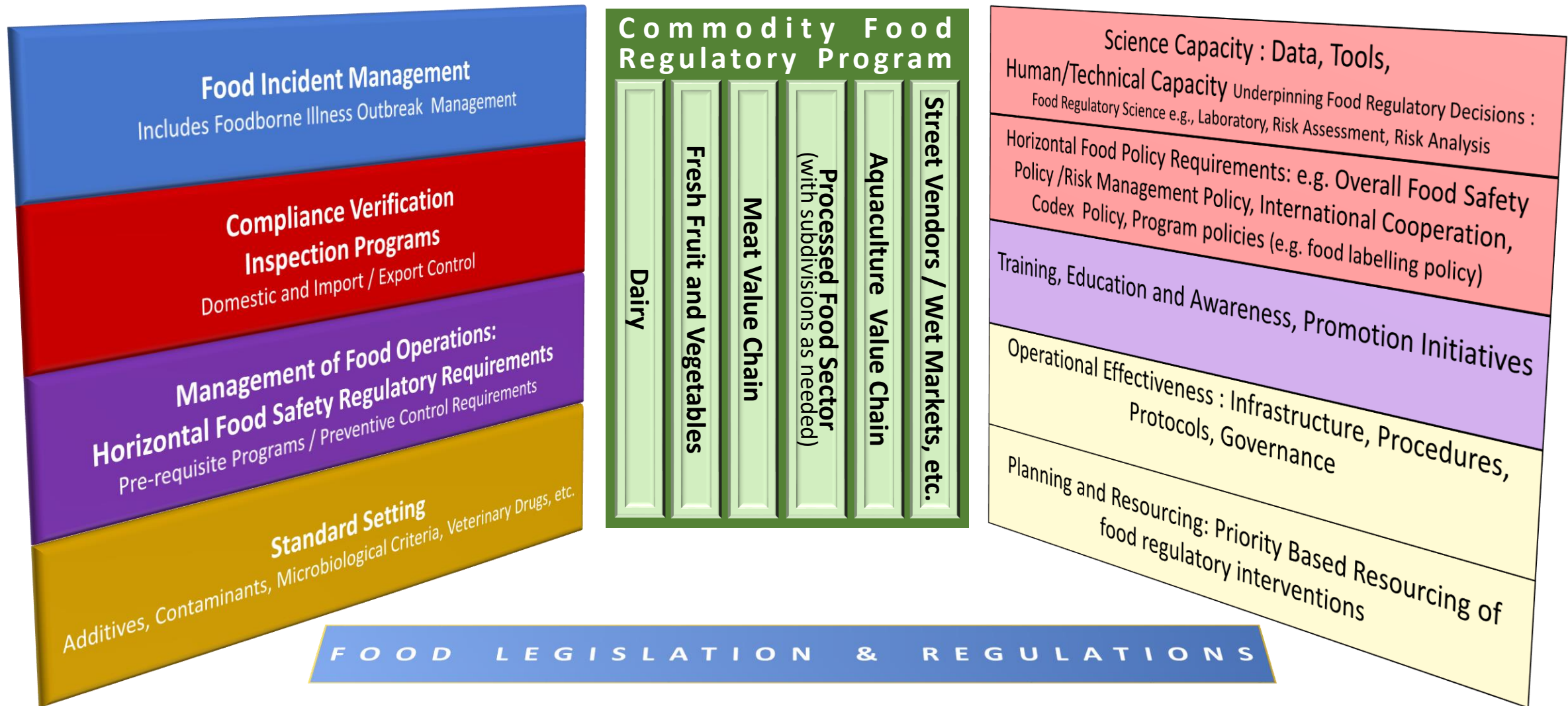
An Effective Food Safety Competent Authority:

- ❑ Anchors its actions and operations in a *robust legislative and regulatory framework* that enables it to “develop, establish, implement, maintain and enforce a national food control system”.
- ❑ Bases its food safety decisions on the application of the *Risk Analysis Principles*.
- ❑ Ensures effective *food regulatory operations* both for ***standard setting and compliance and enforcement***
- ❑ Is supported by a **focused:**
 - ***Scientific capacity for risk assessment*** and
 - ***Laboratory operations***.



Proposed Food Regulatory Functions

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Foundations that Need to Exist / to be Mapped

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1. Review and enhance **food legislation and regulations**.
2. **Food safety standard setting function:**
 - Premarket and post-market technical regulations.
3. **Conditions of Operations of Food Establishments (including Importers)**
4. **Compliance Verification / Conformity Assessment:**
 - **Mainly through Food inspection capacity** for domestic establishments, imported and exported goods.
5. **Food safety incident Capacity and foodborne illness management.**
6. Food Regulatory Science Capacity: **food safety testing capacity, Food Risk Analysis (in particular Risk Assessment)**
 - **Scientific foundations for food decisions:** competencies, data/tools, processes
7. **Horizontal Food (Safety) Policy Directions:**
 - General Food Safety Policy / Strategic Direction, contribution to and reliance upon **international standard setting processes**.
8. **Operational effectiveness of the food regulatory program:**
 - **Infrastructure, Resources, Governance, Procedures and Protocols, Engagement with Stakeholders, Transparency**



PRINCIPLE

Foods are Inherently Safe Products



Post-market Rules

- ❑ General provisions against adulteration and other unsanitary practices
- ❑ Limits for selected contaminants in food
- ❑ Nutrition and other labelling provisions

Regulatory Requirements
Set Rules related to
Safety and Quality

Pre-market Oversight

- ❑ Pre-approval of added substances, e.g. additives
- ❑ Pre-approval of novel processes, e.g. GMOs
- ❑ Pre-approval of foods destined to specific subsets of the population, e.g. infant formula

R I S K

1- Review and Enhance Food Legislation and Regulations

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The review of food safety legislation & regulations aims to conform with principles 11 & 12 of **CAC/GL 82-2013**.

Capacity building interventions will aim to:

- ☐ Review current statutes, laws and regulations that require consolidation and/or modernization.
- ☐ Develop drafting instructions in support of a legislative and regulatory policy that:
 - Aligns with modernized food safety statutes internationally.
 - Focuses on prevention and emphasizes the responsibility of food business operators.
 - Enshrines risk analysis at the core of food regulatory decision-making.
- ☐ Identify the necessary regulation-making authorities and recommend a structure for a food regulatory system that is:
 - Risk-based.
 - Adaptable to changes in the food supply chain and the evolution of the scientific evidence.
 - Supportive of the operationalization of the regulatory mandate of the competent authority / authorities:
 - Premarket review and approval mandate.
 - Promulgation of regulatory / food safety interventions, for example Microbiological criteria, Maximum levels of contaminants, Inspection and certification functions domestically and for imports.

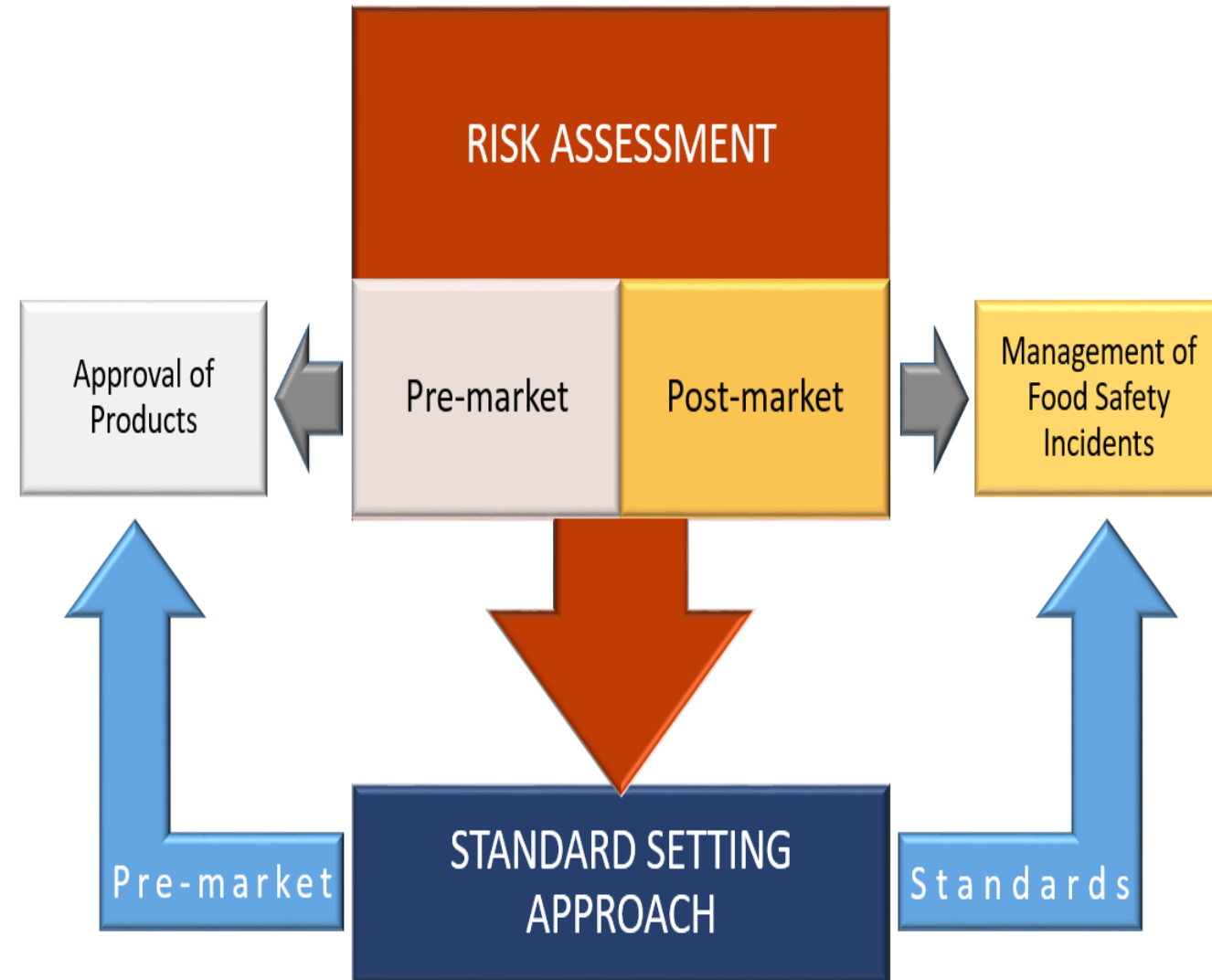


Premarket :

- ☐ Food additives.
- ☐ Irradiation processes.
- ☐ Infant formula.
- ☐ Other food for special dietary purposes.
- ☐ Novel foods (including GMOs).

Operations of Premarket Program:

- ❑ Processing of applications from the industry sector
- ❑ Handling of preliminary risk assessments, along with international comparisons.
- ❑ Consolidation of existing approvals supported by international benchmarking and aligned with Codex approaches.
- ❑ Formulation of requirements for applicants.



2- Enact a Food Safety Standard Setting Function (2)

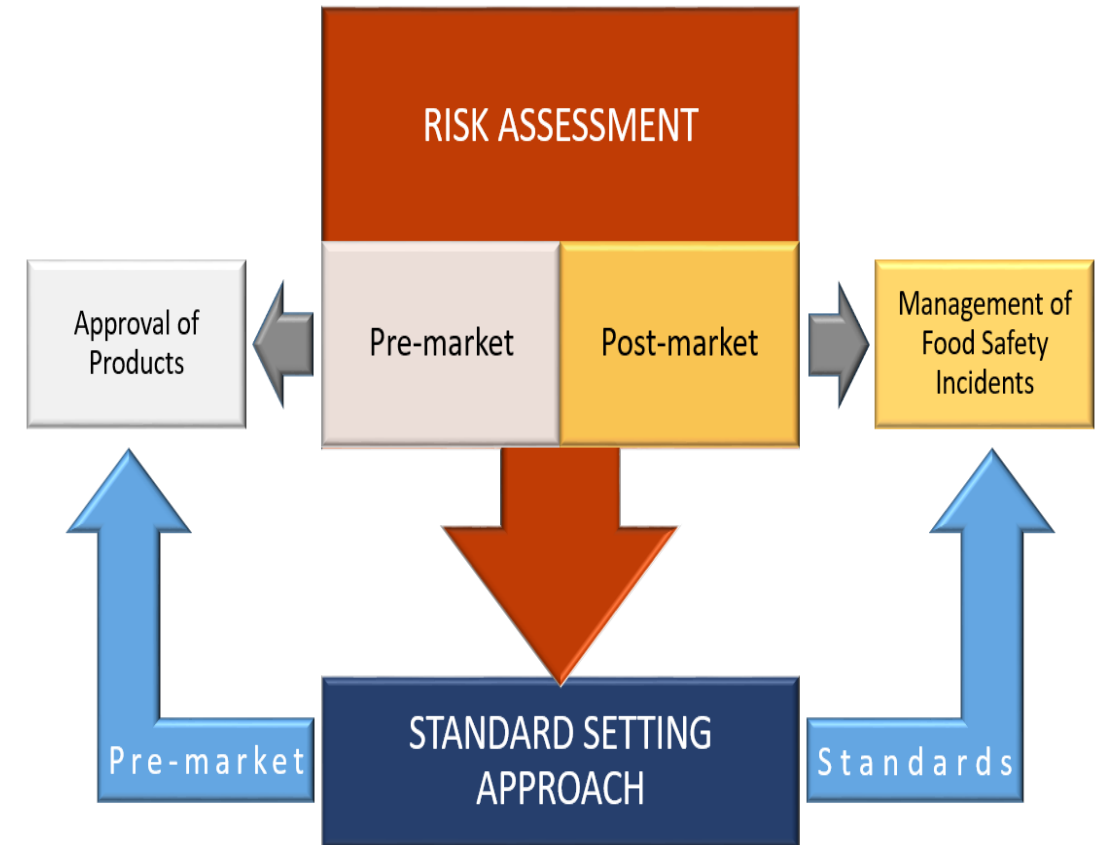
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Post-market:

- ☐ Maximum levels of contaminants.
- ☐ Microbiological criteria.
- ☐ Labelling requirements, for example:
- ☐ Nutrition labelling.
- ☐ Allergen labelling, etc.

Operations of Standard Setting Program:

- ☐ Review of existing provisions in each category of post-market standards.
- ☐ Update of provisions in accordance with Codex standards and / or other international benchmarks, such as (US FDA provisions, EU provisions, etc.
- ☐ Establishment of processes, as well as scientific and regulatory policy foundations, for the long-term development of such requirements anchored in the the national food regulatory structure.



3- Conditions of Operations of Food Establishments ¹⁰

- ❑ Requirements destined to food business operators and production establishments – from farm to retail –
Support registration and licensing regimes.

Preventive approach:

Development and implementation of preventive controls, as part of an integrated food safety and quality management scheme, adapted to the size of the operation and encompassing Pre-Requisite Programs (PRPs), Preventive Controls (PCs) and Traceability. In addition, and of equal importance, is the documentation of which authority is responsible for a particular area of registration or licensing, and identifying possible overlaps and/or gaps.

Post-market Management Programs Enhance Food Inspection Capacity for Domestic Establishments, Imported & Exported Goods

4- Enhance Food Inspection Capacity for Domestic Establishments, Imported and Exported Goods

- Review the current food inspection model, as part of the compliance and enforcement policy of the Competent Authority
- Apply a risk-based approach: measure commensurate with the risk – incremental approach
 - E.g. **VADE** approach (**V**oluntary compliance, **A**ssisted compliance, **D**irected compliance and **E**nforced Compliance)



5- Enhance Food Safety Incident and Foodborne Illness Management

- Develop and adopt procedures for (food safety) incident management (including measures to collect data, coordinate actions, assess results and formulate options for decision-making in the context of food safety incident management)
- Develop and Adopt Relevant procedures and protocols in a manner that is adapted to the structure of the food control system and involved partners (e.g. multiagency system versus single agency jurisdictions) – e.g. recall procedure, emergency response protocols
- Train Personnel to address food safety incidents and emergencies, **including the simulation of foodborne illness outbreaks**

6- Enhance Food Safety Laboratory Testing Capacity

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- ❑ Access and adoption to laboratory methodologies that can be relied upon in data collection efforts.
 - E.g. multi-residue pesticide analysis, multi-residue veterinary drug analysis, multiple mycotoxins and other natural toxins.
- ❑ Training (where Applicable) must follow a scalable, reproducible approach following a “train the trainers” methodology.
 - Accreditation of selected laboratory procedures against the ISO17025 standard.
- ❑ Food laboratory operation is meant to be adapted to respond to compliance and enforcement activities.



7- Develop/Upgrade Scientific Foundations for Food Decisions

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A food regulatory system, must be based on robust evidence, anchored in data portraying **the level of exposure of consumers to contaminants** and their intake of key nutrients:

❑ *Total Diet Study*

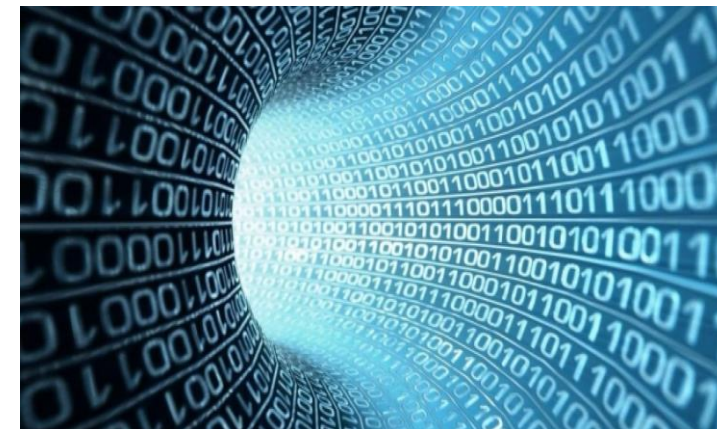
- Collection of data on the **occurrence of key food contaminants** in a **market basket of foods** relevant to the national population, as consumed.

❑ *Food Consumption Data Collection*

- Data collection is imperative on how the national population, with its different age / gender and socioeconomic strata, consume food products
- Food consumption data collection methodology: follows internationally accepted methodologies to the region / country targeted.

❑ *Biomonitoring Initiatives*

- Where possible, interventions will be planned to contribute to design and implementation of biomonitoring programs that help estimate the overall intake of nutrients and exposure to contaminants, as well as the contribution of food as a vector for such exposures: e.g. human milk surveys conducted periodically



8- Enhance the International Standard Setting Processes

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Enhance the contribution to and reliance upon international standard setting processes:

- ☐ Development of International collaborations and key partnerships with sister agencies regionally and internationally.
- ☐ Effective Contribution to the International Standard Setting Process (Codex) including the ability to rely on Codex and other international standards in developing national standards and shaping the food safety policy agenda.



9- Enhance Overall Operational Effectiveness

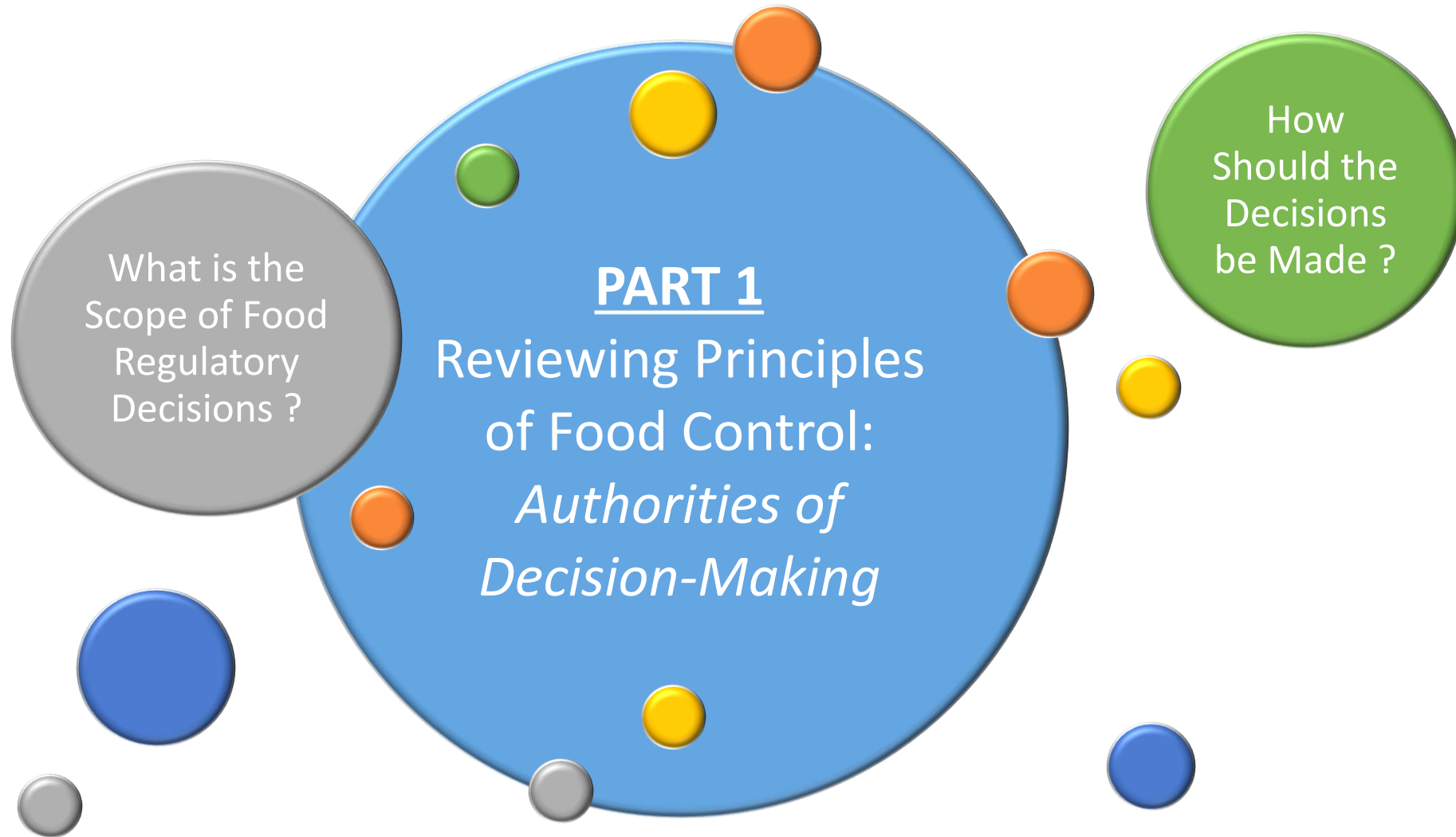
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Enhance the overall operational effectiveness of the food regulatory program:

- ☐ Personnel and Competencies
 - Adequate Training and Continued Education Prog
- ☐ Procedures and Protocols
 - Includes Governance Structure
- ☐ Tools
 - Includes Information Management and IT



PART 1

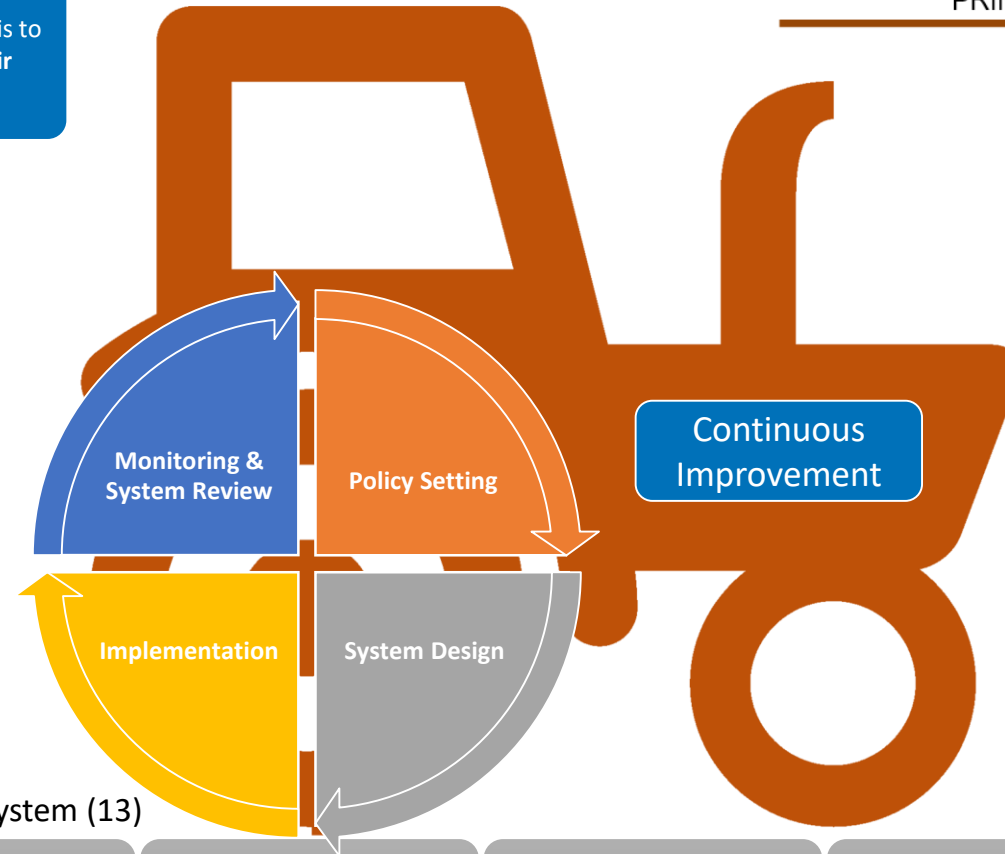


Effective Food Control System

« The objective of a national food control system is to **protect the health of consumers and ensure fair practices in the food trade** »

PRINCIPLES AND GUIDELINES FOR NATIONAL FOOD CONTROL SYSTEMS

CAC/GL 82-2013



Principles of a National Food Control System (13)

PROTECTION OF CONSUMERS

THE WHOLE FOOD CHAIN APPROACH

TRANSPARENCY

ROLES AND RESPONSIBILITIES

CONSISTENCY AND IMPARTIALITY

RISK BASED, SCIENCE BASED AND EVIDENCE BASED DECISION MAKING

COOPERATION AND COORDINATION BETWEEN MULTIPLE COMPETENT AUTHORITIES

PREVENTIVE MEASURES

SELF ASSESSMENT AND REVIEW PROCEDURES

RECOGNITION OF OTHER SYSTEMS (INCLUDING EQUIVALENCE)

LEGAL FOUNDATION

HARMONISATION

RESOURCES

Principles of a National Food Control System

13 principles as per CXG 82-2013:

1

Protection of Consumers

- Supersedes other (e.g. trade / economic considerations)

2

Food Control System

- i.e. oversight, should cover a whole chain approach

3

Transparency

- While protecting Confidential Business Information (CBI)

4

Clear Definition of Roles and Responsibilities amongst Partners and Stakeholders

- Food business operators at all levels of the chain, Consumers, Regulators, Scientists / Academia

5

Consistency and Impartiality

- Absence of conflict of interest
- Consistent application of rules (all aspects of a food control system) between all players and particularly FBOs

6

Risk-based / Science-based and Evidence-based Decision-making

- Decisions are to be anchored in documented evidence including scientific information
- Decisions are to be based on the risk analysis principles

7

Cooperation Between Competent Authorities Within One System

- Clear roles and responsibilities; No duplication / gaps; Effective use of resources

8

Preventive Nature of Interventions – Core Elements:

- Prevention; Intervention; Response

9

Self Assessment / Review Procedures

- Ability to support continuous improvement



Public Health Mandate

Disease Surveillance
E.g. Salmonellosis
Prioritization
Prevention
Treatment



International
Health
Regulations

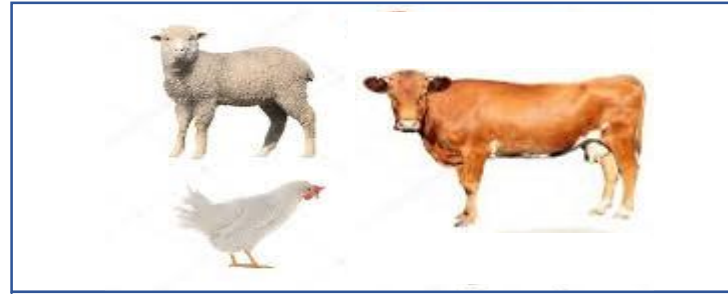


**Raw Meat, Vegetables, Milk and
Processed Food**

Oversight on Food Products and
Feed

← **CODEX** →

**Food Competent Authority/
Authorities**



**Zoonoses Surveillance / Disease
Prevention Management**

Management of Resource
Oversight on Animal Health

← **OIE** →

Animal Health Authority



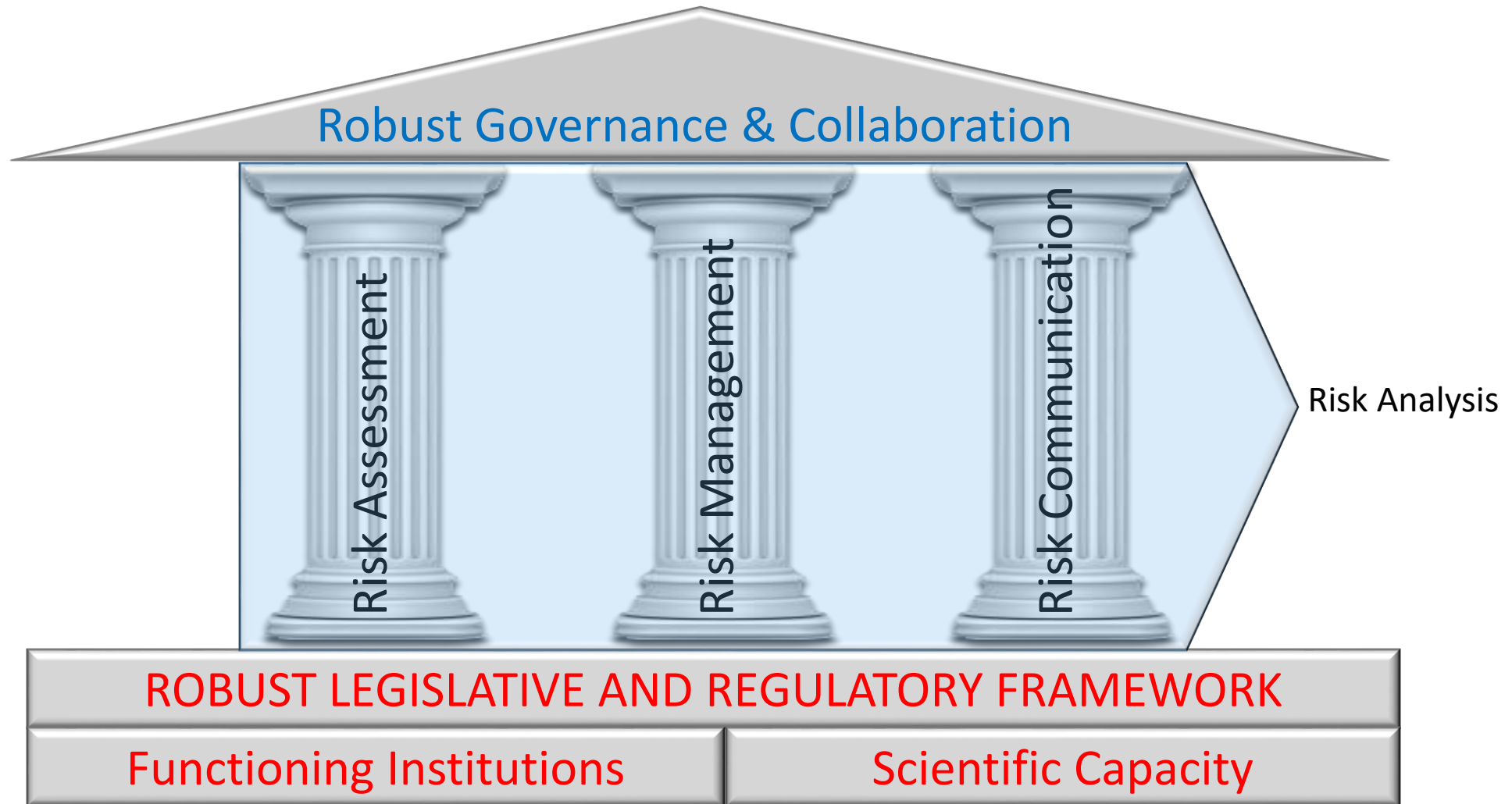
**Surveillance / Prevention
Management**

Management of Resource
Oversight on Plant Health

← **IPPC** →

Plant Health Authority

Design and Operation of a Food Control System — CXG82-2013



Clear Organization Chart

- Roles and responsibilities

Clear Governance Structure

- Who decides what?
- Process to review and vet decisions

Clear Procedures

- Internally
- For regulated parties: Recall protocols; Possible third party actors to deliver mandate

Scientific Structure / Support

- Including (relationship with) laboratory infrastructure

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Competent Authorities / Regulators

What?

- Oversight comes from a clear delegation of responsibility
- Shared responsibility with stakeholders (industry / consumers)
- **Decisions should be evidence / science / risk – based**
- Preventive measures should prevail
- Legal foundation for action

How?

- Transparency
- Impartiality
- Cooperation
- Coordination
- Continued improvement
- Alignment with international standards

Scope of Interventions of a Competent Authority

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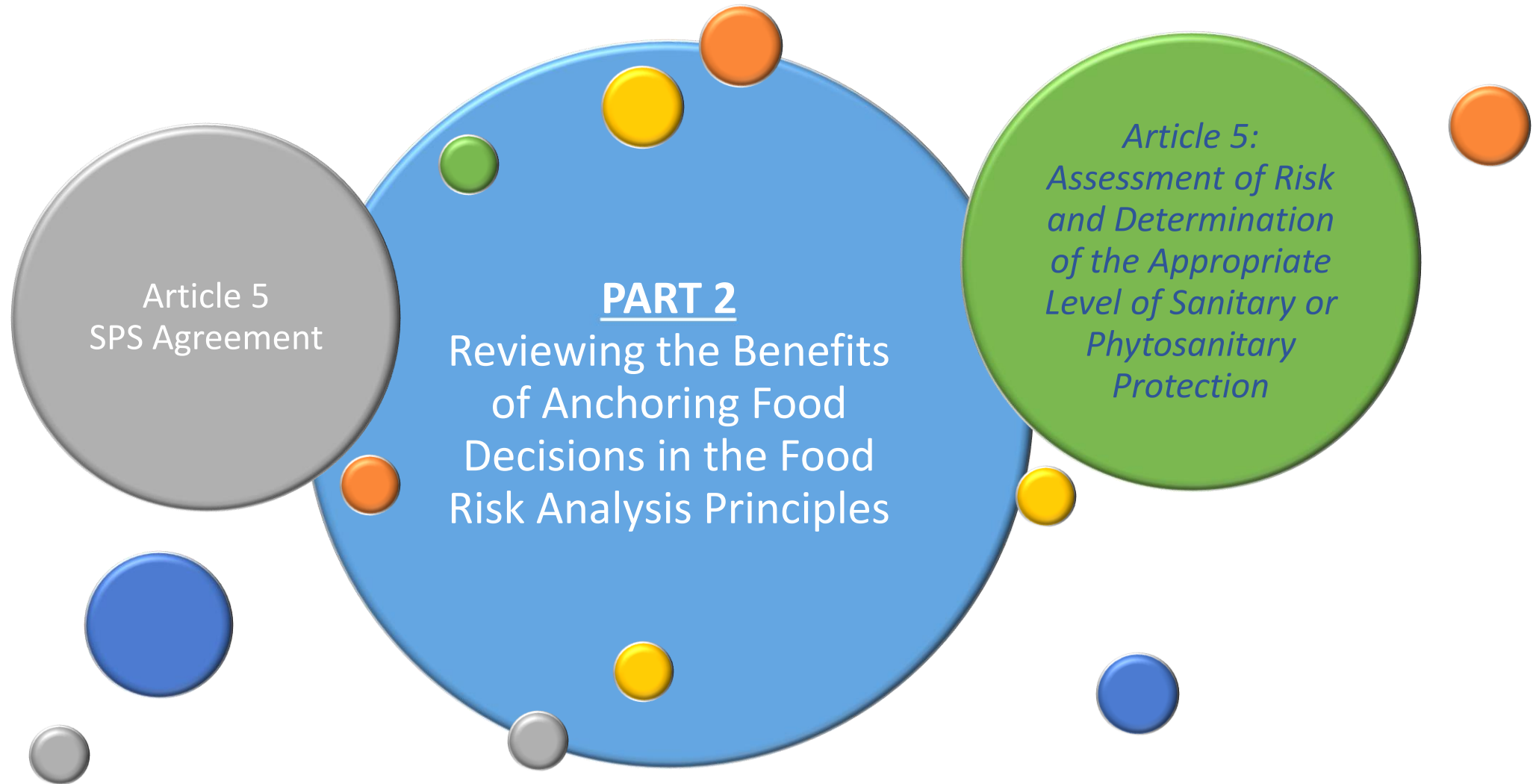
- ❑ To Protect Consumer Health and Ensure a Fair Environment for Food Trade
 - Regulatory Instrument ----- Products (not people)
 - Other interventions may address consumers' behavior
 - Education, outreach, etc.
- ❑ Across the Supply Chain
 - Continuity of interventions and Cohesive Approach
- ❑ In Favor of Preventive Approaches
 - Interventions should be as early as possible in the production process
 - End product control may be considered the least effective



- ❑ Transparency
- ❑ Impartiality / Consistency
- ❑ Risk-Based Interventions / and Application of Risk Analysis Principles
 - Anchoring decisions in Evidence and particularly in scientific evidence
- ❑ Legal Foundation where decisions are to be anchored
 - Enforceable decisions
- ❑ Aim for Harmonized decisions with Codex standards
- ❑ Aim for avoiding duplication and reliance on other systems where relevant / useful



PART 2



ENSURE FOOD SAFETY AND ANIMAL AND PLANT HEALTH MEASURES SETS OUT THE BASIC RULES IN THE WTO

☐ SPS Agreement

- Applies to **all sanitary and phytosanitary measures** which may, directly or indirectly, affect international trade.

☐ TBT Agreement

- Ensures that technical regulations, standards, and conformity assessment procedures are **non-discriminatory and do not create unnecessary obstacles to trade**.
- Applies to **all products, including industrial and agricultural products**
- **Does not apply** to sanitary and phytosanitary measures as defined in SPS Agreement



SPS Measures

1



WORLD TRADE
ORGANIZATION

G/SPS/N/CHN/XXX
20XX

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	Notifying Member: CHINA If applicable, name of local government involved:
2.	Agency responsible: National Health Commission (NHC)
3.	Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): XXX
4.	Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners, or <input type="checkbox"/> Specific regions or countries:
5.	Title of the notified document: National food safety standard General Principles for the Labeling of Prepackaged Foods Language: Chinese Number of pages: 14
6.	Description of content: The food labelling requirements for prepackaged foods
7.	Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
8.	Is there a relevant international standard? If so, identify the standard: <input checked="" type="checkbox"/> Codex Alimentarius Commission Codex Stan 1-1985 General Standard for the Labelling of Prepackaged Foods <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. <i>Terrestrial or Aquatic Animal Health Code, chapter number</i>) <input type="checkbox"/> International Plant Protection Convention (e.g. <i>ISPM No.</i>) <input type="checkbox"/> None
	Does this proposed regulation conform to the relevant international standard? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no, describe, whenever possible, how and why it deviates from the international standard:
9.	Other relevant documents and language(s) in which these are available: None



WORLD TRADE
ORGANIZATION

G/TBT/N/CHN

2019

Page: 1/1

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	Notifying Member: CHINA If applicable, name of local government involved (Article 3.2 and 7.2):
2.	Agency responsible: National Health Commission of the People's Republic of China Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other []:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):
5.	Title, number of pages and language(s) of the notified document: National food safety standard General Principles for the Labeling of Prepackaged Foods Language: Chinese Number of pages: 14
6.	Description of content: The mandatory food labelling requirements for prepackaged foods
7.	Objective and rationale, including the nature of urgent problems where applicable: Consultation
8.	Relevant documents: Not applicable
9.	Proposed date of adoption: Not applicable Proposed date of entry into force: Not applicable
10.	Final date for comments:
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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.



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 the **logical framework** that underlies **decision-making** concerning all kinds of risks (not only for food safety and nutrition)*

Applied 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

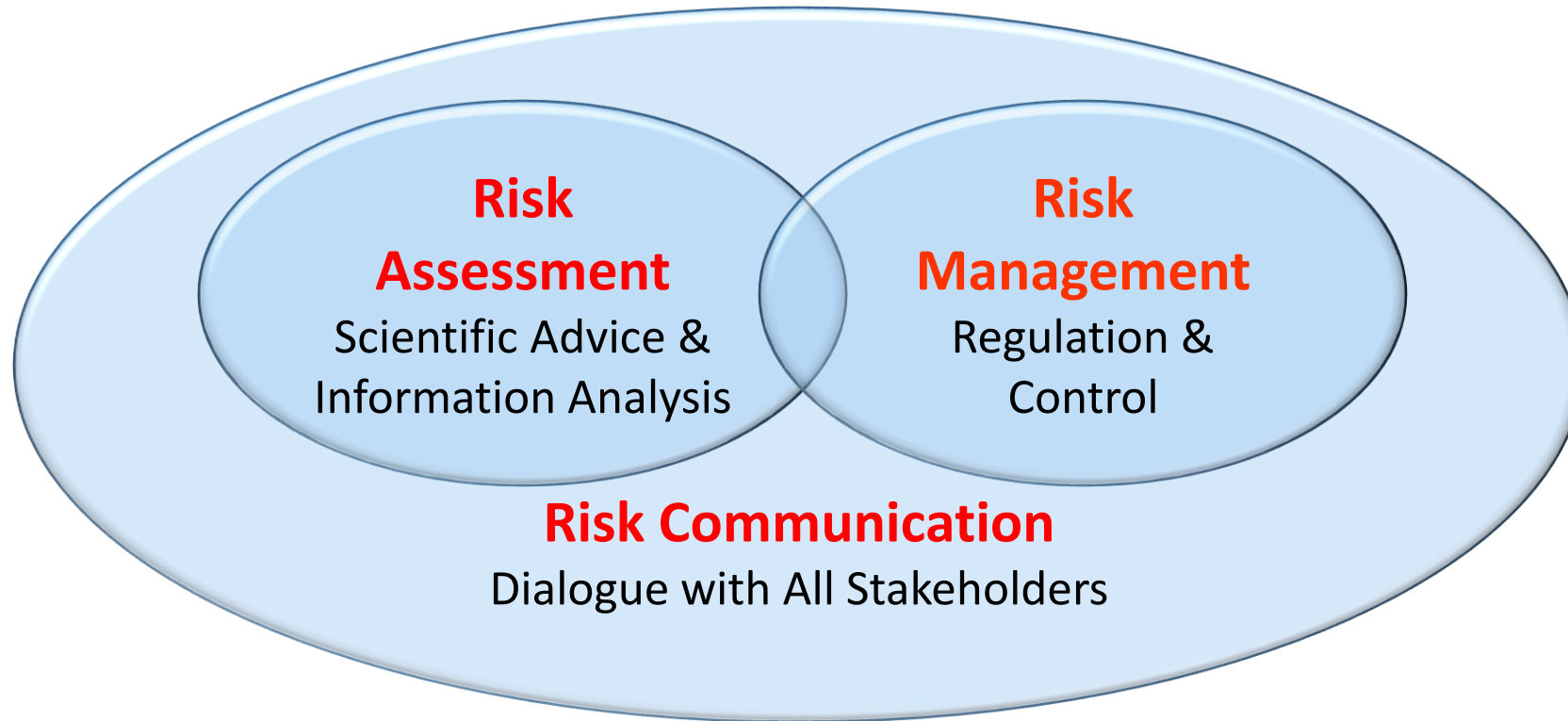
Risk Communication



The Risk Analysis Paradigm Provides Structure

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Robust Food Decisions



In Conclusion: From Risk Analysis To Food (Regulatory) Decisions

- ❑ Provides structure to the process
- ❑ Clear and transparent framework
- ❑ Objective
 - It is based on evidence (scientific and other evidence).
- ❑ Clarifies roles, responsibilities and accountabilities of all partners involved
 - Government or competent authorities, industry and consumers. Such clarification promotes the separation of risk assessment (mainly scientific assessment) and risk management (weighing the options using additional evidence).
- ❑ Promotes communication and interaction between the various players involved in the process
 - Risk assessors and risk managers
- ❑ Promotes communication and interaction between and amongst those involved in applying the decision-making process and those that will be impacted by its outputs/outcomes
 - Consumers, industry, civil society



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