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TECHNICAL TRAINING ON RISK ANALYSIS FOR SAARC COUNTRIES

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Quality Council of India

Preliminary Risk Management Activities

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Overview of Risk Management

Definition - Risk management is

«The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.»

Reference: Definition of Risk Analysis Terms Related to Food Safety, Procedural Manual of the Codex Alimentarius Commission, 21st Edition

Overview of Risk Management

Risk management is an integral component of the overall risk analysis

«Risk analysis is a process consisting of three components:

- Risk assessment
- **Risk management**
- Risk communication»

Overview of Risk Management

Introduction

«**Risk analysis must occur in a context** and, to be done effectively, **it requires a formal process**. In a typical instance, a food safety problem/issue is identified and risk managers initiate a risk management process, which they then see through to completion.

Reference: Food safety risk analysis, A guide for national food safety authorities, FAO Food and Nutrition Paper 87, Rome, 2006

Overview of Risk Management

Introduction contd.

This is best accomplished within a **systematic**, **consistent** and **readily-understood framework** in which scientific knowledge on risk and evaluations of other factors relevant to public health protection are used to select and implement appropriate control measures.

Overview of Risk Management

Introduction contd.

The responsibilities of risk managers during this process also include commissioning a risk assessment when one is needed, and making sure that risk communication occurs wherever necessary.»

Risk management – National Govts.

«National government decisions on risk management, including sanitary measures taken, should have as their primary objective the protection of the health of consumers.

Unjustified differences in the measures selected to address similar risks in different situations should be avoided.»

Reference: Working Principles for Risk Analysis for Food Safety for Application by Governments, CAC/GL 62-2007

Preliminary risk management activities:

First phase of the RMF

Preliminary risk management activities form the first phase of the RMF;

The other three phases are:

- **Identification and selection of risk management options;**
- **Implementation;**
- **Monitoring and review of the decision taken.**

Risk management framework

Important

The application of a risk management framework represents a systematic way of thinking about all food safety issues that require risk management.

Some examples that benefit from the application of a Risk Management Framework

Some examples (Source: Box 2.2, page 15 FAO/WHO, 2006)

- A new or emerging potential hazard that constitutes an unknown level of risk; e.g. Shiga toxin producing *E. coli* (STEC) from mammals;
- An indication of a high level of risk to consumers from a specific pathogen in a specific food; e.g. *Listeria monocytogenes* in delicatessen meats;
- An indication of a high level of risk to consumers associated with a category of foods; e.g. imported spices;
- Evaluation of new animal production methods, e.g. new veterinary drugs for the treatment of animal diseases or changing intensity of animal husbandry;
- Introduction of a new pesticide chemical for use on food or animal feed crops;
- Evaluation of a new food processing technology, e.g. an alternative pasteurisation regime for a heat-treated food product;
- Etc.

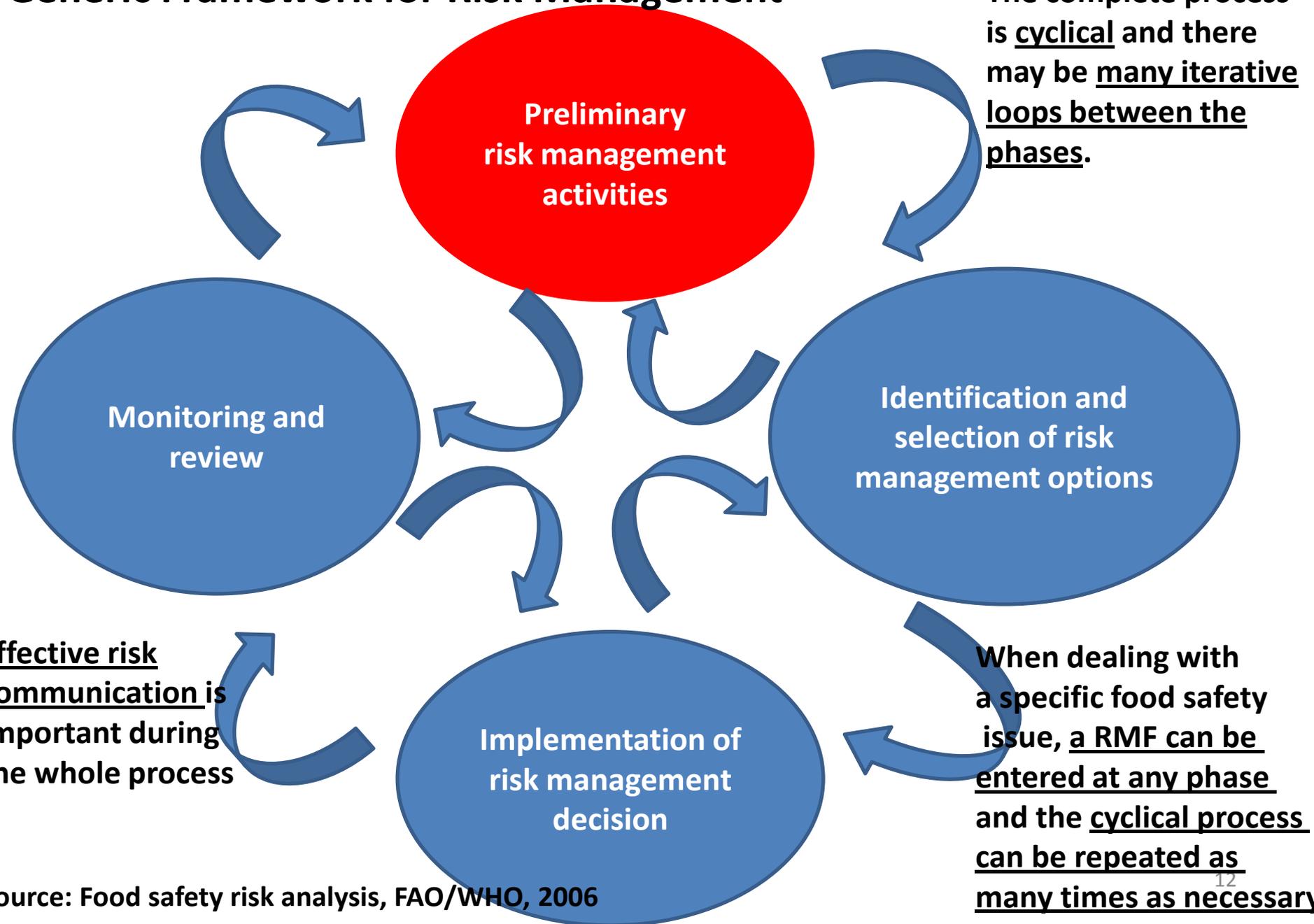
Risk management process

Important

The risk management process should be

- **Transparent;**
- **Consistent;**
- **Fully documented.**

Generic Framework for Risk Management



Preliminary risk management activities

1. Identify food safety issue
2. Develop a risk profile
3. Establish risk management goals
4. Decide on a need for a risk assessment
5. Establish risk assessment policy
6. Commission risk assessment, if necessary
7. Consider results of risk assessment
8. Rank risks, if necessary

Preliminary risk management activities: A recent case study from Switzerland

1. Campylobacter in Switzerland: Risk analysis by the Swiss Federal Office of Public Health

Also refer to

<http://www.bag.admin.ch/themen/lebensmittel/04861/13399/index.html?lang=en>

Preliminary risk management activities

Once a **food safety problem has been identified**, available information is aggregated into a **risk profile** that will guide further action.

During this first phase, **good risk communication** is important between the risk managers and risk assessors (internal communication) and between risk managers and other external interested parties.

Preliminary Risk Management

Activities: 8 steps

1. Identification and description of the food safety problem;
2. Development of a risk profile;
3. Establishment of broad risk management goals;
4. Decision as to whether a risk assessment is necessary;
5. Establishment of a risk assessment policy;
6. Commissioning the risk assessment;
7. Consideration of the results of the risk assessment;
8. Ranking food safety issues and setting priorities for risk management

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

1. **Identify food safety issue**
2. Develop a risk profile
3. Establish risk management goals
4. Decide on a need for a risk assessment
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6. Commission risk assessment, if necessary
7. Consider results of risk assessment
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Step 1: Identification and description of the food safety issue.

This is an essential first task for risk managers.

- Sometimes the issue is already “recognised” and accepted as a food safety problem;

- Sometimes the authorities need to evaluate new

Issues e.g. new food processing technologies or new food production methods or new pesticides for use on food or animal feed crops, etc.

Food safety authorities may learn about a food safety problem in different ways e.g.

- Domestic and international point of entry inspection;
- Food or environmental monitoring programmes;
- Laboratory, epidemiological, clinical and toxicological studies;
- Human disease surveillance;
- Food-borne disease outbreak investigations;
- Etc.

Preliminary Risk Management Activities: Step 1

Step 1: Identification and description of the food safety problem

Some examples

(Source: Box 2.3, page 16 FAO/WHO, 2006)

- *Methylmercury in fish*
- *Listeria monocytogenes*
- *The agent of BSE*

Important ! A brief initial description of the food safety issue provides the basis for developing a risk profile.

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

1. Identify food safety issue
2. **Develop a risk profile**
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Step 2: Developing a risk profile

- A risk profile requires gathering relevant information on an issue and may take a number of forms.
- The main purpose of developing a risk profile is to assist risk managers in taking further action.
- The information gathered should always be sufficient to guide risk managers in determining the need (if any) for a risk assessment.
- Usually, the risk profile is developed primarily by risk assessors and experts with specific technical knowledge about the issue at hand.

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

1. Identify food safety issue
2. **Develop a risk profile**
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Step 2: Developing a risk profile

By gathering available information on risks, the risk profile should assist risk managers in

- **setting work priorities,**
- **deciding how much more scientific information on the risks is needed,**
- **developing a risk assessment policy,**
- **identifying possible risk management options (where relevant),**

A good risk profile provides the basis for commissioning a risk assessment where this is considered necessary.

Preliminary Risk Management

Activities: Step 2

Step 2. Developing a risk profile

A typical risk profile includes a brief description of:

- The situation, product or commodity involved;
- Information on pathways by which consumers are exposed to the hazard;
- Possible risks associated with that exposure;
- Consumer perceptions of the risk;
- The distribution of the possible risks among different segments of the population.

Preliminary Risk Management

Activities: Step 2

Examples of information that may be included in a risk profile

(Source: Box 2.5, page 18 FAO/WHO 2006)

- Initial statement of the food safety issue
- Description of the hazard and food(s) involved
- How and where the hazard enters the food supply
- Which foods expose consumers to the hazard and how much of those foods are consumed by various populations
- Frequency, distribution and levels of occurrence of the hazard in foods
- Identification of possible risks from the available scientific literature
- Etc. (please also refer to the source noted above)

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

1. Identify food safety issue
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Step 3: Establishment of risk management goals

Following the development of a risk profile, risk managers need to decide on the broader risk management goals.

Preliminary Risk Management

Activities: Step 3

Examples of generic risk management goals that may require a risk assessment to resolve a food safety issue (Source: Box 2.6, page 19, FAO/WHO 2006)

- Developing specific regulatory standards or other risk management measures that can be expected to reduce risks associated with a specific food-hazard combination to an agreed acceptable level (e.g. for an emerging microbiological hazard).
- Ranking risks associated with different hazard-food combinations to establish priorities for risk management (e.g. *Listeria Monocytogenes* in different food categories, Annex 3).
- Etc. (please also refer to the source noted above)

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

1. Identify food safety issue
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4. **Decide on a need for a risk assessment**
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7. Consider results of risk assessment
8. Rank risks, if necessary

Step 4: Decision as to whether a risk assessment is necessary

A risk assessment is likely to be especially desirable when

- the nature and magnitude of the risk are not well characterised,
- when a risk brings multiple societal values into conflict,
- the issue is a pressing public concern,
- the risk management has major trade implications.

Practical issues that may impact the commissioning of a RA:

- *Time*
- *Resources*
- *Urgency of a risk management response*
- *Consistency with response to similar issues*
- *Availability of scientific information.*

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

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Step 5: Establish a risk assessment policy

Codex definition:

“Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.”

*Risk managers should establish the **risk assessment policy** in collaboration with risk assessors. The process should be open and transparent and it should allow for inputs from relevant stakeholders.*

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

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6. **Commission risk assessment, if necessary**
7. Consider results of risk assessment
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Step 6: Commission a risk assessment

Once the decision is made that a risk assessment is necessary, risk managers should arrange to get the risk assessment done.

There should be a functional separation between risk assessment and risk management activities.

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

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7. **Consider results of risk assessment**
8. Rank risks, if necessary

Step 7: Consider the results of the risk assessment

The RA should, as far as possible and given the availability of data, clearly and fully answer the questions asked by the risk managers and where appropriate, identify and quantify sources of uncertainties in risk estimates.

Risk Management Framework: First Phase: Preliminary Risk Management Activities

Preliminary risk management activities

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Step 8: Rank food safety issues and set priorities for risk management*

The primary criterion for ranking is generally the perceived relative level of risk each issue presents to consumers, so that risk management resources can be optimally allocated to reduce overall food-borne public health risks.

* In cases where risk management is focused on a single hazard, this step will not apply.

Issues may also be prioritised based on other factors e.g.

- *Restrictions to international trade,*
- *Pressing public or political demand that attention be paid to a particular issue*
- *The relative ease or difficulty of resolving an issue,*
- *Etc.*

Preliminary risk management activities

Importance of risk communication

Good risk communication is important during this “preliminary” phase.

“External” communication

Communication with external stakeholders is often needed to fully identify the food safety issue, obtain sufficient scientific information for risk profiling, and formulate questions to be answered by the risk assessment.

Preliminary risk management activities

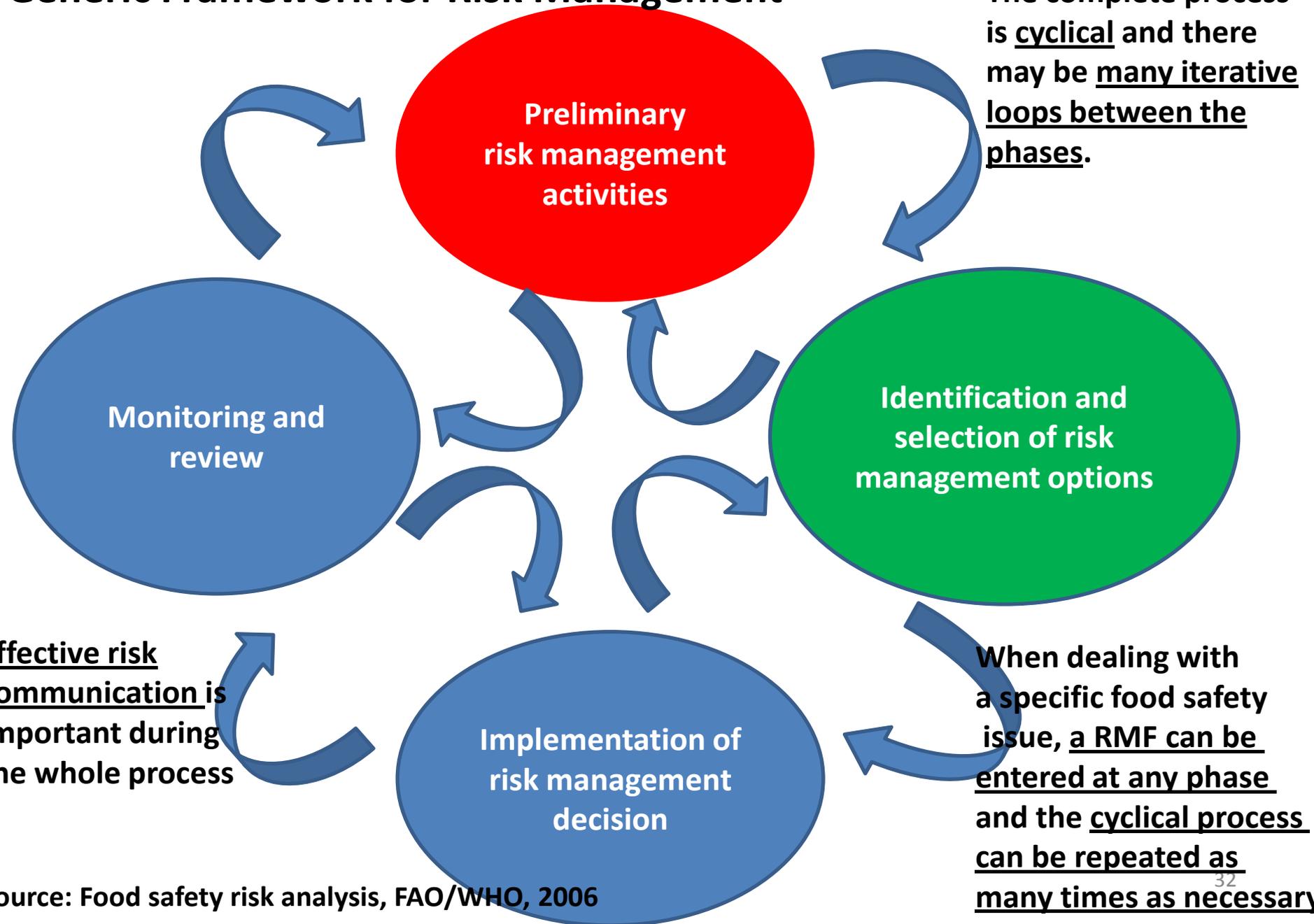
Importance of risk communication

Good risk communication is important during this “preliminary” phase.

“Internal” communication

Internal communication between risk managers and risk assessors is important in order to ensure that the scope of the risk assessment is reasonable and achievable, and that the results are presented in a readily understandable form.

Generic Framework for Risk Management



Thank you for your attention!