3rd GLOBAL FOOD REGULATORY SCIENCE SYMPOSIUM

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RISK BASED FOOD MONITORING ACTIVITIES AS A FOUNDATION FOR ROBUST FOOD SAFETY SYSTEM

Dr. Karima Zouine, food safety expert –GFoRSS

OUTLINE

1. Monitoring activities
   - Why is it important?
   - Application of risk assessment as a basis: advantages/logical steps
2. How it could be applied to improve the regulatory system?
3. Experience
4. Challenges

Why is it important to implement monitoring activities?

Why is it important to implement monitoring activities?

The food supply chain faces significant challenges related to health risks due to multiple factors

- **The increased globalization** makes it harder to trace food products and identify contamination sources quickly and to face multiplicity of sanitary and phytosanitary hazards and risks ;
- **The variety of food sources and changing consumer preferences** can introduce new pathogens and chemical contaminants, complicating risk analysis;
- **Environmental factors**, such as climate change, also increase these risks by facilitating the spread of foodborne diseases.
- **A changing sanitary environment** in perpetual evolution (emergence and re-emergence of sanitary crises);

A challenging environment

The same questions come up in every crisis regarding the effectiveness of our food safety system and strategy

Dioxin chicken crisis

1999

Melamine in foodstuffs

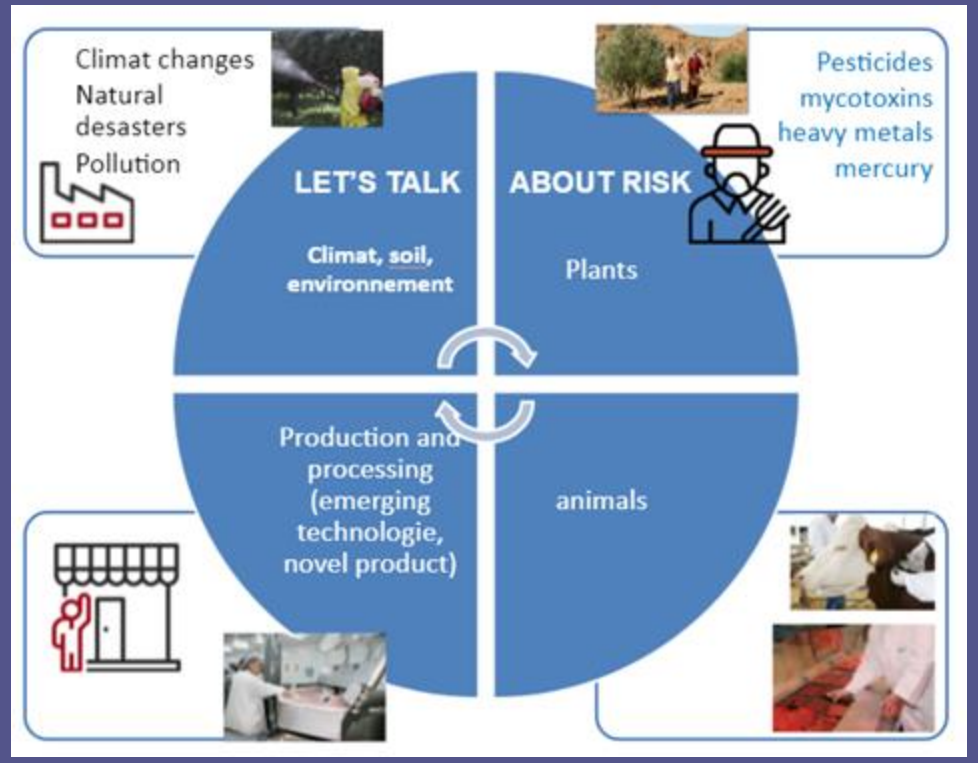
2007

- Do we know the issue? Is the source known?
- Is our assessment correct?
- Do we have enough information to determine mitigation measures?
- Is our food safety system efficient?
- Do we have the right approach?
- Etc.

WE NEED TO HAVE A ROBUST MONITORING ACTIVITIES TO ANSWER ALL THE QUESTIONS AND TO ANTICIPATE CRISES

Let's talk about hazards/risks

The establishment of robust MP is vital for optimizing food safety management.
By this tool, we ensure the protection of public health, improved export guarantees, and more efficient control measures throughout the food chain.



Risk management tool

Give us the reality of what happened in our food chain and evaluate our food safety system

To guide our decision making process

To evaluate our regulatory measures

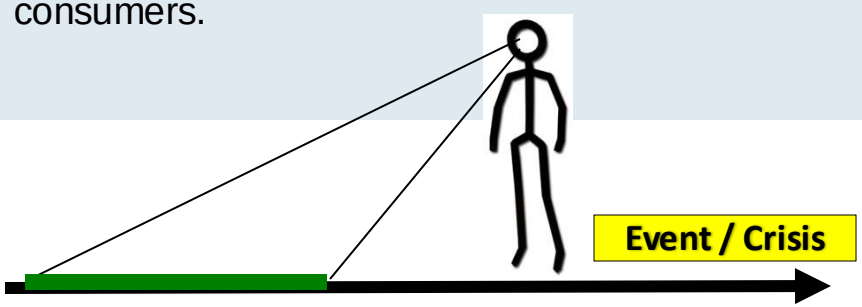
Provide more guarantees for exported products

Critical role in ensuring food safety

Importance of monitoring activities

MP play a critical role in ensuring food safety and quality of food products throughout the supply chain

To detect and address issues before they reach consumers.



IN A GLOBALIZED FOOD SYSTEM

Identify potential hazards at each stage, from production to consumption, reducing the risk of contamination, fraud, and non-compliance with regulatory standards.

These plans not only safeguard consumers but also help maintain the integrity of international markets by ensuring that exported products meet rigorous safety requirements.

Food products meet national and international safety standards, protecting public health and facilitating trade.

Ensure that corrective actions are implemented promptly when non-compliance is identified.

Risk-based approach
Advantages

ADVANTAGES OF RISK BASED MONOTORING ACTIVITIES

Applying risk assessment in the establishment of monitoring activities for food safety is essential for several scientific reasons

Identification of Critical Hazards: Risk assessment helps prioritize the most significant hazards (pathogens, chemical contaminants) based on their likelihood and impact, ensuring resources focus on the highest risks to public health.

Proactive approach: It supports the implementation of science-based preventive controls, such as identifying critical control activities, ensuring proactive risk mitigation.

Reducing Uncertainty: By integrating up-to-date scientific data, risk assessment enhances the precision of monitoring plans and helps anticipate emerging threats (e.g., new pathogens, environmental contamination).

ADVANTAGES OF RISK BASED MONOTORING ACTIVITIES

Risk-based monitoring activities ensure a more effective, targeted, and adaptable approach to food safety management.

Continuous Improvement: Risk assessment enables dynamic adjustment of monitoring plans as new scientific evidence or food production practices evolve, ensuring ongoing public health protection.

International Compliance: It aligns with international food safety standards (e.g., CODEX, WHO, FAO, etc.), ensuring consistent safety measures for both imports and exports, and promoting global collaboration in crisis response.

Resource Optimization: It allows authorities to target specific high-risk points in the food chain, making monitoring efforts more efficient and avoiding unnecessary, broad-based controls.

RISK BAZED MONITORING ACTIVITIES INTERNATIONAL RECOMENDATION

Integrating risk assessment into the development of monitoring activities to ensure food safety is in compliance with international standards.

World Trade Organization (WTO)

•**Document**: *Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)*
•**Description**: Requires risk-based sanitary controls in line with international standards (Codex, OIE, FAO).
•**Link**: WTO – SPS Agreement

FAO (Food and Agriculture Organization)

•**Document**: *Manual on Risk-Based Veterinary Drug Residue Surveillance (FAO/WHO 2017)*
•**Description**: Offers detailed guidance on risk-based surveillance for veterinary drug residues.
•**Link**: FAO – Veterinary Drug Residue Surveillance

•**Document**: *Risk-Based Approach to Food Control Systems (FAO/WHO 2021)*
•**Description**: Framework for designing risk-based national food control systems.
•**Link**: FAO – Food Control

Codex Alimentarius (FAO/WHO)

•**Document**: *Guidelines for the Design and Implementation of National Residue Control Programs for Veterinary Drugs (CAC/GL 16-1993)*
•**Description**: Provides guidance on establishing risk-based surveillance programs for veterinary drug residues in food.
•**Link**: Codex – Veterinary Drug Residues

•**Document**: *Guidelines for National Food Control Systems (CAC/GL 82-2013)*
•**Description**: Outlines risk-based approaches for designing national food control systems.
•**Link**: Codex – Food Control Systems

European Union (EU)

•**Document**: *Regulation (EC) No 882/2004 on Official Controls*
•**Description**: Defines risk-based surveillance for food and animal health controls in the EU.
•**Link**: EU Official Controls Regulation

INTERNATIONAL ORGANISATIONS RECOMMENDATIONS

Risk-based monitoring activities to ensure food safety in compliance with international standards. (WHO, FAO, CODEX)

key recommendations

1. **Risk-based targeting monitoring**: to prioritize high-risk areas, substances, and products to ensure resources are efficiently allocated.

2. **Scientific evidence**: to guide decisions that must be based on sound scientific data, focusing on the likelihood and impact of risks, such as contaminants or disease outbreaks.

3. **Proportional measures**: Monitoring activities should be proportionate to the identified risks, avoiding overly restrictive controls that could hinder trade.

4. **Continuous monitoring**: dynamic process, adjusting to emerging risks and new scientific evidence.

Monitoring plans should be both effective and efficient, protecting public health while facilitating international trade.

RISK-BASED MONITORING ACTIVITIES

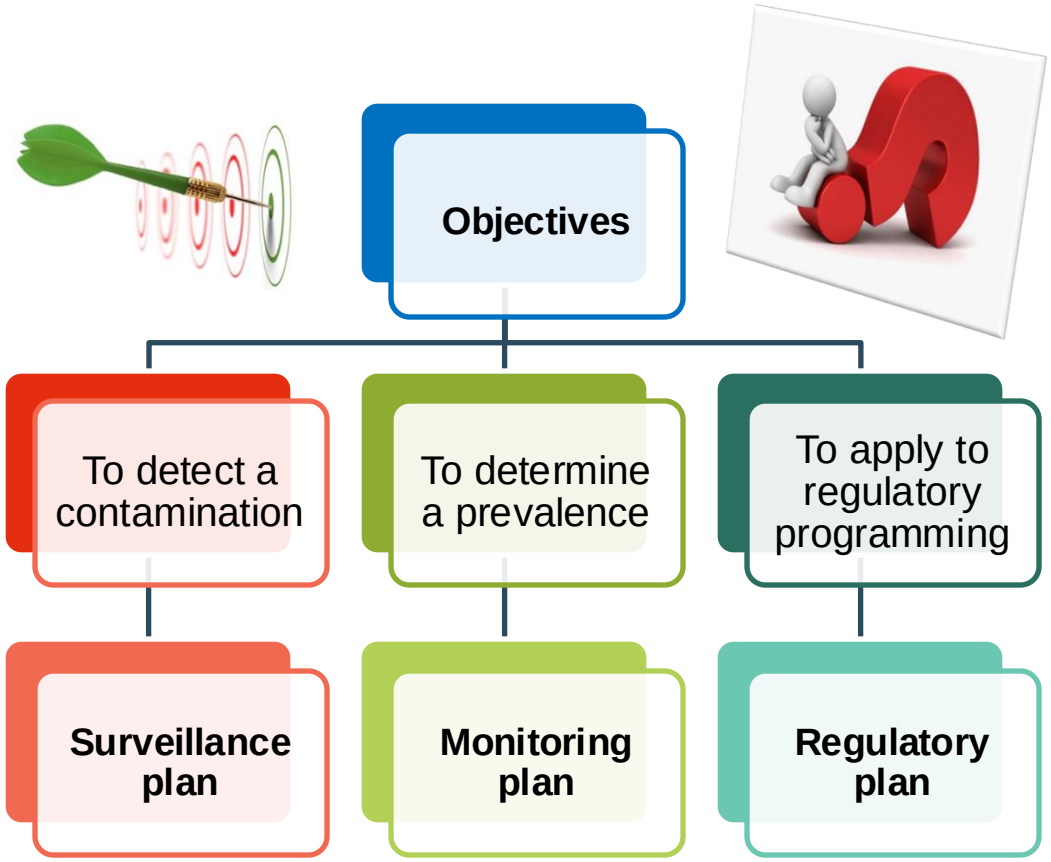
APPROACHES AND METHODOLOGY

Risk-based monitoring methodology

Primarily Conceptual Approach to Risk-Based Monitoring Activities

- Definition of Outcomes/Goals: Clearly articulating the desired outcomes and objectives of the risk-based monitoring activities.
- Risk Ranking Methodology: Applying a road-based risk ranking approach to systematically identify and prioritize significant risks based exclusively on public health considerations.
- Data Needs Assessment and Necessary Logistic (analytic tools and methodology) : essential for effective resource prioritization.

The scheduling of monitoring activities depends on the objectives



Monitoring activities: Choice of programming approach

1. Random Objective: Samples are selected randomly to ensure representativeness and minimize bias.

2. Selective Objective (Targeted): Samples are chosen based on specific criteria, focusing on particular segments of interest.

The chosen sampling method significantly impacts the interpretation of results, with random sampling providing broader insights and selective sampling offering detailed information on specific issues.

Applications of monitoring activities according to the objectives targeted

	MONITORING	SURVEILLANCE
Objective	To assess the overall exposure of the consumer to a particular risks by evaluating the prevalence of the contaminants in products at different stages in the food chain	To control risks by searching for the anomalies, non-conformities and even fraud
Approch	based on random sampling of identified population (product) or sub-population (in space and/or time).	targeted sampling, that are taken on the basis of predetermined targeting criteria
Scope	Identification of management measures	Evaluate the effectiveness of management measures

The scheduling of monitoring activities

Consequence

Prevalence

Disease burden

THE STEP OF RISK RANKING

1. Risk-ranking of pathogen-product combinations
What should be monitored?

2. Risk-based selection of FBO's
Who should be monitored?

- Food safety climate
- Historical data
- Product type
- Size of the company

Methods for risk ranking should ideally be quantitative, should be transparent about the assumptions, uncertainties and limitations, and should be easily updated when new data become available

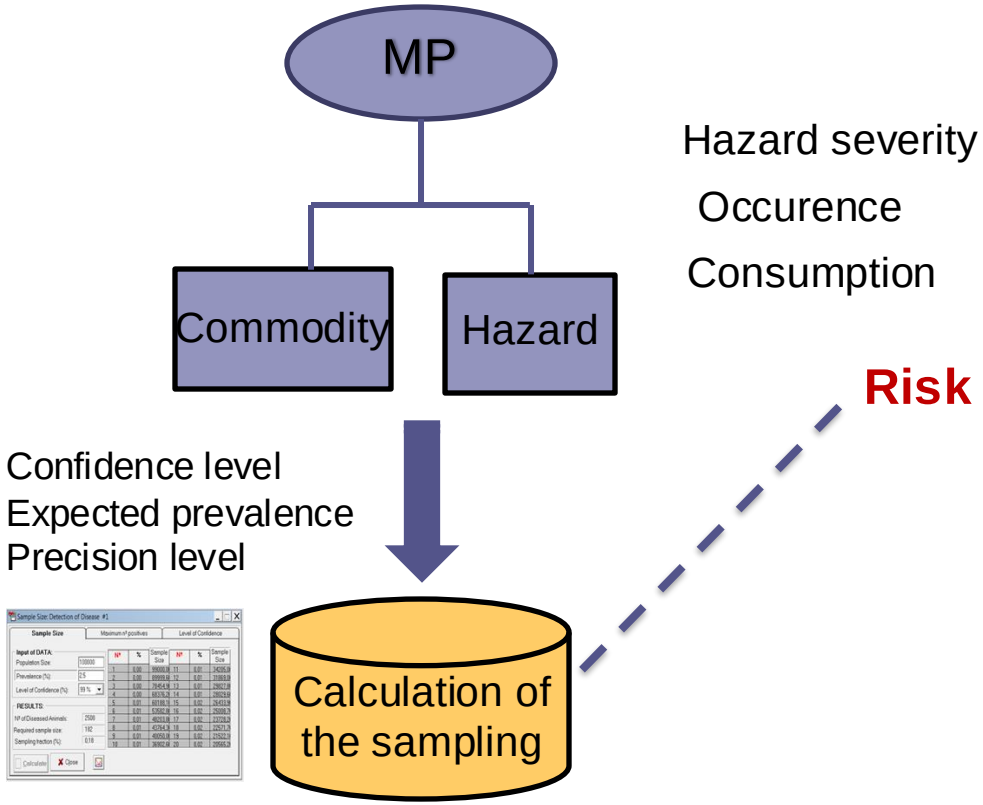
In the scientific literature different methods can be found to rank hazards such as: risk assessment, ***disease burden methods, expert judgement methods, flow charts or decision trees, risk ratio methods, scoring method, multi criteria decision analysis, and risk matrices.***

Monitoring activities based on risk: methodology

Following steps:

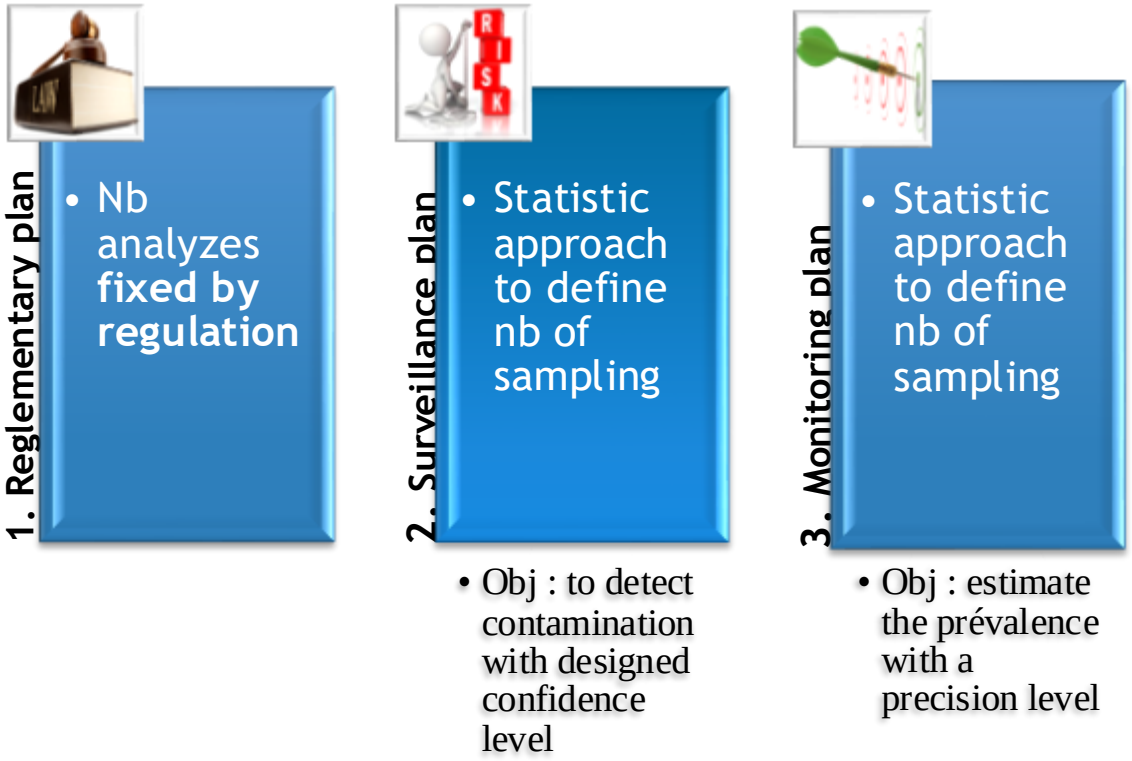
- Identification of **pertinent hazards/active substances**
- Description of the population and identification of the matrices to be sampled
- Determination of the number of sampling
- Distribution of analyzes between matrices and sampling locations
- Analytical research

Calculation of the sampling based on risk assessment



$$n = p_e(1-p_e)\left(\frac{z_{1-\alpha/2}}{\varepsilon}\right)^2$$

$$\varepsilon = z_{1-\alpha/2}\sqrt{\frac{p_e(1-p_e)}{n}}$$

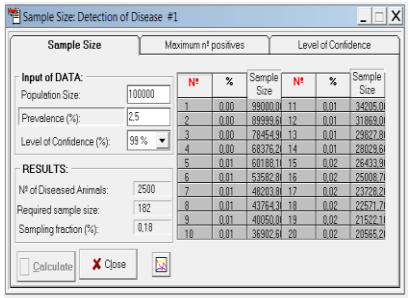


Two major strategies: random sampling or targeting sampling.

Statistical approach based on the integration of parameters that take into account the risks

Statistical algorithms and models based on risks

Formula	Inputs	Aim
$n = \frac{\log(\alpha)}{\log(1-cf)} \sim \frac{3}{cf}$	cf: An estimate of the contaminated fraction (%) α: the probability of rejection	To reject a lot with a certain probability
$n = \left(1 - \alpha^{1/N*cf}\right) * \left(N - \frac{N*cf-1}{2}\right)$	cf: An estimate of the contaminated fraction (%) α: the probability of rejection *N*: the population size	To estimate the contaminated fraction
$n = \frac{\frac{Z_\alpha^2\, cf(1-cf)N}{2}}{(N-1)e^2 + \frac{Z_\alpha^2\, cf(1-cf)}{2}}$	cf: An estimate of the contaminated fraction (%) *e*: the acceptable error *N*: the population size $Z_{\alpha/2}$ the 97.5th percentile of a normal distribution with mean $\bar{n}$ and standard deviation $\bar{n}p(1-p)$ with $\bar{n}$ being the average sample size during the past three years	To estimate the contaminated fraction



$$n = \left[1 - (1-\gamma)^{1/(P\times N)}\right] x \left[N - \frac{(P\times N)-1}{2}\right]$$

Cannon & Roe

Surveillance Plan

Hazard

Prévalence to be controled

Adverse effect

Scoring

Adverse effect+ (Occurrence x Contribution)

Occurrence

Contribution

Confidance level

1% 2,5% 5% 10%

90% 95% 99%

Exposure

Calculation of the number of sampling

Belgium model

Location 1
- Matrice 1

Location 2
- Matrice1
- Matrice 2

Location 3
- Matrice1
- Matrice 2

Risks

Products

EXAMPLE OF MONITORING PLAN
DETECTION OF AFLATOXINES IN FOOD PRODUCTS

Aflatoxines : carcinogenic, classe 1 (CIRC) : (4)

Grains: Corn, wheat, barley, and rice

Nuts: Peanuts, almonds, and pistachios

Seeds: Sunflower seeds and cotton seeds

Dried Fruits: Raisins, figs, and dates

Spices: Chili powder and paprika

Animal Feed: Ingredients used in livestock feed

Dairy Products: Milk and cheese (from animals fed contaminated feed)

Oils: Vegetable oils extracted from contaminated seeds or nuts

Hazard

Expected prevalence

Adverse effect

1234

Confidence level

Occurrence

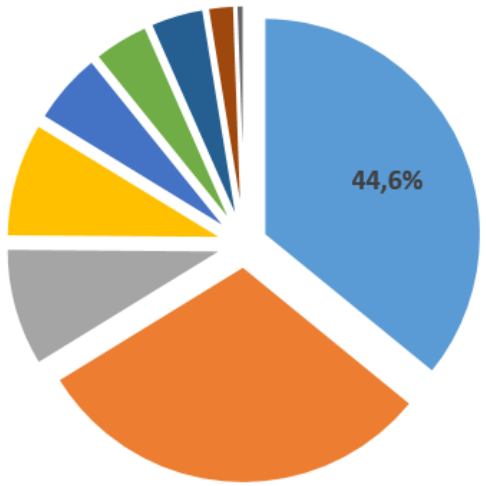
1NM4

Frequency of excess observed during previous controls? Default: (2)

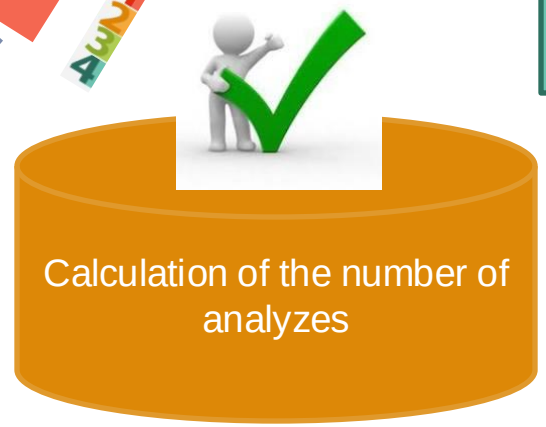
Contribution

4NM1

Risk



Consomption data: (4)



Belgium model

Ex : Estimation of the prevalence of Salmonella spp. in poultry carcasses at processing facilities.

Surveillance plan

- Population size: infinite (> 100,000 carcasses)
- Confidence level: 95%
- Expected prevalence: 5%
- Accuracy level: 2%

Number of analyzes= 454

Ex: Regulatory monitoring plan

IN THE CONTEXRE OF TRADE WITH EU

FOLLOWING NEW REGULATION

- To integrate risk assessment into the establishment of surveillance plans for active substances, pesticides, and contaminants, in compliance with current European regulations.
- Sampling fixed by EU regulation is focused on matrices involved in trade with EU countries.

The adopted method was a semi-quantitative, multi-criteria decision-making model based on expert judgement.

It allows for the integration of a wide range of parameters to select relevant chemicals while also prioritizing according to the objectives of the surveillance plan.

Risk-Based Decision-Making Approach

- **Identification of the pairs hazards (analytes)/matrices for analysis and application of Risk Ranking Methodology based on risk assessment**

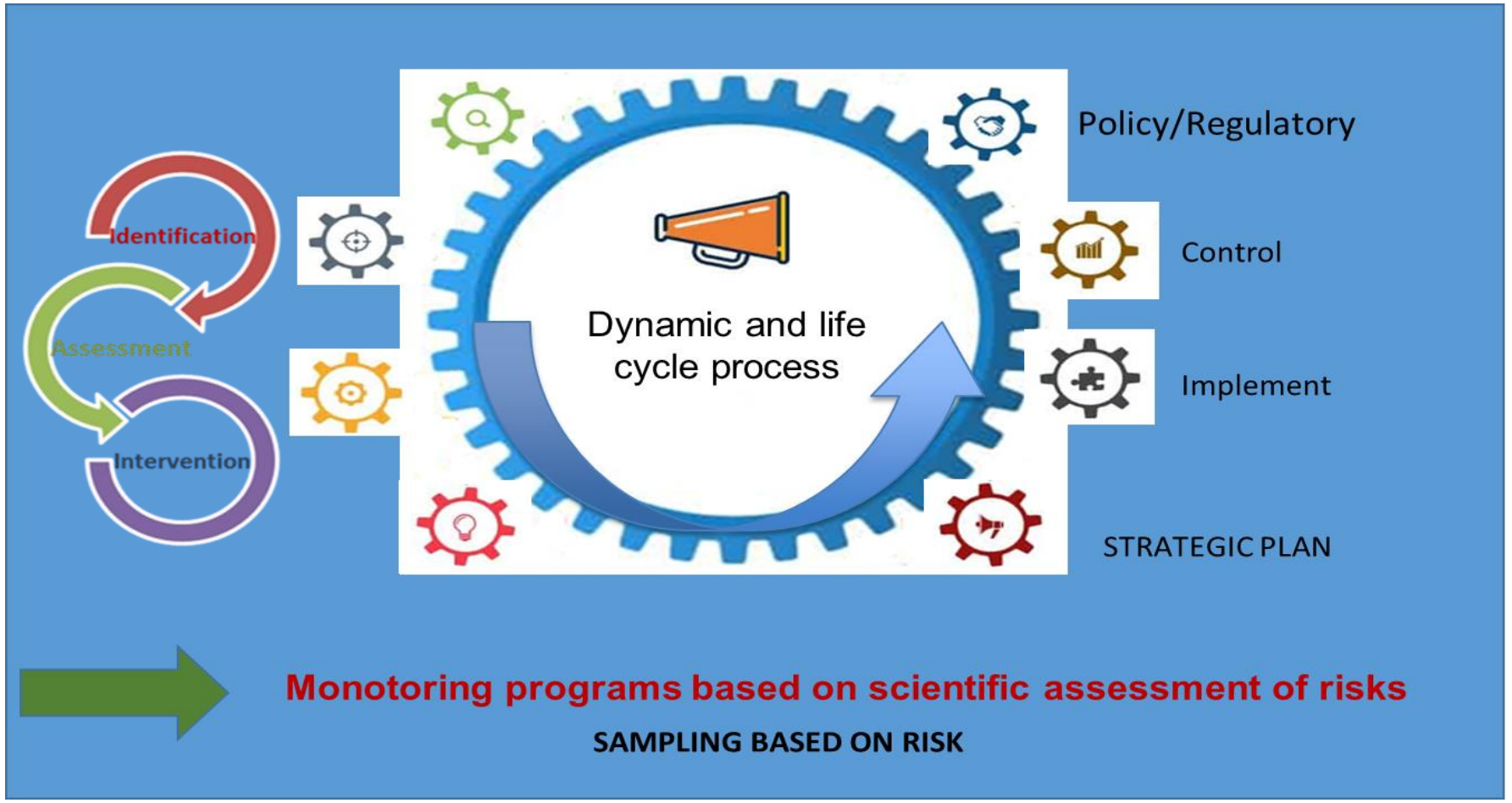
A methodology for selecting chemical substances by food matrix was established to categorize the food product-chemical pairs justified by criteria that reflect the risk levels associated with the active substances.

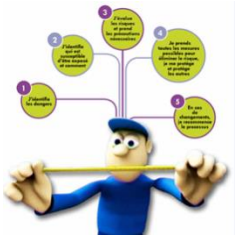
The criteria for risk assessment and ranking include:
- **Adverse effects**: Based on the toxicological profile, the severity of the hazard, and socio-economic impact.
- **Occurrence of the hazard**: Assessed through prior control results, likelihood use, and the effectiveness of control systems.
- **Matrix contribution**: The food product's role in exposure to the associated risk, relative to overall exposure.

- **Establishment of the surveillance plan according to the requirements established in the EU regulation.**

How it could be applied to improve the regulatory system?

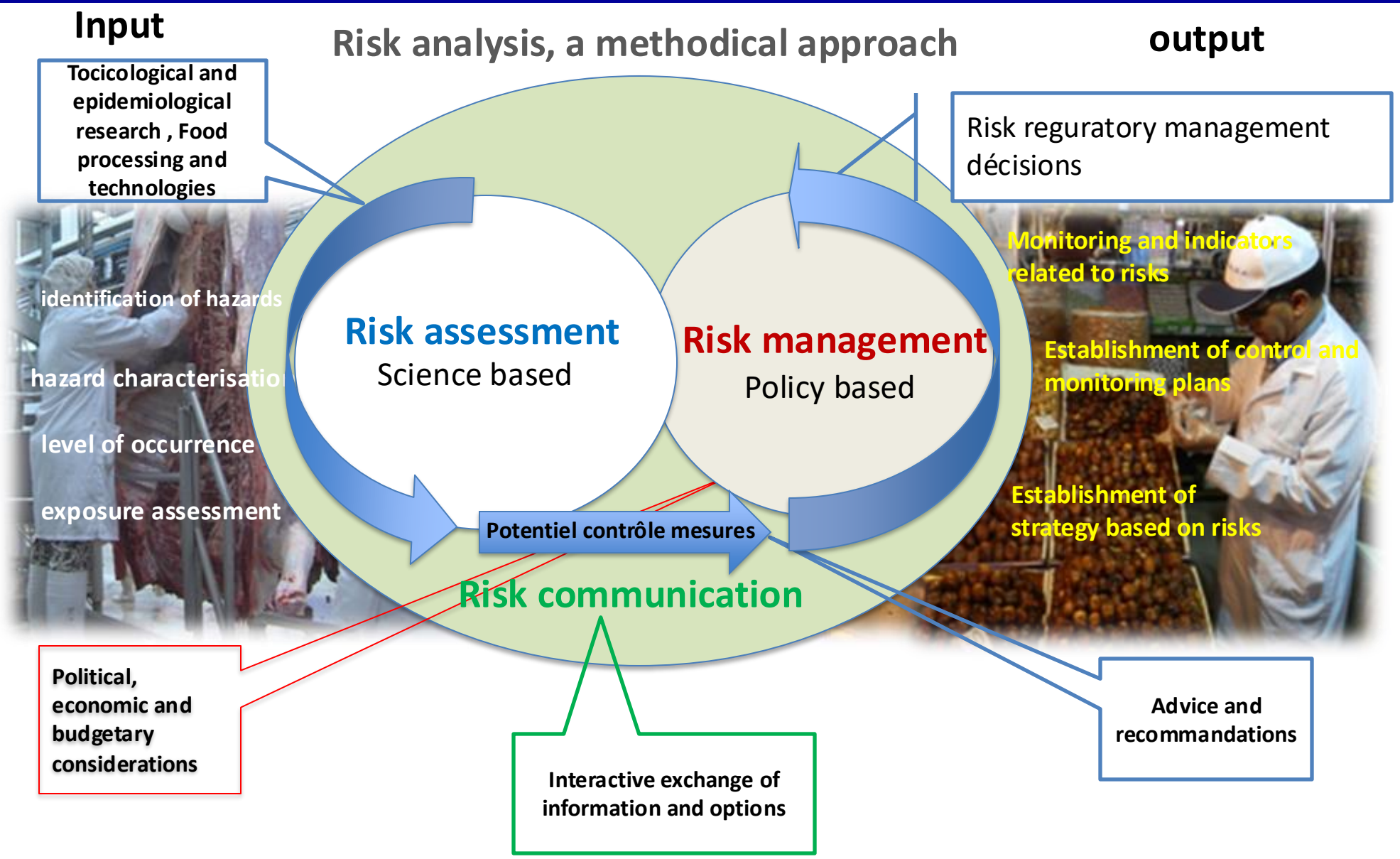
Monitoring programs should be designed to accurately reflect the realities of our food safety system and effectively identify all potential risks within the food chain.



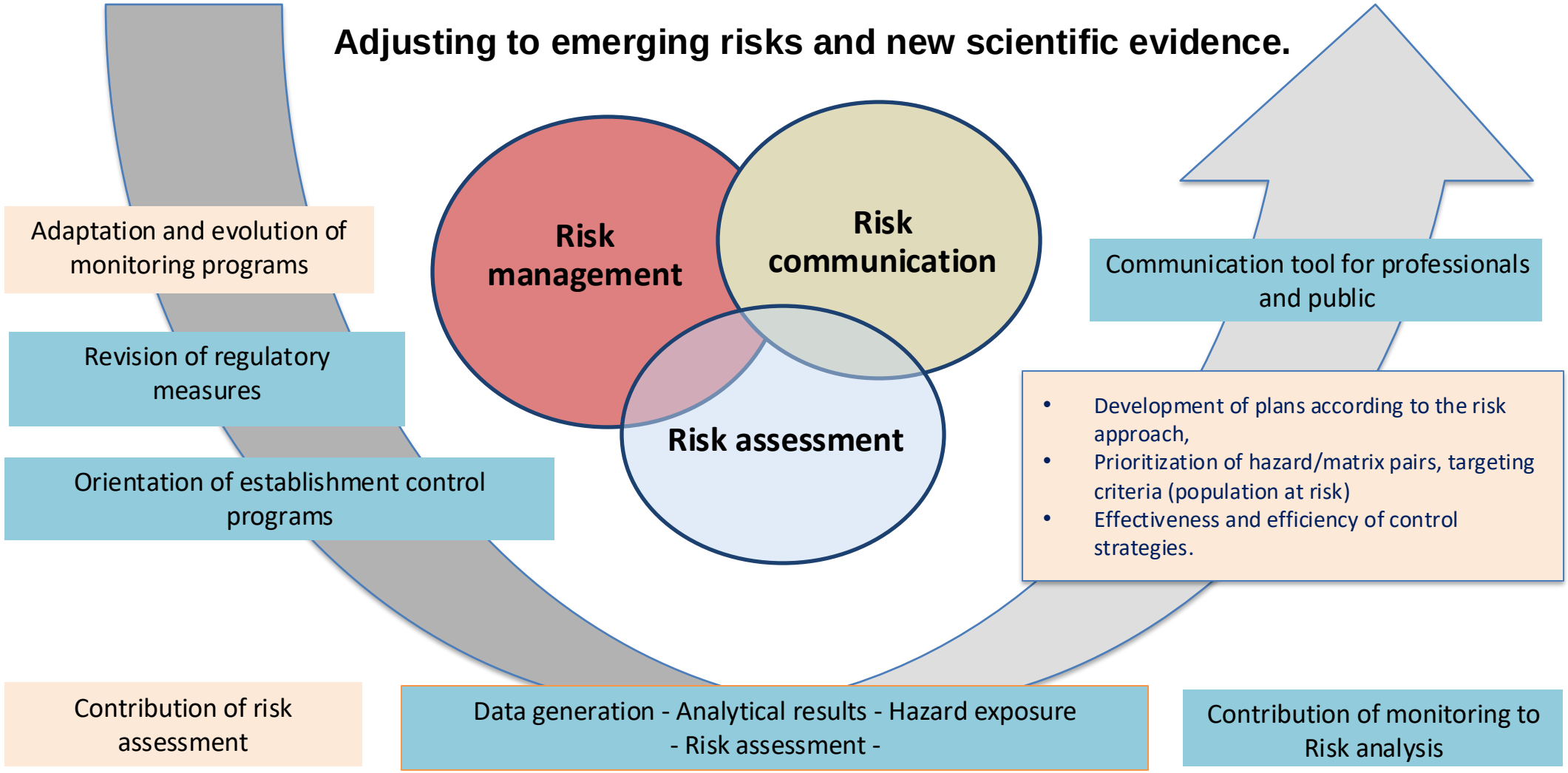


MONITORING ACTIVITIES: RELY ON A STRUCTURED APPROACH BASED ON SCIENTIFIC ASSESSMENT OF RISKS

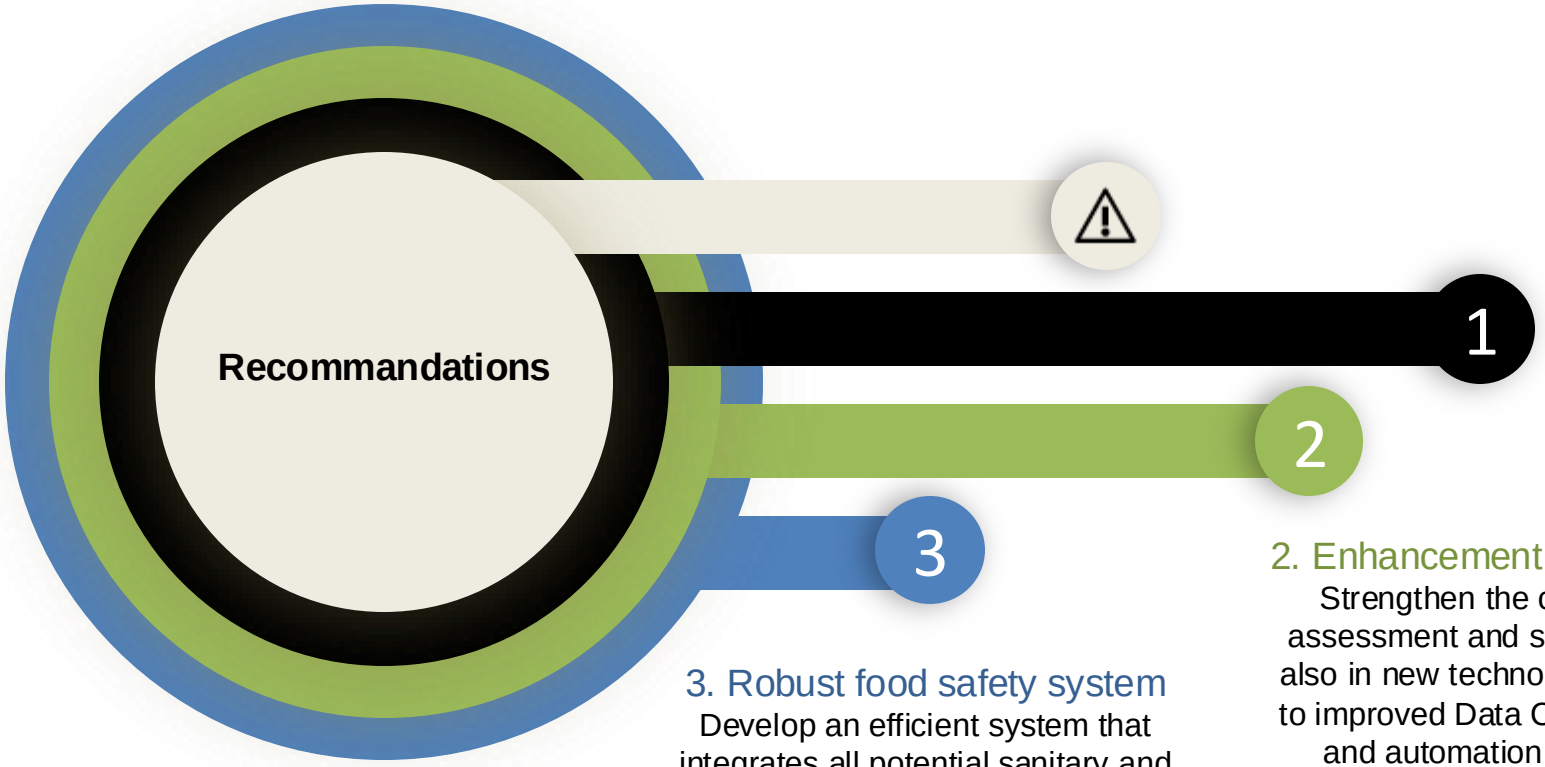
INTEGRETED APPOACH FOR FOOD CONTROL



Monitoring by dynamic Risk Analysis process



Challenges and opportunities



1. Communication

Develop an interactive mechanism with actors and key partners for sharing and transmitting the information needed for timely risk monitoring.

2. Enhancement capacities

Strengthen the competences in risk assessment and scientific expertise and also in new technologies like AI notabelly to improved Data Collection and Analysis and automation of risk assessment

3. Robust food safety system

Develop an efficient system that integrates all potential sanitary and phytosanitary risks.

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